

APPENDIX IX - B

Total number of pages = 191

**Data Collection Forms for Subjects Excluded/Withdrawn
from the Study**

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 103	Study #
Subject Qualification	07 / 15 / 03 mm dd yy	T / K / W F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>47</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

3524 / 7.15.03

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>Sulf drugs, Bees</u>	✗	✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>see below</u>	✗	✓	

Is the subject taking any medication? If yes, please specify below:

3524 / 7.15.03

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?		✓	

Comments: Ortho Micronor - 1x day - Birth Control
Synthroid - 1.25mcg 1x day - Thyroid

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:

Susan R. HarrisDate: 07 / 15 / 03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1155

Visit Code	Date	Subject Initials	Subject Screen #: <u>103</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>T/K/W</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

subject excluded due to WBC out of range 7/17/03 gsh

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SRH 17.15.03

Investigator's Signature: [Signature]

Date: 9/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 104	Study #
Subject Qualification	07/15/03 mm dd yy	JITH F M L	Permanent #: NA	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>45</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Stacey E. Barchediny</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: **IV-1157**

Visit Code	Date	Subject Initials	Subject Screen #: 104	Study #
Subject Qualification	07, 15, 03 mm dd yy	J, T, H f m l	Permanent #: NA	03-122085-106

INCLUSION CRITERIA

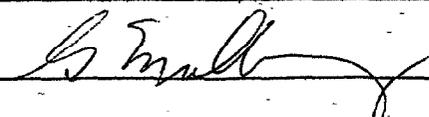
Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: **SEP 17/15/03**

Investigator's Signature:  Date: **09 11 103**
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			105	
Subject Qualification	07/15/03 mm dd yy	J L S F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>29</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>pollen, mold</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Apri 1x day birth control</u>		✓	

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Jami BusmeyerDate: 07/15/03
mm dd yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-1159

Visit Code	Date	Subject Initials	Subject Screen #: 105	Study #
Subject Qualification	07/15/03 mm dd yy	J/L/S f m l	Permanent #: NA	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA subject withdrawn 7/23/03 ghr

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 107.15.03

Investigator's Signature: [Signature]

Date: 8 11 103
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 109	Study #
Subject Qualification	07/15/03 mm dd yy	B, T, H F M L	Permanent #: NA	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>23</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. Dairy Products - in past		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: Tinea versicolor	✓	✓	

Is the subject taking any medication? If yes, please specify below: Depression

③SH/7.15.03

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓	✓	

Comments: Zoloft - 50mg 1xday - Depression

③SH/7.15.03

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Susan R. BasmiDate: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1161

Visit Code	Date	Subject Initials	Subject Screen #: <u>109</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>B T H</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SRH, 7.15.03

Investigator's Signature: _____

Date: 8/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	07/15/03	M/K/M	111	03-122085-106
Subject Qualification	mm dd yy	F M L	Permanent #:	
			NA	

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>49</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>stroke 2001</u>		✓	
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>cholesterol</u>		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>Coumadin 5mg 1xday, Accupril 10mg 1xday</u>		✓	
4. Insulin ?	✓		
5. Other ? <u>Lipitor 20mg 1xday</u>		✓	

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Stacey E BorkendingDate: 07/15/03

mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1163

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/15/03</u> mm dd yy	<u>M, K, M</u> f m l	<u>111</u> Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one

YES

NO

Subject:

<input checked="" type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...

YES

NO

N/A

Subject:

	<input checked="" type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>		4. Has artificial nails or nail tips?
	<input checked="" type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" type="checkbox"/>		6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
		<input checked="" type="checkbox"/>	8. Is currently lactating ?
	<input checked="" type="checkbox"/>		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	<input checked="" type="checkbox"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" type="checkbox"/>		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	<input checked="" type="checkbox"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified**

for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEB, 7/15/03

Investigator's Signature: [Signature]

Date: 07/15/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			112	
Subject Qualification	07/15/03 mm dd yy	N/J/G F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>58</u> Years
--	----------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>Seasonal</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Susan R. HarrisDate: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-116

Visit Code	Date	Subject Initials	Subject Screen #: <u>112</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>N/J/G</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>Partial Hyst.</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1983</u> <input checked="" type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH / 7.15.03

Investigator's Signature: _____

Date: 8/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 118	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>C/R/S</u> F M L	Permanent #: NA	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>20</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:

Susan R. Harris

Date:

07/15/03

mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1167

Visit Code	Date	Subject Initials	Subject Screen #: 118	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>C, R, S</u> f m l	Permanent #: NA	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SLH, 7-15-03

Investigator's Signature: _____

Date: 07/15/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 119	Study #
Subject Qualification	07/15/03 mm dd yy	S, M, S F M L	Permanent #: NA	03-122085-106

Gender: Male Female Age: 19 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>back, knee pain</u>		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Lodine 500mg taken when needed</u>		✓	
Comments: <u>0588 7/2/03 (muscle relaxer)</u>			

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Stacy E. Bachelder Date: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1169

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/15/03</u> mm dd yy	<u>S.M.S</u> f m l	<u>119</u> Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles. <u>babysits 7 days a week;</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ? <u>willing not to babysit during study period</u>

NA subject withdrawn 7/23/03 gsn

*3
808
7/15/03*

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified Not Qualified for participation in this study.

Reasons for disqualification: 808 7/15/03 Interviewer's Initials/Date: 808 7/15/03

Investigator's Signature: [Signature]

Date: 07/15/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 122	Study #
Subject Qualification	07/15/03 mm dd yy	L/A/M F M L	Permanent #: NA	03-122085-106

Gender: Male Female Age: 40 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:

Jami Busmeyer

Date: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1171

Visit Code	Date	Subject Initials	Subject Screen #: <u>122</u>	Study #
Subject Qualification	<u>07.15.03</u> mm dd yy	<u>L.A.M</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1999</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 07.15.03

Investigator's Signature: [Signature] Date: 07.11.03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>122</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>L I A I M</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No

If no, please indicate condition: scratch by cat; pulled outicle

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No

If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: Scratched by cat; pulled outicle

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Betty M. Conover Date: 07/23/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 124	Study #
Subject Qualification	07/15/03 mm dd yy	D/-/F F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>60</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Susan R. HarrisDate: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1174

Visit Code	Date	Subject Initials	Subject Screen #: <u>124</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>D1-1F</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one			Subject:
YES	NO		
<input checked="" type="checkbox"/>	<input type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one				Subject:
YES	NO	N/A		
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	<input checked="" type="checkbox"/>	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1995</u> If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SLH / 7.15.03

Investigator's Signature: [Signature] Date: 07/15/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>124</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>D / - / F</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
 If no, please indicate condition: cut on thumb

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
 If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: cut on thumb

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Susan R. Harris Date: 07 / 23 / 03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 127	Study #
Subject Qualification	07 / 15 / 03 mm dd yy	D / E / W F M L	Permanent #: NA	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>50</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>HBP</u>		✓	
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>see below</u>	✓	✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>Pro Toprol - 100mg 1xday</u>		✓	
4. Insulin ? <u>DSRH/7.15.03</u>			
5. Other ?			

Comments: Univasc - 15mg 1xday - Blood pressure
Nexium - 40mg - 1x night - Stomach
wellbutrin - 150mg 1xday - Mild Depression

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Susan R. Harris</u>	Date: <u>07 / 15 / 03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1177

Visit Code	Date	Subject Initials	Subject Screen #: <u>127</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>D/E/W</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH, 7-15-03

Investigator's Signature: _____

Date: 07/15/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>129</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>KIDIG</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: Male Female. Age: 20 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>environmental</u>	✓	✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Jami Busemeyer Date: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1179

Visit Code	Date	Subject Initials	Subject Screen #: <u>129</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>KIDIG</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA Subject withdrawn 7/23/03 gsn

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB / 07-15-03

Investigator's Signature: [Signature] Date: 07/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 133	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>P, L, R</u> F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>55</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Stacy E Bacheidin</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1181

Visit Code	Date	Subject Initials	Subject Screen #: <u>133</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>P, L, R</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1978</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SES, 7/15/03

Investigator's Signature: _____

B. Smith

Date: 9/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 134	Study #
Subject Qualification	<u>07 / 15 / 03</u> mm dd yy	<u>B A B</u> F M L	Permanent #: NA	03-122085-106

Gender: Male Female Age: 25 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>Seasonal</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?		✓	

Comments: Allegra-D - 1 tablet 2x day - Allergies
60mg added as per subject 7/15/03 gr

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Susan R. Harris Date: 07 / 15 / 03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1183

Visit Code	Date	Subject Initials	Subject Screen #: <u>134</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>BIA/B</u> f m i	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ..			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA subject withdrawn 7/24/03 gm

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SLH / 7-15-03

Investigator's Signature: [Signature] Date: 8/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 135	Study #
Subject Qualification	07 / 15 / 03 mm dd yy	C / R / W F M L	Permanent #: NA	03-122085-106

Gender: Male Female Age: 26 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Jami Busemeyer Date: 07 / 15 / 03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: II-1185

Visit Code	Date	Subject Initials	Subject Screen #: 135	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>CIRIW</u> f m l	Permanent #: NA	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

*NA subject
with Andrew
7-24-03
gn*

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: **JNB, 07.15.03**

Investigator's Signature: *[Signature]*

Date: 9/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 137	Study #
Subject Qualification	07/15/03 mm dd yy	K, A, S F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>42</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>HBP</u>	✗	✓	
4. Liver Disease ?	✓	⑤ SEH 7.15.03	
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>Anxiety</u>	✗	✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>Monopril - 20mg 1xday,</u>		✓	
4. Insulin ?	✓		
5. Other ?		✓	

Comments: Effexor XR - 75mg - 2, 1xday - anxietyBased on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Susan R. Harrie</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1187

Visit Code	Date	Subject Initials	Subject Screen #: <u>137</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>KIAS</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one			Subject:
YES	NO		
<input checked="" type="checkbox"/>	<input type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input type="checkbox"/>	<input type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input type="checkbox"/>	<input type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input type="checkbox"/>	<input type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input type="checkbox"/>	<input type="checkbox"/>		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input type="checkbox"/>	<input type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ..				Subject:
YES	NO	N/A		
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male		7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>Tubal</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1996</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH / 7.15.03

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>137</u>	Study #
Test Period	<u>07 / 24 / 03</u> mm dd yy	<u>K / A / S</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
 If no, please indicate condition: cut on finger

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
 If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: cut on finger

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician
 Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Shan L. Harris Date: 07 / 24 / 03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 139	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>S.F.G</u> F M L	Permanent #: NA	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>19</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Eczema ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Skin Cancer ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Hives ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>poisonivy</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. Hepatitis ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Liver Disease ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Kidney Disease ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Tuberculosis ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Cancer ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Organ transplant ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Any other condition not listed ? Please specify:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Heart Medication ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Insulin ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Other ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:

Stacey C Bacheidig

Date:

07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1190

Visit Code	Date	Subject Initials	Subject Screen #: <u>139</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>S, F, G</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SEB, 7/15/03

Investigator's Signature: S. Small Date: 07/15/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 145	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>SIAID</u> F M L	Permanent #: NA	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>25</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>San R. Harris</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1192

Visit Code	Date	Subject Initials	Subject Screen #: <u>145</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>S/A/P</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified**

for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SLH / 7-15-03

Investigator's Signature: _____

Date: 8/16/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>146</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>DIAID</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: Male Female Age: 40 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Jami Busenberger Date: 07/15/03
 mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1194

Visit Code	Date	Subject Initials	Subject Screen #: <u>146</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>DIAID</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1986</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 07-15-03

Investigator's Signature: _____

Date: 07/11/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>146</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>D/A/D</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No

If no, please indicate condition: scratched on hand

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No

If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: scratched on hand

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Betty M. Conover Date: 07/24/03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 151	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J, D, P</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>33</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	/		
2. Eczema ?	/		
3. Skin Cancer ?	/		
4. Skin Allergies ? Please specify:	/		
5. Hives ?	/		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>Seasonal</u>		/	
2. Hepatitis ?	/		
3. Heart and Vascular Disease?	/		
4. Liver Disease ?	/		
5. Kidney Disease ?	/		
6. Tuberculosis ?	/		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	/		
8. Cancer ?	/		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	/		
10. Organ transplant ?	/		
11. Any other condition not listed ? Please specify:	/		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	/		
3. Heart Medication ?	/		
4. Insulin ?	/		
5. Other ?	/		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Stacey E. Bacheider</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1197

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/15/03</u>	<u>J, D, P</u>	<u>151</u>	
Subject Qualification	<u>mm dd yy</u>	<u>f m l</u>	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA subject substituted 7-24-03 gsn

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEB, 7/15/03

Investigator's Signature: _____

[Handwritten Signature]

Date: 07/15/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 152	Study #
Subject Qualification	07/15/03 mm dd yy	G / - / A F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>39</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease? <u>HBP</u>		<input checked="" type="checkbox"/>	
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify:	<input checked="" type="checkbox"/>		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ? <u>Toprol - 200mg 1xday</u>		<input checked="" type="checkbox"/>	
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ?	<input checked="" type="checkbox"/>		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Sam R. Harris</u>	Date: <u>07/15/03</u> mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-199

Visit Code	Date	Subject Initials	Subject Screen #: <u>152</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>G / - / A</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>Hyst.</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>2003</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH / 7.15.03

Investigator's Signature: _____

Date: 8 / 11 / 03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
		<u>S.S.A</u>	<u>153</u>	
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>S.S.A</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: Male Female Age: 39 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	/		
2. Eczema ?	/		
3. Skin Cancer ?	/		
4. Skin Allergies ? Please specify:	/		
5. Hives ?	/		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	/		
2. Hepatitis ?	/		
3. Heart and Vascular Disease? <u>hbp</u>		/	
4. Liver Disease ?	/		
5. Kidney Disease ?	/		
6. Tuberculosis ?	/		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	/		
8. Cancer ?	/		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	/		
10. Organ transplant ?	/		
11. Any other condition not listed ? Please specify:	/		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	/		
3. Heart Medication ? <u>Zestril 10mg 1x day</u>	<u>X</u>	/	
4. Insulin ?	/		
5. Other ?	/		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Stacey Borchert Date: 07/15/03
 mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1201

Visit Code	Date	Subject Initials <i>SAB 7/15/03</i>	Subject Screen #: <i>53</i>	Study #
Subject Qualification	<i>07/15/03</i> mm dd yy	<i>JDA</i> f m l	Permanent #: <i>NA</i>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: *SAB, 7/15/03*

Investigator's Signature: *[Signature]* Date: *07/15/03*
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 155	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>R, R, R</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>53.54</u> Years <u>05/14/7.15.03</u>
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Suzanne L. Harris</u>	Date: <u>07/15/03</u> mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-1203

Visit Code	Date	Subject Initials	Subject Screen #: 155	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>R/R/R</u> f m l	Permanent #: NA	03-122085-106

INCLUSION CRITERIA

Check one

YES NO Subject:

<input checked="" type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input type="checkbox"/>		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one

YES NO N/A Subject:

	<input checked="" type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>		4. Has artificial nails or nail tips?
	<input checked="" type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" type="checkbox"/>		6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
		<input checked="" type="checkbox"/>	8. Is currently lactating ?
	<input checked="" type="checkbox"/>		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	<input checked="" type="checkbox"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" type="checkbox"/>		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	<input checked="" type="checkbox"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH 17.15.03

Investigator's Signature: [Signature] Date: 07-11-03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 159	Study #
Subject Qualification	07/15/03 mm dd yy	M/EIT F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>18</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	—		
2. Eczema ?	—		
3. Skin Cancer ?	—		
4. Skin Allergies ? Please specify:	—		
5. Hives ?	—		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify. <u>Mold, Pollen</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Susan R. Harris</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1205

Visit Code	Date	Subject Initials	Subject Screen #: 159	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>M/E/T</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

*NA subject withdrawn
7-24-03
JSH*

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH / 7-15-03

Investigator's Signature: [Signature] Date: 8-1-03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>160</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J/L/K</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: Male Female Age: 19 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:

Jami Busmeyer

Date:

07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1207

Visit Code	Date	Subject Initials	Subject Screen #: <u>160</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J, L, K</u> f m l	Permanent #:	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA subject withdrawn 7.24.03 g8

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB, 07.15.03

Investigator's Signature: [Signature] Date: 8/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 161	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>K/D/S</u> F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>45</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>Aspirin</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Tylenol Sinus 30mg taken when needed</u>		✓	

Comments: ① added as per subject 7/15/03 gfaBased on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:

Stacey E. Bacherdig

Date:

07/15/03
mm dd yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-1209

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/15/03</u>	<u>K, D, S</u>	<u>161</u>	
Subject Qualification	mm dd yy	f m l	Permanent #:	03-122085-106
			<u>NA</u>	

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA subject excluded 7.24.03 ghr

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SPB, 7/15/03

Investigator's Signature: [Signature] Date: 8/11/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>161</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>K/D/S</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No

If no, please indicate condition: open hangnail
① SRH/7-24-03

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No

If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: open hangnail

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Susan R. Harris

Date: 07 / 24 / 03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 162	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>T/J/H</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>40</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Susan R. HarrisDate: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1212

Visit Code	Date	Subject Initials	Subject Screen #: <u>162</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>T/J/H</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>Tubal</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1987</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH, 7-15-03

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>163</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>K, S, S</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>39</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>arm pain</u>		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Soma 350mg 1x day Muscle relaxer for arms</u>		✓	

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Jamie Busmeyer</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1214

Visit Code	Date	Subject Initials	Subject Screen #: <u>163</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>K I S I S</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>2001</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB, 07-15-03

Investigator's Signature: _____

Date: 8/11/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>163</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>K/S/S</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No

If no, please indicate condition: open sore on finger

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No

If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: open sore on finger

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Betty M. Conover Date: 07/24/03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 166	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L.A.S</u> F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>24</u> Years
--	----------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify. <u>Sulfa</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Ortho-Tricyclen (birth control)</u>		✓	

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Stacey E Bacheiding</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1217

Visit Code	Date	Subject Initials	Subject Screen #: <i>1666</i>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L.A.S</u> f m i	Permanent #: <i>NA</i>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

*NA subject understood
7-24-03
gjh*

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SEB, 7/15/03

Investigator's Signature: <i>[Signature]</i>	Date: <u>8/11/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 167	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>C/W/L</u> F M L	Permanent #: NA	03-122085-106

Gender: Male Female Age: 64 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>HBP</u>		✓	
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>see below</u>	✓	✓	

Is the subject taking any medication? If yes, please specify below:

③ SEH / 7.15.03

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>Norvasc - 2.5mg 1xday</u>		✓	
4. Insulin ?	✓		
5. Other ?		✓	

Comments: ZOCOR - 10mg 1xday - Cholesterol
Aspirin - 1xday preventative

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Susan R. Harris Date: 07 / 15 / 03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1219

Visit Code	Date	Subject Initials	Subject Screen #: <u>167</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>C/W/L</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male <input checked="" type="checkbox"/>	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRH, 7.15.03

Investigator's Signature: [Signature] Date: 9/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 172	Study #
Subject Qualification	07/21/03 mm dd yy	JIAIP F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>59</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature:

Janni Buemeyer

Date:

07 / 21 / 03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1221

Visit Code	Date	Subject Initials	Subject Screen #: <u>172</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>JIA/P</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one

YES

NO

Subject:

<input checked="" type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one

YES

NO

N/A

Subject:

	<input checked="" type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>		4. Has artificial nails or nail tips?
	<input checked="" type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" type="checkbox"/>		6. Has eczema or psoriasis on their hands or wrists ?
Female	<input checked="" type="checkbox"/>	Male	7. Is currently pregnant ? <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1978</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
	<input checked="" type="checkbox"/>		8. Is currently lactating ?
	<input checked="" type="checkbox"/>		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	<input checked="" type="checkbox"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" type="checkbox"/>		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	<input checked="" type="checkbox"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

Qualified **Not Qualified**

for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB 107-21-03

Investigator's Signature: [Signature]

Date: 9/11/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>172</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>J/A/P</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
If no, please indicate condition: cut on thumb

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: cut on thumb

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Mary M. Wether Date: 07/28/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 176	Study #
Subject Qualification	07/21/03 mm dd yy	J/R/C F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>37</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <i>antihistamine</i>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <i>Hypo-thyroidism</i>		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <i>Synthroid 100mg 1x day for Hypo-thyroidism</i>		✓	

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <i>Mary M. Watson</i>	Date: <u>07/21/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1224

Visit Code	Date	Subject Initials	Subject Screen #: <u>176</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>SIRIC</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>TL</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1996</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: mmw 17-21-03

Investigator's Signature: _____

Date: 07/21/03
mm dd yy

Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>176</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>S/R/C</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
 If no, please indicate condition: open cuticle

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
 If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.
 Reasons for disqualification: open cuticle

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician
 Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: Stacey E. Borchering Date: 07/28/03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>178</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>T L M</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: Male Female . Age: 44 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Jamie Buschmeier Date: 07/21/03
 mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1227

Visit Code	Date	Subject Initials	Subject Screen #: <u>178</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>T/L/M</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1992</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 07-21-03

Investigator's Signature: <u>[Signature]</u>	Date: <u>9/1/03</u> mm dd yy
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Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>178</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>TILIM</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
 If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
 If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: extra subject

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Mary M. Waitam Date: 07/28/03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 179	Study #
Subject Qualification	07/21/03 mm dd yy	B J B F M L	Permanent #: NA	03-122085-106

Gender: Male Female Age: 45 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Mary M. Watham

Date: 07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1230

Visit Code	Date	Subject Initials	Subject Screen #: <u>179</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>B J B</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: MMW 17-21-03

Investigator's Signature: [Signature] Date: 08-11-03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 181	Study #
Subject Qualification	07/21/03 mm dd yy	D/L/A F M L	Permanent #: NA	03-122085-106

Gender: Male Female Age: 46 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>hbp</u>		✓	
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>bi-polar</u>		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>Novasc 10mg 1xday, Synthroid 25mg 1xday</u>		✓	
4. Insulin ?		✓	
5. Other ? <u>Resperdol 2mg 1xday (bi-polar), vitamins</u>		✓	

Comments: added as per PAN 7/21/03 gr

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Stacey E. Ruchendy Date: 07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1232

Visit Code	Date	Subject Initials	Subject Screen #: <u>181</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>DIA</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1981</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SEB, 7/21/03

Investigator's Signature: [Signature] Date: 8/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/21/03</u>	<u>R, -1, W</u>	<u>183</u>	03-122085-106
Subject Qualification	mm dd yy	F M L	Permanent #:	
			<u>NA</u>	

Gender: Male Female Age: 54 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	/		
2. Eczema ?	/		
3. Skin Cancer ?	/		
4. Skin Allergies ? Please specify:	/		
5. Hives ?	/		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>grass, weeds, penicillin</u>	/	/	
2. Hepatitis ?	/		
3. Heart and Vascular Disease? <u>hbp</u>		/	
4. Liver Disease ?	/		
5. Kidney Disease ?	/		
6. Tuberculosis ?	/		
7. Diabetes? Controlled? Diet [] Oral [] Insulin []	/		
8. Cancer ?	/		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	/		
10. Organ transplant ?	/		
11. Any other condition not listed ? Please specify:	/		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	/		
3. Heart Medication ? <u>Enalapril 90mg 1x day (11)</u>	/	/	
4. Insulin ?	/		
5. Other ?	/		

Comments: (11) added as per SPAN INFO 7/21/03 gn

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Stacy E. Beckering Date: 07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1234

Visit Code	Date	Subject Initials	Subject Screen #: <u>183</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>R, - , W</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, <u>antibiotic</u> , Polysporin® and/or perfume allergies ? <u>penicillin</u>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: penicillin allergy Interviewer's Initials/Date: SPB, 7/21/03

Investigator's Signature: _____

Date: _____
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>184</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>DMH</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: Male Female Age: 39 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Jani Buemeyer Date: 07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1236

Visit Code	Date	Subject Initials	Subject Screen #: <u>184</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>D/M/H</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	<input checked="" type="checkbox"/>	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>2001</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 107-21-03

Investigator's Signature: [Signature] Date: 07/21/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>187</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>A I K A</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>41</u> Years
--	----------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>Seasonal</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Allergies - Allegra 60 mg prn</u>		✓	

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Mary M. Wautton</u>	Date: <u>07/21/03</u> mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-1238

Visit Code	Date	Subject Initials	Subject Screen #: <u>187</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>A I K I B</u> f m i	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA subject excluded 7/28/03g

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: MMW 17-21-03

Investigator's Signature: _____

[Handwritten Signature]

Date: 8/11/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	07/28/03 mm dd yy	A / K / B F M L	187 Permanent #: NA	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
 If no, please indicate condition: open cut on finger

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
 If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.
 Reasons for disqualification: open cut on finger

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician
 Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Stacey E Backlund Date: 07/28/03
 mm dd yy

Data Collection Form 1
DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 188	Study #
Subject Qualification	07/21/03 mm dd yy	M/J/F F M L	Permanent #: NA	03-122085-106

Gender: Male Female. Age: 59 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>high blood pressure</u>		✓	
4. Liver Disease ?	✓	✓	Ⓜ 2 errors
5. Kidney Disease ?	✓	✓	07-21-03
6. Tuberculosis ?			
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ? <u>breast cancer 1998 (in remission)</u>		✓	
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>Cholesterol / acid reflux / bladder problem</u>		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>Verapamil 240mg 1x day Pravachol 40mg 1x day</u>		✓	
4. Insulin ?	✓		
5. Other ? <u>Lisinopril 20/25 1x day Cholesterol</u>		✓	

Comments: Other meds: Nexium 40mg 1x day acid reflux
Ditropan 10mg 1x day bladder

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Jami Bussmeyer Date: 07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1241

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/21/03</u> mm dd yy	<u>M, J, F</u> f m l	<u>188</u>	03-122085-106
Subject Qualification			Permanent #:	
			<u>NA</u>	

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1986</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 107-21-03

Investigator's Signature: [Signature] Date: 8/17/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>188</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>M / J / F</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No

If no, please indicate condition: cut

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No

If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: cut

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Mary M. Wathen

Date: 07 / 28 / 03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 189	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>L.L.D</u> F M L	Permanent #: NA	03-122085-106

Gender: Male Female Age: 44 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>irregular heartbeat</u>	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Jacey E. Bacherdin Date: 07/21/03
 mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1244

Visit Code	Date	Subject Initials	Subject Screen #: <u>189</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>L L D</u> f m i	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one

YES NO Subject:

<input checked="" type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one

YES NO N/A Subject:

	<input checked="" type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>		4. Has artificial nails or nail tips ?
	<input checked="" type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" type="checkbox"/>		6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1984</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
	<input checked="" type="checkbox"/>		8. Is currently lactating ?
	<input checked="" type="checkbox"/>		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	<input checked="" type="checkbox"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" type="checkbox"/>		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	<input checked="" type="checkbox"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SOB 17/21/03

Investigator's Signature: _____

Date: 01/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 190	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>J1-1J</u> F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>59</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:			

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Mary M. WeirhamDate: 07/21/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 191	Study #
Subject Qualification	07/21/03 mm dd yy	CILIS F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>41</u> Years
--	----------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	/		
2. Eczema ?	/		
3. Skin Cancer ?	/		
4. Skin Allergies ? Please specify:	/		
5. Hives ?	/		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	/		
2. Hepatitis ?	/		
3. Heart and Vascular Disease?	/		
4. Liver Disease ?	/		
5. Kidney Disease ?	/		
6. Tuberculosis ?	/		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	/		
8. Cancer ?	/		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	/		
10. Organ transplant ?	/		
11. Any other condition not listed ? Please specify:	/		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	/		
3. Heart Medication ?	/		
4. Insulin ?	/		
5. Other ?	/		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.Interviewer's Signature: Stacey E BachendingDate: 07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1248

Visit Code	Date	Subject Initials	Subject Screen #: <u>191</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>C, C, S</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1990</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JPS, 7/21/03

Investigator's Signature: [Signature] Date: 07/21/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>191</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>C/L/S</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No

If no, please indicate condition: open cuticle

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No

If no, please explain: _____

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: open cuticle

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician

Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Stacey E. Barchewitz Date: 07/28/03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 192	Study #
Subject Qualification	07/21/03 mm dd yy	B, L, W F M L	Permanent #: NA	03-122085-106

Gender: Male Female. Age: 42 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Jamie Busarney Date: 07/21/03
 mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1251

Visit Code	Date	Subject Initials	Subject Screen #: <u>192</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>B, L, W</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ..			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA subject excluded 7.28.03 g8

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 107-21-03

Investigator's Signature: [Signature] Date: 8/11/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
		<u>L</u>	<u>192</u>	
Test Period	<u>07/28/03</u> mm dd yy	<u>B, D, W</u> F M L	Permanent #: <u>N/A</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Yes No
 If no, please indicate condition: open cut on hand

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? Yes No
 If no, please explain: 3 SOB 7/28/03

III. Has subject been ill since the last visit? Yes (Complete below) No

IV. Has subject used any new oral or topical medication? Yes (Complete below) No

Based upon the above responses, the subject is: Qualified Not Qualified to continue on the study.

Reasons for disqualification: open cut on hand

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? Not related Possibly related Definitely related Other (explain)

Action Taken: None Continued on study Withdrawn from the study Consulted physician
 Medication taken (Complete below) Hospitalized Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Stacey E. Bocheidj Date: 07, 28, 03
 mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 194	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>CIMW</u> F M L	Permanent #: NA	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>33</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: <u>Mary M. Warkum</u>	Date: <u>07/21/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-1254

Visit Code	Date	Subject Initials	Subject Screen #: <u>194</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>C/M/W</u> f m l	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified Not Qualified for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: mmw 12-21-03

Investigator's Signature: [Signature] Date: 8/11/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>195</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>CIAIY</u> F M L	Permanent #: <u>NA</u>	03-122085-106

Gender: Male Female Age: 22 Years

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>Seasonal, cockroaches</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Clorinex 10mg x day (as needed for allergies)</u>	✓	✓	

Comments: 11 mg added as per subject 7. 22.03 gm 3 JNB 07-21-03

Based on the above medical history, the subject is: Qualified or Not qualified for the study.

Interviewer's Signature: Joni Busmeyer Date: 07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-125b

Visit Code	Date	Subject Initials	Subject Screen #: <u>195</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>C, A, Y</u> f m i	Permanent #: <u>NA</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female <input checked="" type="checkbox"/>	Male <input type="checkbox"/>	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

NA subject with the 7/30/03

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
 Qualified **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB, 07-21-03

Investigator's Signature: _____

Date: 8/11/03
mm dd yy