Dallas Center for Resuscitation Research
Community Consultation Summary

The Dallas Center for Resuscitation Research (CRR) began discussion with the University of Texas Southwestern (UTSW) Medical Center's Institutional Review Board (IRB) and the Dallas City manager in June 2004 to develop a community consultation plan for public notification of the Resuscitation Outcomes Consortium (ROC) trials that Dallas and the surrounding area communities will be participating in. In the following two years the Dallas CRR team, Drs. Idris, Pepe, Fowler and Minei, have met with Dallas and the surrounding area community leaders and attended city council meetings as well as multiple community out-reach opportunities through multi-media requests.

The Dallas Area Community Consultation Committee (CCC) was established to facilitate and comply with a federally-approved mechanism to provide exception to informed consent regarding entry into population-based clinical trial (formal test) of interventions for both cardiac arrest and severe injury. This mechanism includes notification of the public and mechanisms to receive as much feedback as possible from the community at large.

Membership into the Dallas Area CCC was extended to area city council members, city leaders, local newspaper/TV/radio editors, clergymen, and prominent organization members (such as Hispanic/black organizations, medical society). The committee met three times and at each meeting all members expressed their desire for personal and community participation.

We invited multi-media representives to attend the announcement of Dallas and surrounding cities participation in the ROC trials (HS and ITD). On July 11, 2006 a formal public announcement was made to the Dallas and area communities of the forthcoming ROC trials. The public was given notice that the first trial (HS) would start this fall, with the second trial (ITD) to start a few months later. Brief description of the trials and ROC was given and a contact number for more information or to opt-out of the trials was provided. A local TV station offered a poll for people in the Dallas-Fort Worth area to vote yes they would like to participate or no they did not want to participate. 77% voted yes (100 people responded).

Out of a population of 2.5 million, we had 22 calls requesting more information about the trials or opting out. Thirteen of the 22 requested opt-out armbands not wishing to participate in the trials, several requesting 2 armbands (couples). We mailed a total of 22 white silicone bracelets imprinted with DO NOT ENROLL ROC to those requesting to not participate.

UTSW's IRB only required approval of the community consultation plan. We are not required to submit a summary to the IRB following community consultation/public notification. A member of the UTSW IRB was present at all the Dallas Area CCC meetings. We have kept the IRB involved and informed all our activities associated with community consultation and now public notification.

New methods of notification, such a random digit dialing survey, were discussed with the IRB prior to submitting a formal request to the board. We received approval and 9 counties including Dallas county were surveyed in October 2006, targeting English and/or Spanish speaking households. The survey addressed both trauma and cardiac studies (Hypertonic Saline and PRIMED).

> Trauma: approximately 80% English speaking respondents supported self and family participation in a trauma study without consent. 67% favored children ages 15-17 participation without consent. 90-93% Spanish speaking respondents supported self and family participation in a trauma study without consent. 58% favored children ages 15-17 participation without consent.
> Cardiac: approximately 89% English speaking respondents supported self and family participation in a cardiac study without consent. 99% Spanish speaking respondents supported self and family participation in a cardiac study without consent.
> Overall, 83% of respondents said they would not be upset if they were in a severe accident or experienced a cardiac event and later learned they were enrolled into a study without their consent.

We have begun community consultation for the Fort Worth area and surrounding communities. The random digit dialing survey was completed in March 2007 for this area, results pending.

We are fortunate to be associated with a well respected university and medical staff who are frequently invited to attend women/Hispanic/black exposés (8,00 to 25, 000 attendees), community and organization functions, in order to provide health care information to the public. We have attended several of these functions taking every opportunity to talk with the people passing by and handing out written information related to the ROC trials. Our community consultation/public notification is an on going process, we will continue to attend all community functions as the opportunities arise.

Attached are two timeline documents listing our activities associated with community consultation and public notification.

IRB/Community Consultation/Notification Log

Site: Dallas Center for Resuscitation Research

Date	Event Description	Attendance		Expenditures (describe)	Cost	Advertised days	Advertising media (billboard, print, radio, TV)	Activity (IRB, etc.)	Hours Spent
		Expected	Actual						
4-22-06	Lancaster Crossroads Baptist Church Family Safety Fair	50	75	0	0	n/a	n/a	Public Notification	10a-2p (4hrs)
6-26-06	Community Consultation Committee Meeting	30	25	0	0	n/a	n/a	Community Consultation and Public Notification	4p-6p (2hrs)
7-10-06	Press Conference	50	50	0	0	n/a	Dallas/Ft Worth TV stations, radio stations and newspaper reporters	Public Notification	10a-12n (2hrs)
7-11-06	Dallas Morning News Paper	-	-	0	0	n/a	Front page Dallas Morning News Paper	Public Notification	n/a
8-1-06	National Family Night Out (Arlington Recreation Park – Dallas)	50-75	88	0	0	n/a	n/a	Public Notification	6p-8p (2hrs)
8-12,13-06	VIVA Dallas Expo Hispana	20,000 – 25,000	-	0	$50/booth (shared booth with 5 other studies)	n/a	n/a	Public Notification (Hispanic population) Dr. Benitez on stage for 15 min for ROC	8:30a-6p (on 8-12) 12n-5p (on 8-13)

IRB/Community Consultation/Notification Log

Site: Dallas Center for Resuscitation Research

Date	Event Description	Attendance		Expenditures (describe)	Cost	Advertised days	Advertising media (billboard, print, radio, TV)	Activity (IRB, etc.)	Hours Spent
		Expected	Actual						
8-26,27-06	Visions Womens Expo	20,000	-	0	0 (shared booth with 5 other studies)	n/a	n/a	Public Notification	8/12 8a-6p Brochure and newspaper article only, no one from ROC 8/13 12n-3p Brochure and newspaper article only, no one from ROC 3p-6p ROC personnel on site
9-20,21,22, 23-06	Pastoral Conference at the Potter's House	8,000	6,000	0	0	n/a	n/a	Public Notification	9/20 10:30a-5p 9/21 8a-3p 9/22 8a-3p 9/23 8a-11a (total 23 ½ hrs)
12-9 + 10-06	Kawanzaa Fest	20,000 – 25,000	-	0	0	n/a	n/a	Public Notification	12/9 8a-6p 12/10 11a-4p

COMMUNITY CONSULTATION COMMITTEE MEETING

Monday, June 26, 2006

The meeting was opened by CCC Co-Chair, Dr. Elba Garcia, City Council member and Deputy Mayor Pro Tem for the City of Dallas, who discussed a short history of the proposed research and why she feels that it is important for the Dallas area to participate in this ground breaking research study. She then introduced Dr. Paul Pepe, Chairman of Emergency Medicine at The University of Texas Southwestern Medical Center at Dallas.

Dr. Paul Pepe began the meeting by introducing all of the attendees to the audience at large. He spoke about each person's role in the upcoming project and how they each would contribute to the ROC grant and the immediate trial. Some of the participants that attended were: Managing Editors/News directors from Channel 8 (ABC) and Fox 4 News, the CEO of the Dallas County Medical Society, Mr. Gary Griffiths from the Dallas City Council, Public Safety Committee, Dr. John Carlo, Health Authority and Medical Director for the Dallas County Health and Human Services Department, as well as Dr. Ray Fowler, Deputy Director for BioTel (9-1-1 EMS System) and Chief Tommy Tine, EMS Chief from Dallas Fire Rescue.

Dr. Pepe than spoke about the best way to inform the citizens of Dallas about the testing of new treatments in terms of long term and neurologically intact survival and to review the plans and to discuss any questions or concerns. He spoke about the current 4% survival rate for out of hospital cardiac arrest and the 50% survival from traumatic injury. Questions were asked about the care and training of the rescue personnel and Dr. Pepe stated that the usual care within the community participating in a study rose because of increased training initiatives and quality assurance efforts. He also informed everyone that the EMS systems will not have to purchase the equipment for the study or pay for the additional training.

He then introduced Dr. Ahamed Idris, the principal investigator for the ROC study who went into detail about one of the devices that will be used in the studies (ITD) and then explained the particulars about the hypertonic saline solution. He answered questions from the audience about the randomization of patients as well as the items mentioned above. Dr. Idris also demonstrated the ITD for the audience and answered questions about the device.

Dr. Idris stated that the public will be informed about the results of the study and also mentioned the web site that has information on who to contact for more detailed information on the study.

Dr. Idris received unanimous approval by all the attendees (CCC or other on-lookers) at this meeting for themselves and for their family members to participate in the study.

He listed the web site for the ROC on a prepared slide. Dr. Pepe also asked for input regarding the most appropriate place for a news conference and a date for the conference. All participants discussed the dates and July 10th at 10am was selected. The location would be the Dallas County Medical Society.

Dr. James Atkins then spoke about the Immediate Trial research study. He outlined the various sites that would be participating in the trial and he distributed a hand out and also had a slide presentation prepared. Dr. Atkins went into detail about how patients would be selected and what the patients could expect from the study.

Dr. Atkins explained that the patient selected may not be able to give informed consent and that is the reason for this community consultation. He went on to explain what the study entails and the criteria for selection as a patient and also the criteria for those who do not qualify.

Dr. Atkins asked at the end of the presentation if everyone in the audience understood the study and was willing as a member of the community to participate. Again, there was universal acceptance.

Dr. Pepe asked members of the audience for suggestions in how to disseminate this information to the public. Suggestions included links at the various news media websites.

The meeting was adjourned.

Gail Bennett
Assistant to Dr. Paul Pepe

ROC Community Meeting
June 26, 2006

Name	Mailing Address	Email Address	Phone Number
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Jane Wissinton	UTSW		214-648-8555
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Cliff Williams	WFAA News 8	Cwilliams@WFAA.com	214-977-6168

ROC Community Meeting
June 26, 2006

Name	Mailing Address	Email Address	Phone Number
Dixon Lagley	607 N. Duncanville Rd.	Carouselfarm2000@yahoo.com	(972) 291-9967
Barbara Moses	UTSW		86950
Andrew Morris	UTSW		86958
Daysha Crain	UTSW		86953
Ryan Dikes	UTSW		84698
Gail Bennett	UTSW		
Debbie Clemer	UTSW		
Melinda Moffat	UTSW		

June 5, 2006

Dallas ROC

Activities related to preparation for implementation of ROC protocols

A. Institutional Review Board activities
   1. March 16, 2004. Met with Perrie Adams (head of UTSW IRBs) to discuss relationship with other Dallas-area IRBs and most efficient way to submit protocols.
   2. June 17, 2004. Met with Dallas City Manager (Mary Suhm) to discuss ROC, types of studies to be done, and need for community consultation process.
   3. July 14, 2004. Met with Perrie Adams (head of UTSW IRBs), another IRB member, and 2 University attorneys for the IRB. Discussed the ROC, types of studies to be done, and need for community consultation process. Also discussed possible formation of a regional IRB for the Dallas metro area.
   4. July 16, 2004. Met with Mike Ramsay at Baylor to discuss ROC, types of studies to be done, and need for community consultation process. Also discussed possible formation of a regional IRB for the Dallas metro area.
   5. August 13, 2004. Met with John Meyers (Chair of EM at Medical Cities Hospital) to discuss ROC, types of studies to be done, and need for community consultation process.
   6. October 17, 2004. Met with Bob Simonson to discuss ROC, types of studies to be done, and need for community consultation process. Also discussed meeting with IRB reps from Methodist Medical Center.
   7. Nov 12, 2004. Met with Perrie Adams to discuss FWAs, IRB issues, and likely first protocols.
   8. Dec 13, 2004. Met with Jim Atkins to discuss IRB issues and coordination of Immediate trial with ROC protocols.
   9. Jan 3, 2005. Met with Perrie Adams, Joe Minei, Paul Pepe, Ray Fowler to discuss IRB issues and plan for community consultation process.
   10. Jan 15, 2005. Met with Compton Broders (Chief of Staff, Presbyterian Hospital) to discuss ROC, types of studies to be done, and need for community consultation process. Also discussed meeting with IRB reps from Presbyterian Medical Center.
   11. Jan 18, 2005. Met with BioTel Fire Dept agency representatives to discuss ROC, types of studies to be done, and need for community consultation process. FWAs for each agency also discussed.
   12. Feb 2, 2005. Met with IRB representatives from Baylor, and Mike Ramsay to discuss ROC, types of studies to be done, and need for community consultation process. Reps thought that common IRB and consent form would be desirable.
   13. Feb 10, 2005. Participated in a radio talk show to discuss emergency medical system in Dallas, ROC, types of studies to be done, need for

exception from informed consent for ROC protocols, and need for community consultation process. Also discussed ITD and HS protocols and concept of the Hawthorne effect.

14. Feb 14, 2005. Met with Compton Broders and IRB reps from Presbyterian Medical Center to discuss ROC, types of studies to be done, and need for community consultation process.
15. March 14, 2005. Met with Allen Naarden, IRB Chair, Medical Cities of Dallas, to discuss ROC studies, IRB submission, exception from informed consent, and community consultation.
16. March 21, 2005. Met with Suzanne Rivera, acting chair of IRBs at UTSWMC, to discuss ROC protocols, FWAs, IRB submission, exception from informed consent, and community consultation.
17. March 18, 2005. Met with Suzanne Rivera, acting chair of IRBs at UTSWMC, to discuss ROC protocols, FWAs, IRB submission, exception from informed consent, and community consultation.
18. March 29, 2005. Met with Phyliss Everage (Methodist IRB Director and Dr. Cox, IRB chair) to discuss ROC protocols, IRB submission, exception from informed consent, and community consultation.
19. March 21, 2005. Met with Dr. Strauss, IRB chair, Presbyterian Hospital) to discuss ROC protocols, IRB submission, exception from informed consent, and community consultation.
20. April 18, 2005. Met with Suzanne Rivera, acting chair of IRBs at UTSWMC, to discuss FWAs, HIPPA business agreements, organize meeting of representatives from all Dallas-area IRBs to discuss ROC protocols, exception from informed consent, and community consultation.
21. May 5, 2005. Met with Suzanne Rivera, acting chair of IRBs at UTSWMC, to discuss agenda for meeting with representatives from all Dallas-area IRBs.
22. May 9, 2005. Meeting with Dallas Community Consultation Committee at Dallas City Hall.
23. June 3, 2005. Met at FB city hall with Farmer's Branch paramedics to discuss ROC protocols, exception from informed consent.
24. June 3, 2005. Met with Suzanne Rivera, acting chair of IRBs at UTSWMC, to discuss details of submitting ROC protocols to IRBs..
25. June 22, 2005. Met with Suzanne Rivera, acting chair of IRBs at UTSWMC, to discuss agenda for meeting with representatives from all Dallas-area IRBs and community consultation committee.
26. June 23, 2005. Met with fire chiefs from DeSoto Fire Dept. to discuss ROC protocols and exception from informed consent.
27. June 23, 2005. Met with fire chiefs from Duncanville Fire Dept. to discuss ROC protocols and exception from informed consent.
28. June 28, 2005. Met with fire chiefs from University Park Fire Dept. to discuss ROC protocols and exception from informed consent.
29. July 20, 2005. General meeting of Dallas-area IRB representatives to discuss ROC protocols, exception from informed consent, and community consultation.

30. September 28, 2005. Met with Suzanne Rivera, VP of Research, and Diane Shepard chair of IRBs at UTSWMC, to discuss agenda for second meeting with representatives from all Dallas-area IRBs.
31. October 5, 2005. Second general meeting of Dallas-area IRB representatives to discuss ROC protocols, exception from informed consent, and community consultation.
32. November 1, 2005. Met with fire chiefs from DeSoto, Duncanville, and Lancaster Fire Depts. to discuss ROC protocols and exception from informed consent.
33. November 22, 2005. Meeting with Suzanne Rivera, VP of Research, and Diane Shepard chair of IRBs at UTSWMC, to discuss FWAs for Fire Depts., MOUs for agencies, details of protocol submissions to IRBs.
34. December 7, 2005. Met with Garland Fire dept Chiefs and paramedics to discuss ROC protocols and exception from informed consent.
35. December 12, 2005. Met with Matthew Bush, ED Director at Medical Cities to discuss ROC protocols, IRB submission, and exception from informed consent.
36. April 25, 2005. Met with Directors of Dallas-area Trauma Centers to discuss ROC protocols, exception from informed consent, patient/family notification and consent.
37. May 26, 2005. Met with Sue Rivera to discuss use of telephone survey for community consultation process.

We have been providing proactive and on-going community education about exception to informed consent concepts, related FDA regulations, randomization, risk-benefit concepts, and mechanisms for community feedback to the following:

- Dallas City Council Members including Public Safety Committee Chair (04/05), Public Health Committee Chair (02/05), Minority Affairs Leadership 04/05))
- Offices (chiefs of staff) for the Mayor of Dallas (03/05) and the presiding County Judge (highest elected official) for Dallas County (4/05)
- Dallas County Medical Society (09/04)
- Editors for the Dallas Morning News (12/04 and 04/05),
- News Directors for main TV affiliates (11/04, 12/04, 01/05) and KRLD (all news station – 03/05) as well as various assignment editors, producers, and medical reporters (02/05 – 04/05)
- City Managers and/or City Council members for Dallas (02/05, 03/05), Farmer's Branch (03/05), Mesquite (04/05), Carrollton (03/05), Wills Point (08/04), with more scheduled for May and June 2005
- American College of Emergency Physicians EMBRES group (04/05), National Association of EMS Physicians President (02/05) and the American Heart Association office of Emergency Cardiac Care (02/05)\
- Legal Ethicists at Southern Methodist University (04/05)
- State EMS and Trauma Directors (02/05)

- Regional EMS Authorities from the State Health Dept.

a. We have been providing on-going media interviews and public disclosures about the ROC concepts and even some specific interventions, before and after the ROC was organized:

    - November 2003 -- Channel 8 (ABC affiliate) story on the concept of performing a trial of artificial hemoglobin in the prehospital setting under exception from informed consent and community consultation.
    - November 2003 --- provided similar discussions for a "mini-medical school" symposium for the public
    - December 1, 2003 – *Dallas Morning News* lead article on the concept of performing a trial of artificial hemoglobin in the prehospital setting under exception from informed consent..
    - Provided information about regulatory issues at such National conferences as the National EMS Medical Directors Course (01/05) and the U.S. Metropolitan Municipalities EMS Medical Directors Annual State of the Science Symposium (02/05).
    - Provided discussion of ROC initiatives on Radio Talk shows and TV talk shows (02/05)
    - Have scheduled up-coming meetings in May 2005 with local news directors.

b. We have provided a number of lectures on the ROC intervention subjects, including the rationale and procedures for implementing the studies, exception from informed consent and community consultation at various grand rounds, national and international scientific meetings and various research seminars at the University of Texas and elsewhere.

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EXCEPTION TO CONSENT REPORT

October, 2006

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University of Texas Southwestern Medical Center at Dallas
Exception to Consent Research
October 2006

V1.0

TABLE OF CONTENTS

GOAL AND OBJECTIVES 3

METHODOLOGY 4
Geographic Area Surveyed 6
Explanation of Multivariate Analysis 7
RESPONDENT PROFILE 8

SUPPORT FOR BEING ENTERED INTO THE STUDY WITHOUT CONSENT 9

Concerns about Being Entered into the Study Without Consent 11
Support for Entering Family Members in the Study without Consent 13
Concerns about Family Members Being Entered into the Study Without Giving Consent 15
Support for Receiving the Experimental Treatment if There was a Low Risk of an Allergic Reaction 17
Support for Including Children Aged 15 to 17 in the Study 18
Reasons For and Against Including Children Aged 15 to 17 in the Study 19

OKAY WITH PARENTAL CONSENT 22

DEPENDS ON THE INJURY 23

DON'T HAVE CHILDREN 23

SUPPORT FOR BEING ENTERED IN THE CARDIAC STUDY WITHOUT CONSENT 24

Concerns Over Being Entered in the Cardiac Study 25
Support for Entering Family Members in the Cardiac Study without Consent 27
Concerns about Family Members Being Entered into the Cardiac Study Without Giving Consent 28

RESPONDENT'S REACTION IF THEY LEARNED THEY HAD BEEN ENTERED INTO THE STUDY WITHOUT CONSENT 30

POPULAR SOURCES OF INFORMATION 32

ADDITIONAL COMMENTS 33

KEY FINDINGS 36

APPENDIX 38

Questionnaires – October, 2006 38
Answers to Open-Ended Questions 47

Special Thanks to

Ahamed Idris, M.D., for his support, direction and guidance throughout the conduct of this research.

Hebert Research Team

Kenneth Klima, *Research Director*
Karen Marotz, *Research Analyst*
Tom Fisher, *Director of Operations*

Goal and Objectives

Research Goal:
The goal of this research was to provide unbiased community input regarding the use of an experimental fluid with trauma patients who are not able to provide consent, and provide input regarding the use of an experimental valve used in cardiac arrest victims.

Research Objectives:
The following objectives were addressed in conducting research for the University of Texas.

1. Assess the proportion of the adults living in the service area who, if severely injured or if experienced cardiac arrest, would want to receive an experimental treatment without providing consent.
2. Assess the concerns of those respondents who would not want to be included in the study.
3. Examine the proportion of adults who would want their family members to receive an experimental treatment without providing consent.
4. Assess the concerns of those respondents who do not want their family members to receive experimental treatment without providing consent.
5. Determine the proportion of adults who would be upset if they were in a severe accident or suffered a cardiac arrest and later learned they were entered into the study.
6. Evaluate the level of support for including children, aged 15-18 years, in the study.
7. Determine the most effective methods of telling the community about this study.
8. Develop a demographic profile of the respondents.

Methodology

A total of 502 surveys were completed with adults (18 and older) living in the households contacted. Respondents were surveyed proportionate to population by zip code throughout the designated population area for the study (see map). The response rate, which represents the proportion of the population who agreed to participate in the research, was 39.6% percent. The overall incidence rate, which represents the proportion of the population qualified to participate in the full survey, was 100 percent. The maximum margin of error for 502 respondents is +/-4.4 percent.

Of the 502 surveys, 105 (20.9%) were conducted in Spanish. When an interviewer encountered a Spanish-only household, the call was transferred a Spanish-speaking interviewer who completed the survey with the respondent in Spanish. Households with Hispanic surnames were also called by a Spanish-speaking interviewer in the event the household spoke only Spanish.

The data were analyzed using generally accepted univariate measures of central tendency and dispersion. A complete list of responses to open-ended questions will be found in the Appendix.

Hebert Research has made every effort to produce the highest quality research product within the agreed specifications, budget and schedule. The customer understands that Hebert Research uses those statistical techniques, which, in its opinion, are the most accurate possible. However, inherent in any statistical process is a possibility of error, which must be taken into account in evaluating the results. Statistical research can predict consumer reaction and market conditions only as of the time of the sampling, within the parameters of the project, and within the margin of error inherent in the techniques used.

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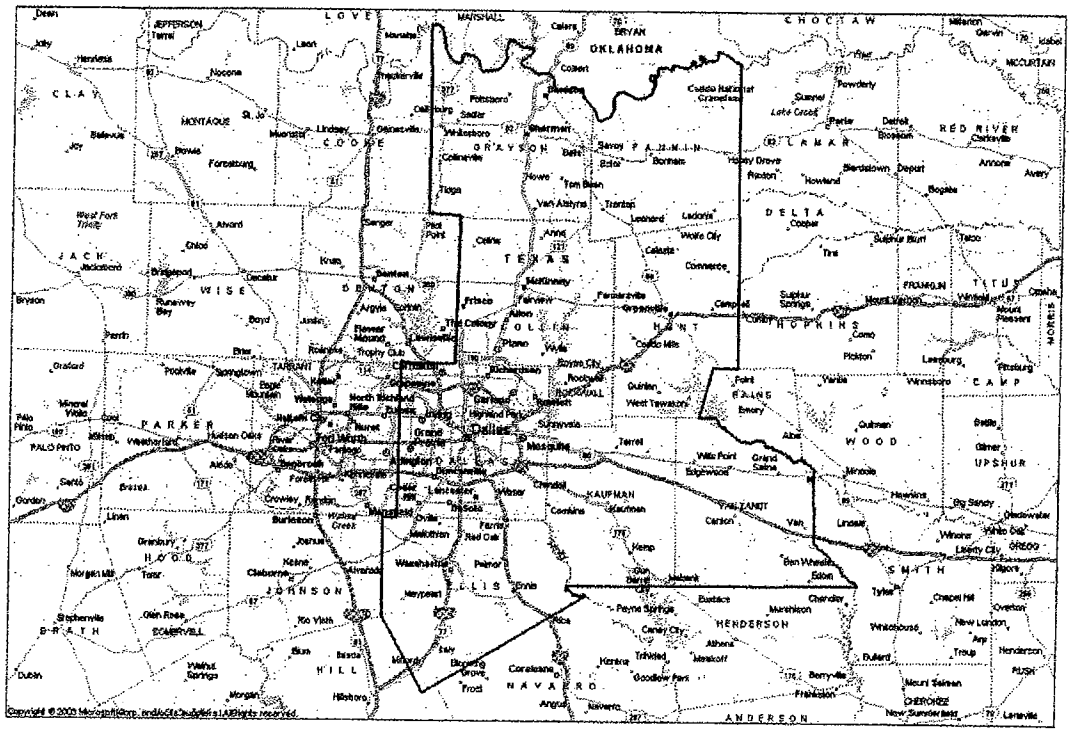
Statistical Weighting

Statistical weighting is a technique that is commonly used in survey research to compensate for sampling and response error. During the process of data collection and immediately after its completion, statistical tests were run to identify demographic factors that cause variance in variables of interest and then these sample parameters were compared with known population parameters to determine if the sample was representative of the population. Demographic data from the U.S. Census was obtained in order to identify population parameters in the counties surveyed. Demographic sample

parameters were then compared with Census parameters to identify a potential response bias. Weights were calculated and applied to the survey sample to ensure that various demographic sub-groups were properly represented. In the final weighting analysis, it was concluded that the sample was representative of the population within the following critical parameters: gender and age.

Geographic Area Surveyed

The map below provides an outline of the counties which served as the population of interest for this study: Grayson, Ellis, Kaufman, Van Zandt, Hunt, Rockwall, Fannin, Dallas, and Collin counties. The research sample of adults was drawn from households in these counties.



Explanation of Multivariate Analysis

Multivariate analysis was conducted in order to examine differences among respondents according to specific pre- and post-classified segments, or groupings. Multivariates included:

- Age
- Gender
- Language of the interview (Spanish vs. English)

Multivariate analysis is an advanced statistical technique used in the testing of hypotheses and measuring the degree of association between variables. It involves Chi Square, analysis of variance and appropriate tests of independence and association.

Interpretations and inferences set forth in the analysis are intended to provide an independent statistical perspective. The statistical procedures utilized were applied with a 0.95 confidence level for estimating values and/or providing significant inferences. This means that if a study were repeated 100 times, 95 times out of 100 the answers would vary by no more than the margin of error. A 0.05 significance level was used as the criterion to test hypotheses. At 0.05, there is no more than a 5 percent likelihood that the answers occurred by chance. The smaller the significance level, the less likely the answers occurred by chance – for example, a 0.001 means it is 1 in 1000 the answers occurred by chance. Multivariate findings, when they are significant and meaningful, are indicated at the end of each section.

In addition to measures of significance in which differences have been determined at the 0.05 level, a measurement of association will also be reported. These measurements vary between 0 and 1. A measurement of 0 indicates the variable in question does not explain (or is not associated with) the dependent variable, and a measurement of 1 indicates that the independent variable explains all of the variation in the dependent variable. This level of association is called Cramer's V, and it is what is reported throughout the report.

Respondent Profile

The following tables present the demographic profile of the sample. As indicated in the methodology section, the sample was statistically weighted to match the population by gender and age. The frequencies in the tables below are the weighted frequencies.

Age	Percentage
18 – 24	12.1%
25 – 34	22.2%
35 – 44	22.4%
45 – 54	18.6%
55 – 64	12.1%
65 and over	11.2%
Refused	1.5%

Gender	Percentage
Male	50.7%
Female	49.3%

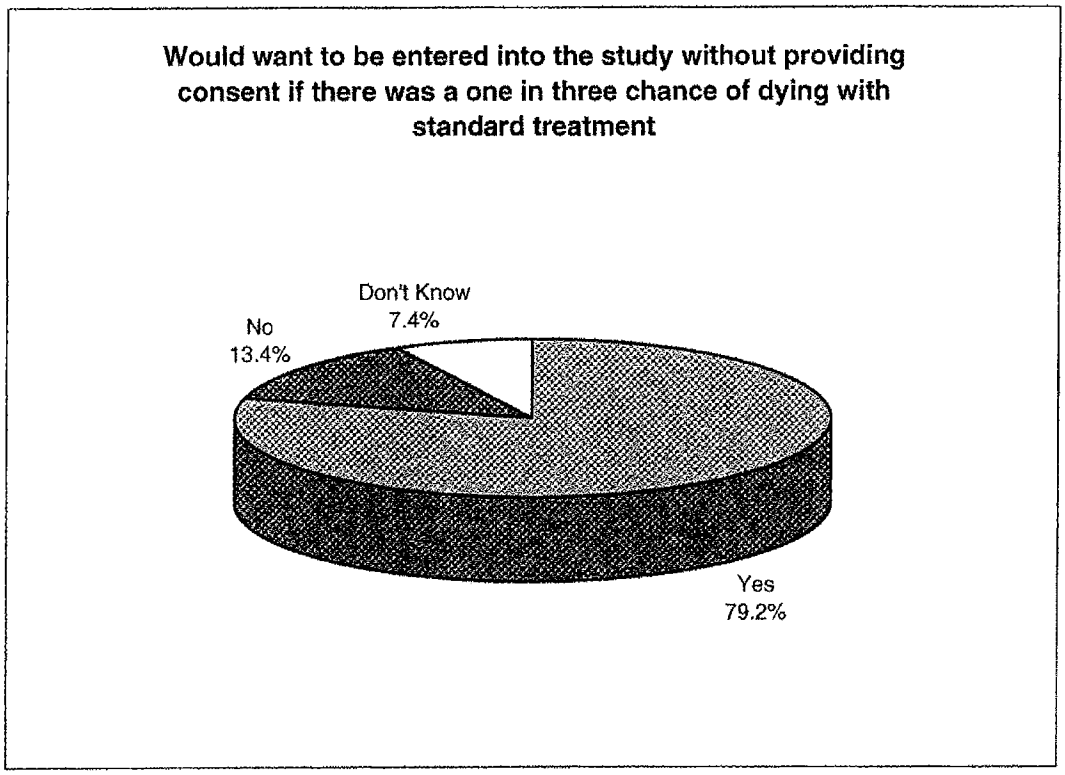
County of Residence	Percentage
Dallas	67.7%
Collin	17.6%
Ellis	5.1%
Grayson	3.1%
Kaufman	2.4%
Van Zandt	1.9%
Hunt	1.3%
Rockwall	0.7%
Fannin	0.2%

Language	Percentage
English	79.1%
Spanish	20.9%

Support for Being Entered into the Study without Consent

Respondents were first read a statement that provided background information about the nature of the study (see questionnaire in Appendix). Respondents were then asked if they would personally want to be entered into the study and possibly receive the experimental treatment if they were severely injured, had a one in three chance of dying and were unable to provide consent.

More than three-quarters (79.2%) of respondents said they would want to be entered into the study without providing consent. Only 13.4% of the respondents said they would *not* want to be entered into the study. 7.4% of respondents said they did not know. The community is highly in favor of being entered into the study if they were severely injured and were unable to provide consent.



No significant differences in responses were found by gender, indicating that men and women were equally likely to want to be entered into the study. There were, however, significant differences by age and language ability.

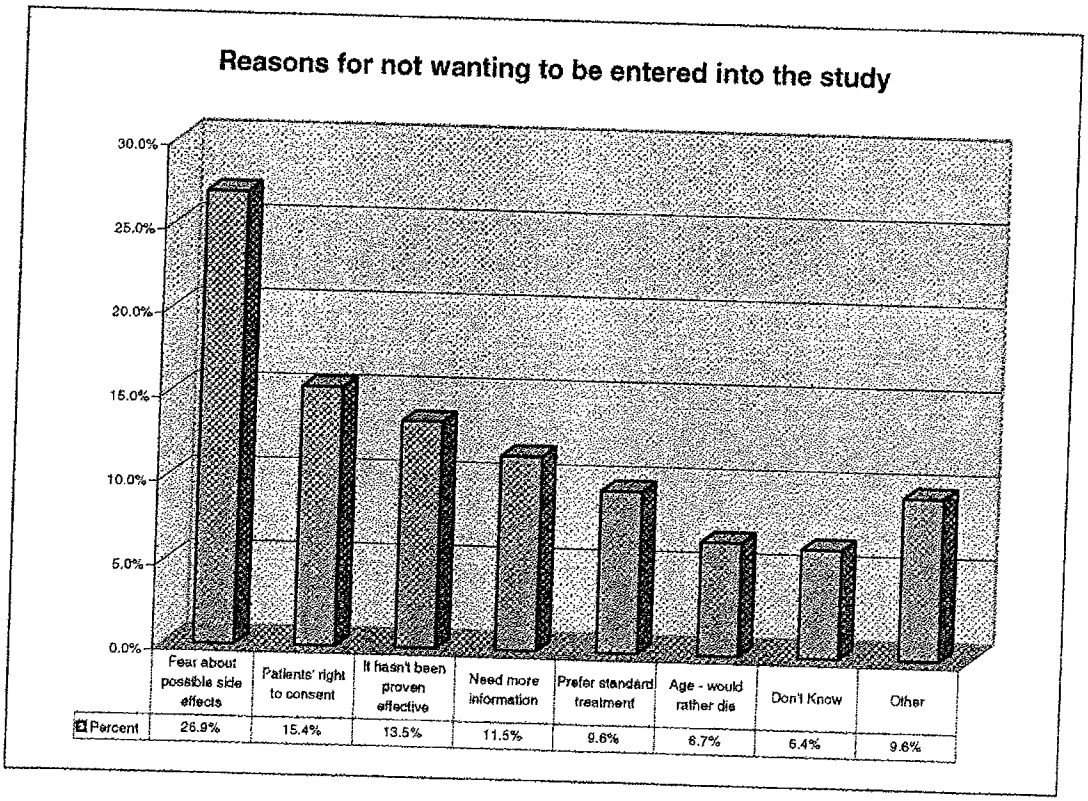
Younger respondents were significantly more likely to want to be entered into the study, compared to older respondents ($p = .036$, Cramer's $V = .14$). The percentages for each age group in favor of being entered into the study were: 18 to 24—95.0%, 25 to 34—76.6%, 35 to 44—81.4%, 45 to 54—79.6%, 55 to 64—73.3%, and 65 and over—67.9%.

Those who completed the interview in Spanish were significantly more likely to want to be entered into the study compared to those who completed the interview in English (93.3% vs. 75.3%, respectively; $p < .001$, Cramer's $V = .183$).

Concerns about Being Entered into the Study Without Consent

Respondents Who Would Not or Did Not Know if They Would Want to be Entered into the Study

The respondents who did not want to be entered into the study (13.4%) or did not know whether they would want to be in the study (7.4%) were asked the reason for their concern. Of this combined sub-group, 26.3% (5.6% of total sample) said they feared the possibility of side effects, and 15.4% (3.2% of total sample) said they believed patients should not lose the right to provide consent. Additional reasons included that the experimental treatment has not been proven effective (13.5%, 2.8% of total sample), and there is a need for more information (11.5%, 2.4% of total sample). Some respondents said they would simply prefer the standard treatment (9.6%, 2.0% of total sample), or that they are old, and would rather die than receive the treatment (6.7%, 1.4% of total sample).



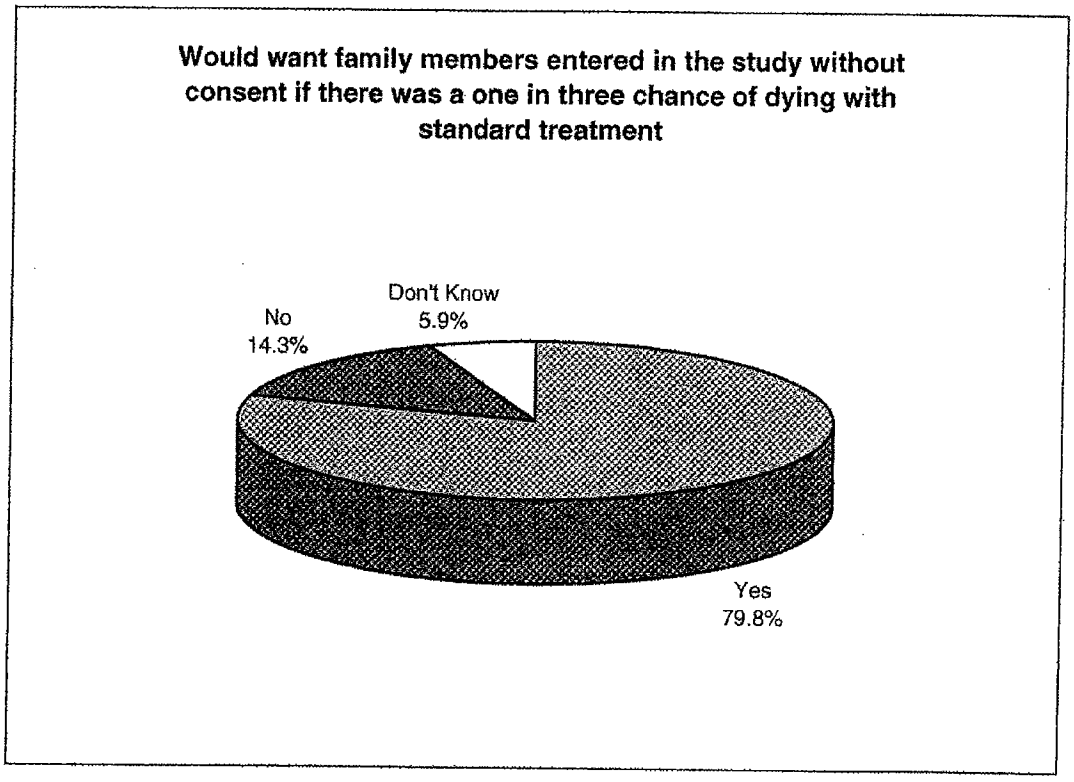
What follows is a representative sample of respondents' "Other" reasons for concern or uncertainty over being in the study without consent:

- *Already in a study with Parker.*
- *I have COPD. The doctor makes the decision.*

- *How informed the team is at the time. How much training they have received at the time.*
- *I don't want to prolong my life. When the Lord is ready for me, then I am ready.*
- *I have a living will and if I'm critically injured, I don't want to be brought back.*
- *If there is a lower probability of survival, then I would not do it. If I had a 1 in 2 chance of survival, I would say yes. If the probability was better (of survival), I would say yes.*
- *If someone is dead, they need to stay that way. I don't believe in frantic effort to revive someone who is already dead.*
- *If it's an emergency, I think they should try to start it if you could save the life. I don't know.*
- *If this is done by someone who is learning, I don't know if I would want them to do it.*
- *I'm conservative about all medical procedures.*
- *Integrity.*
- *It would depend on the severity of the injuries and what the injury related to, or if it was a brain injury.*
- *Will lawsuits result if I don't survive? Family suing UT for taking a family member's life?*
- *It's not FDA approved. As a Christian, whatever the plan that God has for me, that's it.*
- *They should test the standard more.*

Support for Entering Family Members in the Study without Consent

The majority of respondents (79.8%) said that if one of their family members was severely injured and had a one in three chance of dying with standard treatment, they would want their family member entered into the study without consent. 14.3% said they would not want their family members in the study and 5.9% said they did not know.



While no significant differences were found based on gender, there were differences by age and language. Compared to older respondents, younger respondents were significantly more likely to want family members in the study ($p = .005$, Cramer's $V = .160$). 100% of those aged 18 to 24 would want family members in the study while the percentages for other age groups in favor of entering family members into the study were: 25 to 34—76.6%, 35 to 44—77.9%, 45 to 54—81.7%, 55 to 64—73.8%, and 65 and over—73.7%.

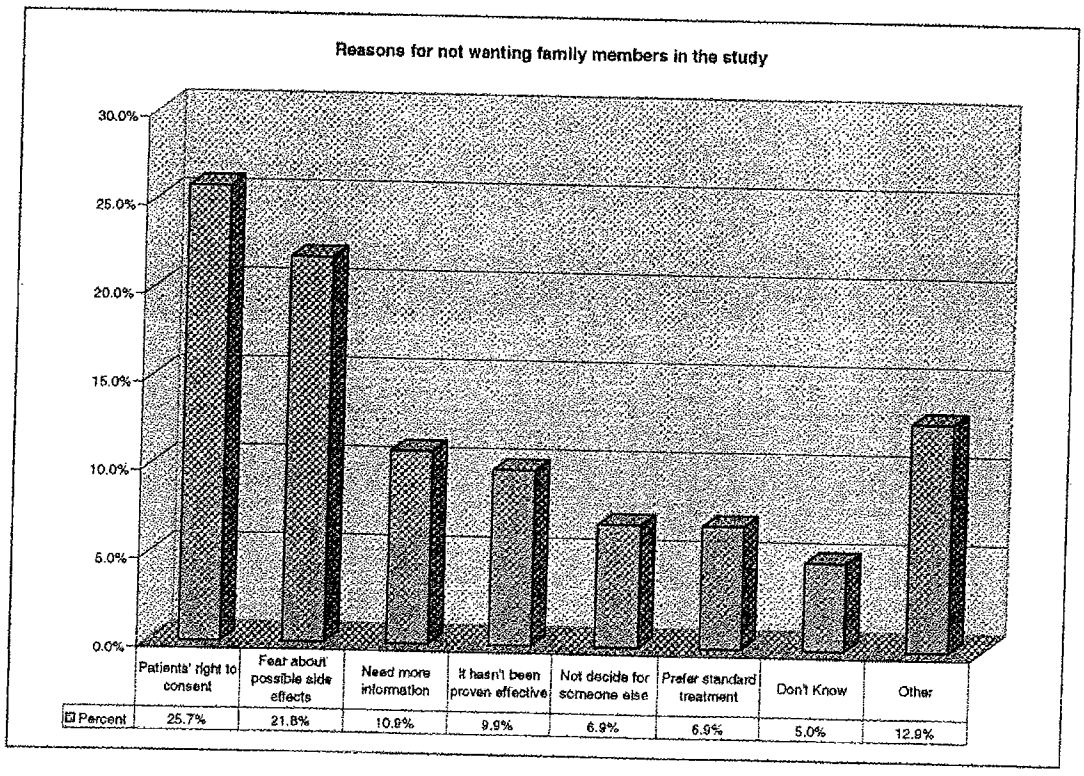
Those who spoke Spanish were also significantly more likely to want family members entered into the study without consent ($p = .006$, Cramer's $V = .143$). 90.5% of those completing the interview in Spanish would want family members entered into the study,

while 77.1% of those completing the interview in English would want family members entered into the study.

Concerns about Family Members Being Entered into the Study Without Giving Consent

Respondents Who Would Not or Did Not Know if They Would Want Family Members to be Entered into the Study

The respondents who did not want family members entered into the study (14.3%) or did not know (5.9%) were asked the reason for their concern. Of this combined sub-group, 25.7% (5.2% of total sample) said they believed patients should not lose the right to provide consent, and 21.8% (4.4% of total sample) said they feared the possibility of side effects. Another 10.9% (2.2% of total sample) said that they would need more information about the experimental treatment, and 9.9% (2.0% of total sample) said that they wouldn't want it administered to family members because it hasn't proven itself to be effective. 6.9% of respondents would not want to make that decision for someone else (1.4% of total sample), and 6.9% (1.4% of total sample) said they would prefer their family members simply receive the standard treatment.

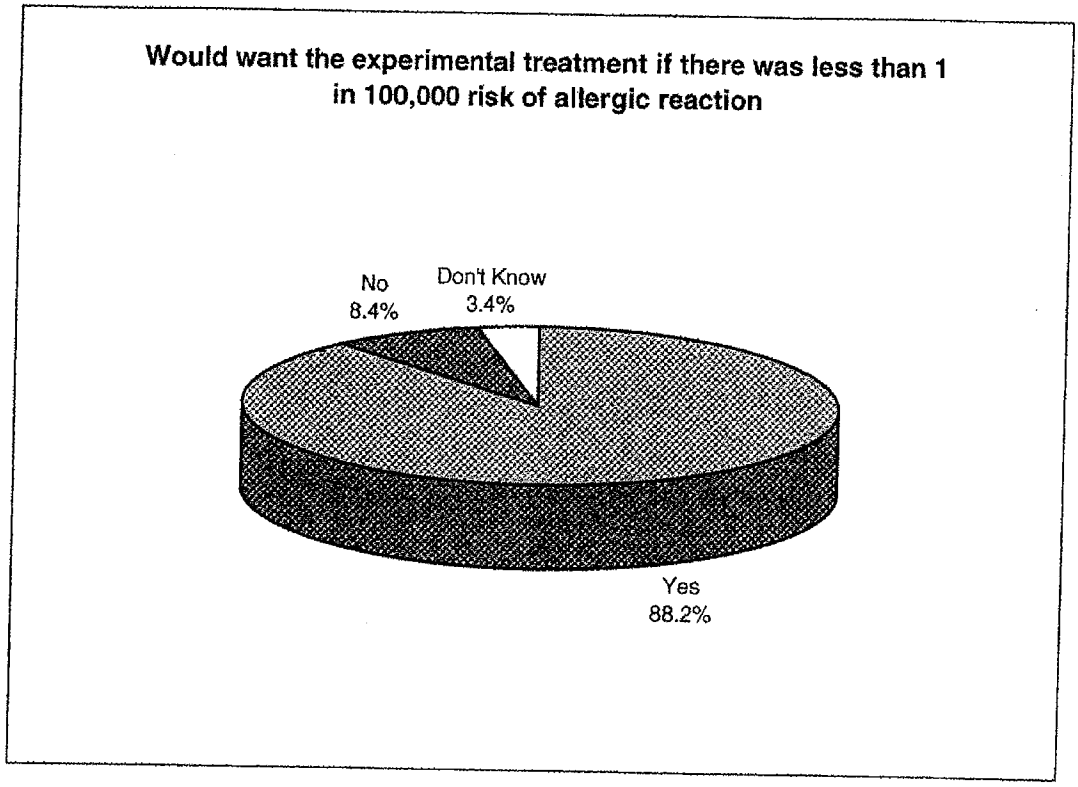


What follows is a representative sample of respondents' "Other" reasons for concern or uncertainty over entering family members in the study without consent:

- *Again, it would depend on their age, everything that can be done to help the younger people is important, and with older people, it is not that important.*
- *Because if they have the last chance for survival, I prefer that.*
- *Chances are too slim.*
- *I'd rather have them die normal.*
- *If someone is dead, they need to stay that way. I don't believe in frenetic effort to revive someone who is already dead.*
- *If they are lying there like my husband was, no, because he was already gone. He would be a vegetable if he lived.*
- *I'm conservative about all medical procedures.*
- *It's more proper that a family member is quickly told the odds of someone dying and if they are high, then, yes, it is okay, and the rule of thumb is the person doesn't have to give consent.*
- *I've lived several years. I wouldn't want to risk it on someone younger.*
- *I'm a Jehovah's Witness.*
- *Not without family member's consent; it should be regulated with legal oversight. There should be ordered ways to compliment ways for the researchers to qualify it.*
- *The chances of survival and the success rate of previous studies.*
- *The consent and the side effects and would it improve your chances of not dying.*
- *The odds might be less with the experimental treatment.*
- *They do so many experiments now - that's where I say no. I don't trust them until it is written on paper. They would have to show me what they're doing before I would say yes.*
- *I would fell guilty if they died.*

Support for Receiving the Experimental Treatment if There was a Low Risk of an Allergic Reaction

The vast majority of respondents (88.2%) would want to receive the experimental treatment if there was less than 1 in 100,000 risk of allergic reaction. With a low risk of allergic reaction, only 8.4% of respondents said they would not want the experimental treatment administered.



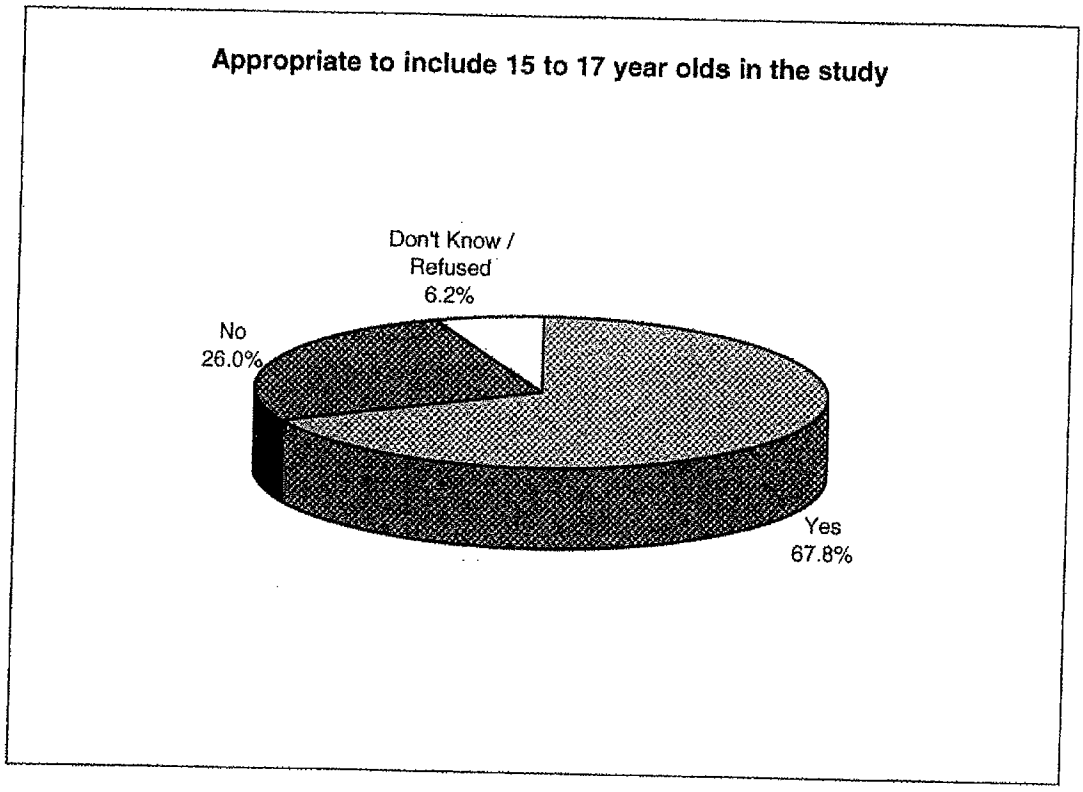
Respondents completing the interview in Spanish were significantly more likely to want the experimental treatment with a low risk of an allergic reaction compared to those completing the interview in English ($p = .005$, Cramer's $V = .145$). 97.1% of Spanish speakers would want the experimental treatment compared to 85.9% of English speakers.

Men were significantly more in favor of receiving the experimental treatment compared to women, 91.3% of males versus 85.0% of females ($p = .014$, Cramer's $V = .130$).

There were no significant differences between age groups.

Support for Including Children Aged 15 to 17 in the Study

Respondents were asked whether they believe it is appropriate to include children aged 15 to 17 years old in the study. More than two out of three respondents, 67.8%, said it would be appropriate to include them in the study. Only 26.0% said that it would not be appropriate.



Respondents over the age of 65 and between the ages of 18 and 24 had significantly higher levels of support for including this age group compared to other respondent age groups ($p = .006$, Cramer's $V = .158$). Levels of support for including children by respondent age group were: 18 to 24—75.0%, 25 to 34—68.5%, 35 to 44—60.2%, 45 to 54—67.7%, 55 to 64—70.0%, and 65 and over—76.8%.

Those completing the interview in English were significantly more likely to favor including 15 to 17 year olds compared to respondents who completed the interview in Spanish (70.3% vs. 58.1% respectively; $p = .006$, Cramer's $V = .144$).

Support for including children also varied by gender with 72.8% of males favoring including this age group compared to 62.8% of females ($p = .036$, Cramer's $V = .115$).

Reasons For and Against Including Children Aged 15 to 17 in the Study

For: Of the 67.8% of respondents who voiced support for including children in the study, a great many said that age made no difference, that we need to do all we can to help this group to survive. "A heart is a heart," one respondent said. Many commented they should be included because 15 to 17 year olds have a higher potential for accidents and should be treated as adults because they have many of the same needs. Many parents commented that they would want everything possible done to save their child. Other reasons given included the fact that this age group has their whole life is ahead of them and deserves a chance to live, they are every bit as important as adults and it is necessary to include them to advance medical knowledge and to prove the treatment effectiveness for this age range.

Against: The 26.0% of respondents who did not support including children in the study explained that informed consent should be necessary, that this group is simply too young and the treatment should be proven on adults first. Some expressed a fear regarding the risks involved with an experimental treatment and that something may go wrong, including the possibility of negative side effects.

Don't know: Many of the respondents who said they didn't know whether children should be included (6.2%) said they would need more information. Some said including children would be okay if there were parental consent. A few others expressed the concerns and positive attitudes described above.

A sample of the responses is listed below; all of the responses can be found in the appendix.

Appropriate to include children 15 to 17 years old in the study:

Age Doesn't Matter—Everyone Should have a chance to Survive

- *I am a trauma nurse and time is crucial; I think all should have a chance at any means to live.*
- *Fifteen to seventeen year olds have the same characteristics as full-grown people; younger people are injured just as much as full-grown people.*
- *Age is irrelevant; youngsters deserve every chance to survive.*
- *I think they deserve an opportunity to live just like anybody else.*
- *They should have the same rights as adults for a better quality of care. When you start reaching that legal age of maturity, they can make those same decisions as the usual adults can.*
- *Because I think that you've got to give them the same chance as you give everybody else.*

- *Why not? If it's that large of a percentage involved in the trauma. If older people are included, then why not everybody?*
- *Well, because we need to find ways to allow them to stay alive, as well. We don't want to exclude any age group as long as they have quality of life.*

They are a High-risk Age Group

- *Because we let 16 year olds drive cars so they should also be treated as a an adult. Plus, they are the ones driving more.*
- *A lot of 15-17 yrs are involved in accidents.*
- *A lot of people in that age group get severely injured where they would need it. It's not that much more of a risk when you are severely injured, and if it would help them, if there's a chance, then try it.*
- *I would think a lot of 15-17 year olds would be involved in accidents, they would be old enough to be included (physically).*
- *If there was an accident with young people driving, the chances are high of an accident for elderly and young people, especially with teenagers.*
- *They're just learning to drive and are a higher risk for accidents. There seems to be an age bracket where there is more fatal accidents.*

Would Want Their Own Children Saved

- *Because I have a 16 year old.*
- *I have 18-year-old boys, and I would like them to have the best chance of survival, even if the treatment is experimental. ANY chance to improve their survival is a good thing to see when dealing with younger kids.*
- *I have a 14 year old so if there is a possibility to help him in a situation I'd want that opportunity.*
- *I have a seventeen yr old and as a parent if I wanted my son to live, I would take any measure to insure it.*
- *I have young children and I want to have them to have opportunities; my daughter started driving at 15 and because she was driving a car, chances were high that something would happen.*

Need to Determine Whether it Works for all Age Groups

- *I just think for a drug to be complete you have to include a whole gambit of ages.*
- *They would be part of the test group including the 15-17 year olds in this study.*
- *Unless you test it, you're not going to know and you have to know.*
- *Why not? If you're going develop new methods, you need to try it on younger people.*
- *If you value the research, it's as valuable for all ages.*

Whole Life Ahead of Them

- *They have the potential the most to gain at that age. They have their lives ahead of them. So they should be given the best chance to survive. Research in other countries also gives them a better chance.*

- *They still have many years ahead of them and should have every chance possible to live.*
- *This is a life and death matter, the younger they are, the more they have to live for. They should have every chance to stay alive.*

Not appropriate to include children 15 to 17 years old:

Informed Consent Needed

- *Not without consent. If parents give consent, it's fine. They're children, they're too young.*
- *Not without parental consent. If there were some kind of prior statement made, like a no resuscitation statement with the elderly, I would say yes. If the odds of survival were less than one in three, I would go with the treatment.*
- *If it were my kid...It's ethics based, I would want to give consent.*
- *Too young; they're not considered as adults. They're not adults until age 21; need parents consent.*
- *With under age 18, there needs to be some parental permission involved.*
- *Not without parental consent. You get into a lot of ethical stuff. It would be okay with my kids. You have religious groups that would turn it down. I can't think of their name. They don't believe in transfusions.*
- *Because you are making a decision for a child that only a parent should make.*
- *I think they should be adults because...I don't know...a minor has a parent that gives consent but adults give their own consent.*
- *It just depends on the parent. Their consent is important. Being that they are young and underage, they are still too young to make a decision. They don't know what's good or bad.*

Uncertainty of Side Effects

- *I heard on the news about how some children are allergic or not allergic to certain types of vaccinations such as flu shots and it depends on the particular health of the person if his or her body can take it or not.*
- *It would be because they're so young and if there were side effects, they would have a lot longer to deal with them.*
- *I think that their bodies are different. An adult is much more likely to survive the rigors of experimental treatment than a teenager.*
- *Because the side effects could be far worse.*
- *I think the study should be just for 18 and over. I don't know if a 17 year old would react the same way. It might not make a huge difference.*
- *I guess primarily they have a longer life ahead of them and if there are any side effects. If there were any side effects, they would have to live with them longer than anyone older.*
- *I don't like to study kids 15-17 year olds in case they die. If there is hope for them it would be okay, but if there is no hope, I don't think they should.*

- *With youth, it's dealing with different metabolism, weight, and size. Generally what might work, especially since experimental tests done on those kinds of variations, there is more risk. I don't know how it's going to affect them.*

Too Young

- *They are not old enough possibly to make that kind of judgment call.*
- *They are too young. It's better to study older people.*
- *They are kids, until it's proven that it works, I don't think anything should be done with kids.*
- *They're too young. If they're going to use somebody, use somebody who's older and is about to croak anyway.*
- *I have a fourteen-year-old son. I wouldn't want experimental treatments being done on him with him being a minor.*
- *Well, I don't really have a reason - people that young should not be in this.*

It is Still Experimental

- *I feel that children are different then adults and until it's 100 percent approved by our government, it shouldn't be used on a child.*
- *I don't think experimental drugs should be used on kids; I don't think kids should be guinea pigs.*
- *Because it's experimental. It hasn't been proven. I don't think I would want to go there unless there was some information that it would be better than the proven, no matter what the age.*

Don't know whether it's appropriate to administer to children ages 15 to 17 years old:

Need more information

- *Need more information.*
- *Don't know enough about it.*
- *Feel I need to know more.*
- *I would need to know more about the fluid and the study. There's no way I can say anything otherwise.*
- *I, again, I don't know enough about it.*
- *I wouldn't know if it would be good for someone at any age - you are talking about an experimental fluid and I don't know enough about it*

Okay with parental consent

- *With parental consent; it's a decision a parent should make, not a child of that age.*
- *Not without consent of their parents. I don't think minors should be included in any medical procedures without the consent of their parents.*
- *With permission only.*
- *Would want consent*

- *I have mixed emotions about doing an experimental procedure on a minor without parental consent.*
- *I would only do this with parental permission.*

Depends on the injury

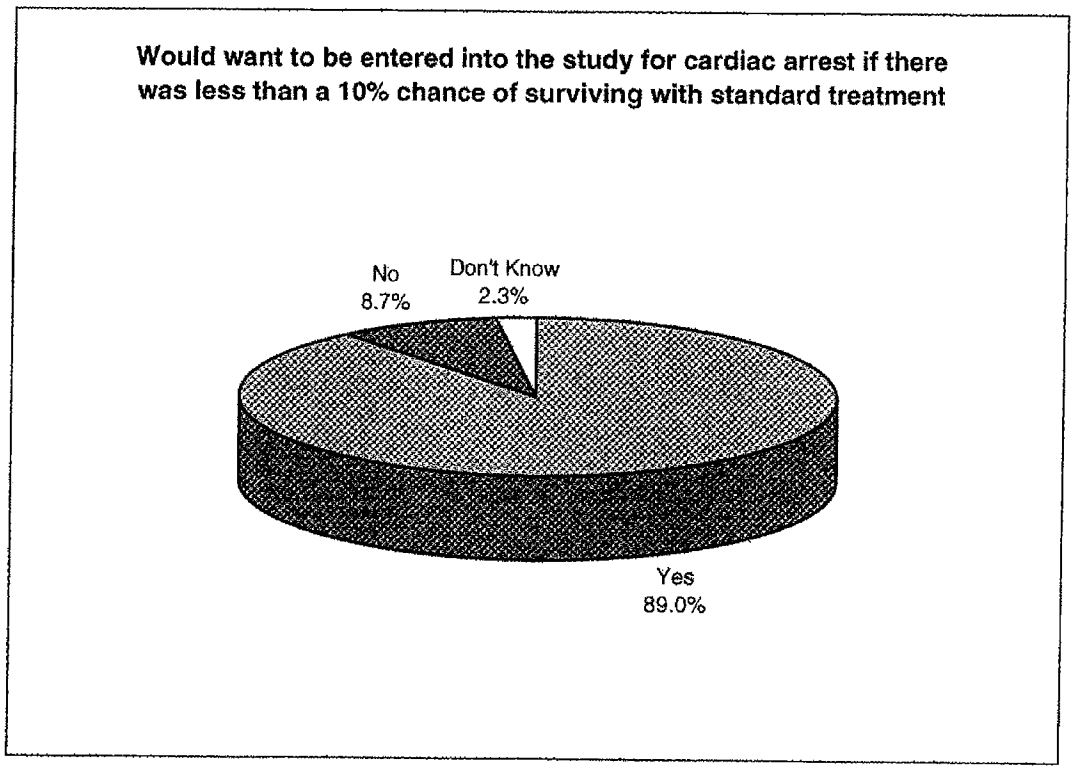
- *If there were anything that could be done, I'd want it done. I would have to know at that time, depending on their condition.*
- *It would more depend how serious the injury was. The EMT would have to have good training to make that call.*

Don't have children

- *Have no kids but I would want to do anything I could to save them.*
- *I would not want to speak for someone else and I have no children.*

Support for Being Entered in the Cardiac Study Without Consent

If respondents suffered cardiac arrest and had less than a 10% chance of surviving with standard treatment, 89.0% would want to be entered into the study with the potential of receiving the experimental treatment, while only 8.7% would not want to be entered into the study.



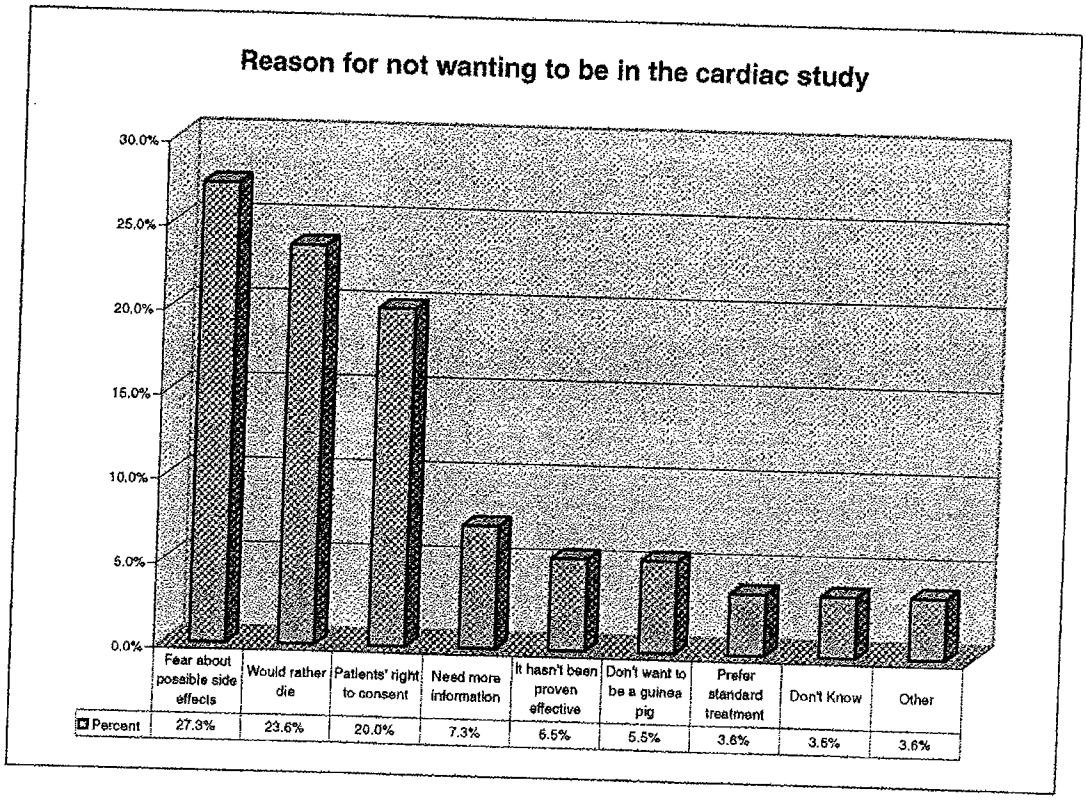
No significant differences were found based on age or gender.

Respondents completing the interview in Spanish were significantly more likely than English-speaking respondents to favor being entered into the study for cardiac arrest (100.0% of Spanish speakers compared to 85.9% of English speakers; $p < .001$, Cramer's $V = .182$).

Concerns Over Being Entered in the Cardiac Study

Respondents who Would Not or Did Not Know if They Would Want to be in the Cardiac Study

The respondents who did not want to be entered into the cardiac study (8.7%) or did not know whether they would want to be in the study (2.3%) were asked the reason for their concern. Respondents said that they were afraid of the side effects (27.3%, 3.0% of total sample), they would rather die than be resuscitated (23.6%, 2.6% of total sample), and the patient should not lose the right to consent (20.0%, 2.2% of total sample). Respondents also reported that they would need more information (7.3%, 0.8% of total sample), and would be concerned because the method hasn't been proven effective (5.5%, 0.6% of total sample). Some respondents reported that they wouldn't want to be treated as a guinea pig (5.5%, 0.6% of total sample), or would simply prefer the standard treatment (3.6%, 0.4% of total sample).



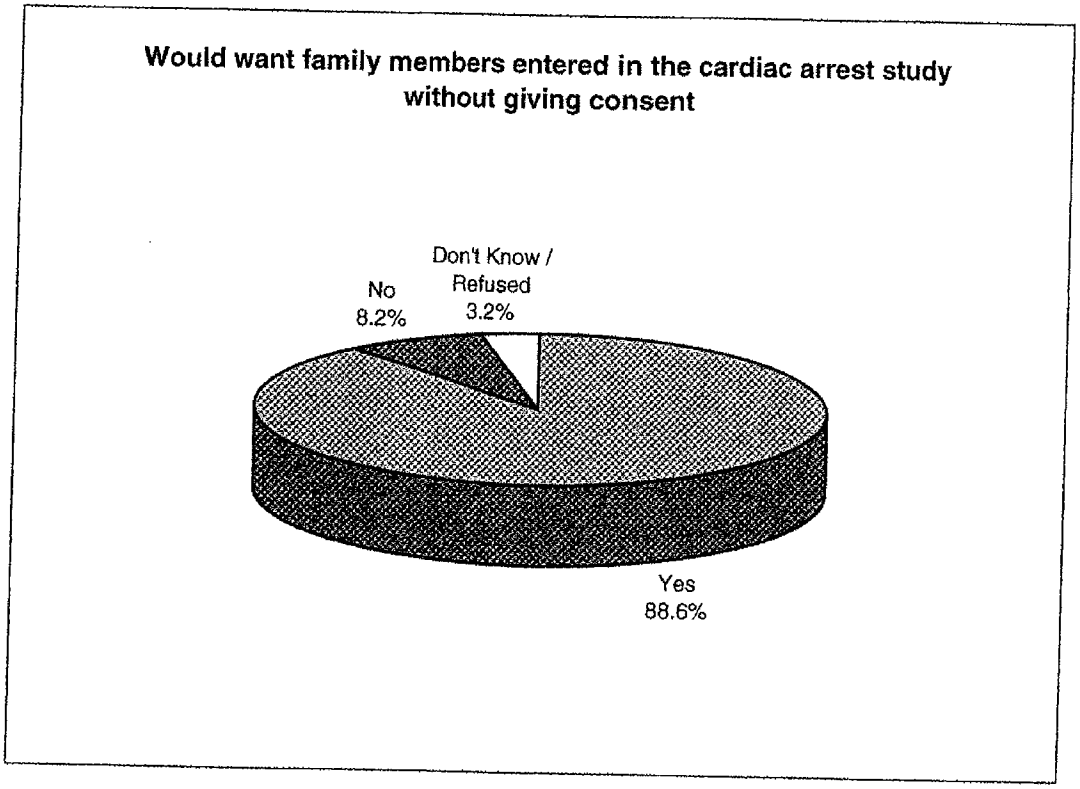
What follows is a representative sample of respondents' "Other" reasons for concern or uncertainty over being in the cardiac study:

- *Chances of good quality of survival.*
- *I don't know how you'd determine the risks or odds ...so if you were taken to the hospital then I agree to the experimental treatment.*
- *I don't trust that theory.*

- *I have a heart problem already; my heart blew up.*
- *I have had a heart attack in the past. I would want to be informed of the results before I would want it for myself.*
- *If there is no hope for that person, I don't think it is right to do the study.*
- *It's experimental and it's a life threatening situation, unless the odds are better than the standard.*

Support for Entering Family Members in the Cardiac Study without Consent

Of those respondents who had family members (99.4% of total sample), the vast majority (88.6%) said that if a family members suffered a cardiac arrest, they would want the family member entered into the cardiac study without giving consent. 8.2% said they would not want family members entered in the study and 4.7% said they did not know.

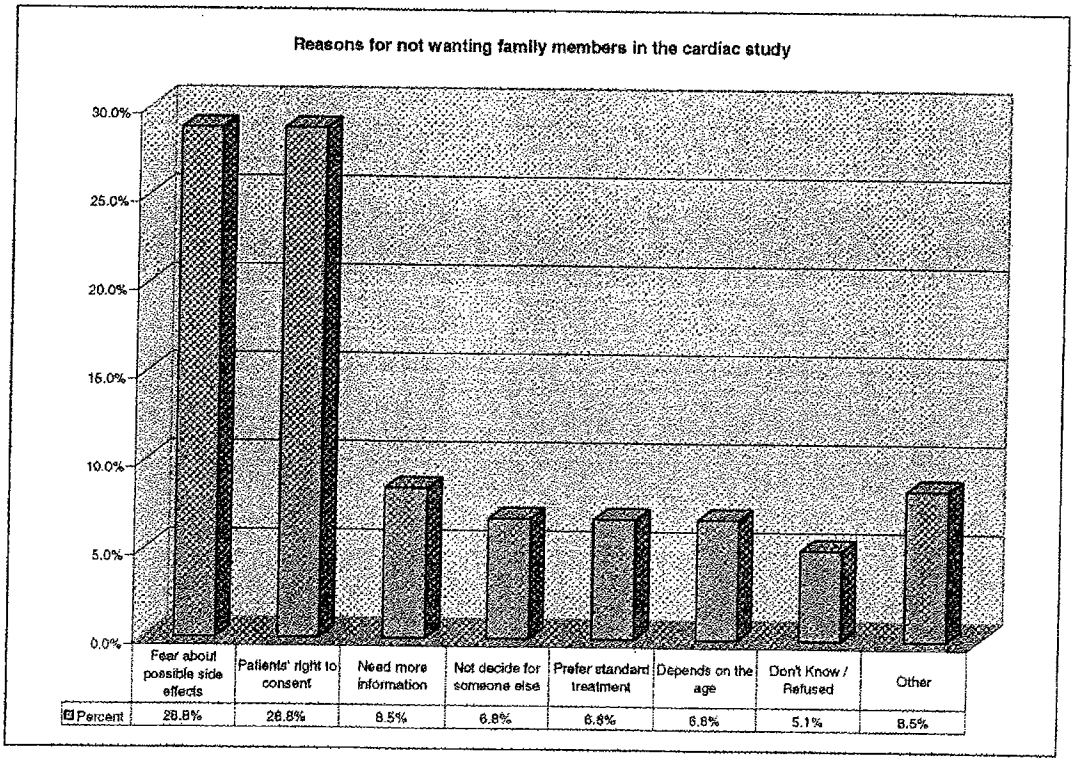


No significant differences were identified between age groups or based on gender, but a significant difference was found between respondents speaking Spanish versus those speaking English. 99.0% of Spanish speakers wanted their family member admitted to the cardiac study which is significantly higher than the 85.8% for English speakers ($p = .001$, Cramer's $V = .171$).

Concerns about Family Members Being Entered into the Cardiac Study Without Giving Consent

Respondents Who Would Not or Did Not Know if They Would Want Family Members in the Cardiac Study

The respondents who did not want family members entered into the cardiac study (8.2%) or did not know (3.2%) were asked the reason for their concern. Many of the respondents explained that they feared the possibility of side effects (28.8%, 3.4% of total sample) or that patients should not lose the right to consent (28.8%, 3.4% of total sample). Respondents also explained that they would need more information (8.5%, 1.0% of total sample), would not want to make a decision for someone else (6.8%, 0.8% of total sample), would prefer their family member receive the standard treatment (6.8%, 0.8% of total sample), or that it would depend on the patient's age (6.8%, 0.8% of total sample) with the general idea of the younger the age the greater the possibility of the treatment being helpful.



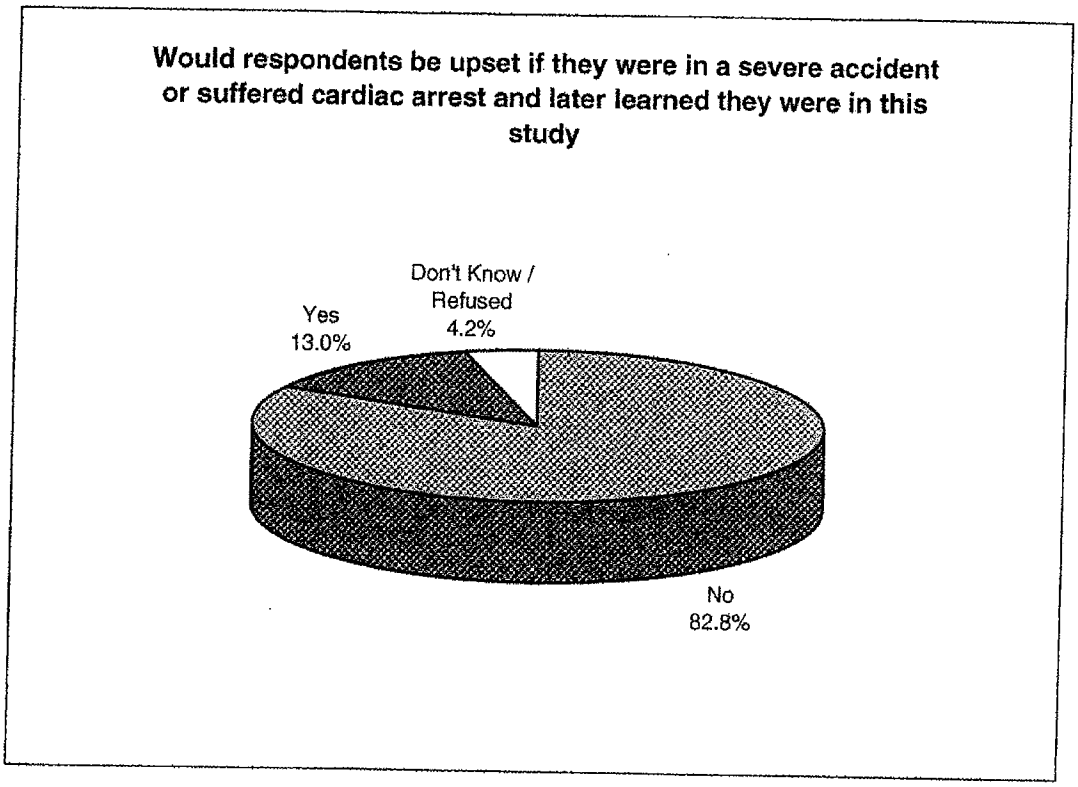
What follows is a representative sample of respondents' "Other" reasons for concern or uncertainty over having family members entered in the cardiac study:

- *Because there is so low a chance of survival there is no need for additional suffering.*
- *I don't want nobody in that study.*

- *I don't want them to be the guinea pigs.*
- *I feel that the 10% chance is too low.*
- *I hadn't talked to them beforehand to see if they'd be willing to do it.*
- *I wouldn't want them to be experimented on.*
- *If there is no hope for them I don't think it is right to do the study. If there was a higher chance of survival with the study, then research might be OK.*
- *It would be up to the parents.*
- *It's not approved.*
- *My mother-in-law was on life support; it was ridiculous.*
- *My parents are my only family and like I told you, when it's time to go, it's time to go!*
- *Should be case by case.*
- *They are more than 50% gone. I don't know then.*
- *With the experienced person it's all right. If it's somebody who is learning, I would like more study before you learn on me.*

Respondent's Reaction if They Learned They had been Entered into the Study without Consent

Overall, 82.8% of respondents reported they would not be upset if they were in a severe accident or suffered a cardiac arrest and later learned they were in this study. A very small group of respondents (13.0%) said that they would be upset, and 4.2% said they did not know.



There were no significant differences by age, gender, or language used for completing the interview.

Reasons for Being Upset

The 17.2% of respondents who said they would or did not know if they would be upset if they learned they were in the cardiac study were asked why they would be upset. Most respondents stated they would be upset because they did not provide consent. Some stated that, as long as they were alive, they would probably not be upset but happy to be alive. Other reasons for respondents being upset involved the fact that the treatment is

experimental in nature and the fear of a poor outcome. Selected comments appear below. The full list of comments will be found in the Appendix.

Did not Provide Consent

- *Possibly initially, but then I would get over it. Obviously the benefits would be there because I would be alive. It would be the consent portion that was against my wishes.*
- *I didn't give consent.*
- *I don't like people doing things without permission.*
- *I still want to give consent first.*
- *I think it would be because it was given without my consent.*
- *If it was unapproved medical treatment without my consent, I would be upset.*

Wouldn't be Upset if Alive

- *I'd be grateful.*
- *If I survived, I'd be happy.*
- *I'd be thankful.*

Fear of a Poor Outcome

- *Because I don't want that and I don't want to end up on life support.*
- *If there were side effects that wouldn't have been if I hadn't had it, I would be upset.*
- *Because quality of life is dependent upon functioning adequately, if in a quadriplegic state, God forbid that, I would be enthusiastic.*

Does Not Want to be Experimented on

- *Because I wouldn't want to be experimented on. If I knew more about it I might change my mind. What the different processes are, the different medications, the different techniques used. I would want to see the research on it.*
- *If I'm going to die and it's the last chance, then do it, otherwise use other alternatives. I don't want to be a guinea pig.*

Uncategorized Comments:

- *My privacy would be invaded. I would feel used.*
- *I am a nervous 71-year-old woman when it comes to those types of things.*
- *There is a possibility...if none of my family members would know about the treatment...nurses kill people, give people shots.*
- *If my quality of life were poor and I were handicapped I would be upset but I don't know about long term ...if I were in a vegetative state I wouldn't be happy about that but I wouldn't know—that's the risk I take so ...I guess it would apply more if a family member were the one making the decision on your behalf...so initially I'd hate to see my sister in a vegetative state...but eventually you think we did everything we could to save her life...maybe some disappointment but even if that person passed on we did the right thing and the burden that would create for the family long term ...but that's the risk you take in this situation, anyway.*

Popular Sources of Information

Respondents were asked about various communication sources they use to get information so that the community could be informed about the study before it begins and other sources that were not on the list read to them. The majority of respondents reported that their main source of information was television (88.3%), the Internet (79.0%), radio (77.8%), and newspapers (72.1%). About half of the respondents get information in newsletters (57.0%), from church (54.0%) and through the schools (49.4%). The full range of sources is listed in the table below.

Sources of Information	Percent
Television	88.3%
Internet	79.0%
Radio	77.8%
Newspaper	72.1%
Newsletters	57.0%
Churches	54.0%
Schools	49.4%
Physicians and Medical Professionals	27.5%
Neighborhood Associations	24.7%
Word of mouth	14.7%
Hospital (Including pamphlets and flyers)	7.8%
Magazines	5.4%
Work	3.0%
Health Insurance	2.8%
Mailings	2.0%
Books	1.8%
Journals	1.8%
Library	1.4%
AARP	1.2%
Phone calls	0.8%
Pharmacy	0.6%
Billboards	0.4%
Health stores	0.2%
Other	2.2%

*Percentages sum to more than 100% due to multiple responses.

Additional Comments

Respondents were given the opportunity to make further comments about the experimental treatments for cardiac arrest victims or severely injured patients being administered without first getting written consent. Approximately one-third of the respondents, both those in favor of and against the study, offered additional comments which largely reiterated concerns already expressed.

A small group repeated the idea that patients should not lose the right to provide consent. Some respondents said they needed to know more about it before making a decision or did not want to make a judgment for others. A few respondents commented on the need for public awareness. Some respondents took notice of the potential legal ramifications of the study such as opening the sponsors and medical professionals to a potential lawsuit for administering the treatment without consent.

Many respondents indicated that we need to do all that we can to save lives, and especially if the standard treatment gives less effective outcomes. As one respondent said: *"When it is not feasible to get consent by the patient or their family, it only makes sense to give them the best possible treatment, which may include the use of promising experimental procedures."* Many felt that if consent is not possible, it is important to do what can be done to help someone. Some stated support for the experimental treatment as long as it did not reduce the quality of life in the patient's future.

A selection of responses appears below; the full range can be found in the Appendix.

Requirement of written consent:

- *I think they should get consent because it is a study, & that people should know what possible side effects there are with different animals that were studied.*
- *I personally have a problem with it. I would not want experimental treatment that I did not consent to.*
- *The family should have the final say; what the family wants.*
- *I am against it and I really think to take advantage of someone who cannot defend themselves it wrong.*
- *The general public doesn't know the treatment for major trauma. It's not right to experiment with medicine and treat without consent. I think it should be done in a researched environment, not in the field.*
- *I have a problem with not getting consent.*
- *I don't really like the idea of someone else making the decision if I'm not capable of doing so myself.*
- *It's best, I think, if you can get written consent. Without written consent, you would be running into...It smacks too much like the Nazis, an experiment they*

carried out in concentration camps. They had no written consent. I just don't like the idea of having this done without a lot more information.

Quality of Life:

- *If it can ensure quality life after treatment, that would make a difference.*

Impractical Aspect of Gaining Consent:

- *No sir. There is no time. Family members are far away. It's not practical because they are far away and hard to contact.*
- *The circumstances you read were emergency situations where no one can give consent. I'm good with that.*
- *When it's not feasible to get consent by patient or their family, it only makes sense to give them the best possible treatment, which may include use of promising experimental procedures.*
- *Because of the fact that they may not be able to answer for themselves or before they're deceased, if standard procedure as it currently exists may or may not work, this probably should happen.*
- *If you can't get consent at the time, you do what you have to do.*
- *If you're about to die and don't have a good chance of living with the standard treatment, and most people want their loved ones to live, I think the experimental treatment is okay without the consent.*
- *I could see where some people might be upset over it, if there's no opportunity to say aye or nay. As long as there's no other way and it didn't make somebody paralyzed, and that person were alive and healthy they should probably be excited to be involved in an experimental treatment and they survived.*

Make every Attempt to Save:

- *I think everyone should be willing to try a new way to do things. If the old way don't work then maybe the new one will.*
- *I basically feel that anything that could help them survive is worth the chance of doing it.*
- *Try everything and anything to save a life. If they are doing everything...try every possible avenue. That includes experimental treatment.*
- *When considering the risk, my opinion is that most people should get anything that might save their lives.*
- *I think if the likelihood of survival is increased, it seems to me to be the thing to do; if incapacitated, do everything to keep them alive. It is like a Good Samaritan; can't fault them for trying. The same is true in medical emergency.*
- *I think it is a very personal thing. My feeling is if I had one of my family members in that situation, I would want to try anything and have every chance they can.*

Public awareness:

- *You need to be sure to let everyone know exactly what the projects are about.*
- *We need to be better informed on this study.*

- *Make it more knowledgable to people so they're not freaking out; the more it's talked about, the more people are aware of it. They should do this with all kinds of education levels. The basic person should know what you're talking about.*
- *What I would like to know is what is in the experimental fluids and the public should be well educated that this exists and if it really does increase their survival rate. Some people with cardiac arrests don't survive, however most of them do.*
- *I think its good if it's public information. So that the community knows it's a possibility they will get treated with it, before it's put to use.*

Legal Ramifications:

- *There may be lawsuits it treatment was given without consent. The more people know about it, the less they'll be skeptical.*
- *They need to hit the news media to say they're implementing the procedure. The latest technology. Don't surprise them with it; keep them informed. Less of a problem with lawsuits.*
- *I think it's dangerous in a way; there are people who would have lots of problems with it. There are people who, if you did this, and that person died, they would sue you.*
- *If the experimental treatments are believed to be helpful so much that the researchers would be willing to receive them, and if the emergency caregivers are free from liability should things go wrong, then I'm fully in favor of them.*

Would like more information:

- *I have a lot of questions because I don't know what it is; I can't adhere to something I don't understand.*
- *I don't really understand what we're talking about; I don't know what the treatment is or the technique. I know what the standard is because my husband went through that. I'd like to read about it though.*
- *I would love to know about what experimental procedures they are doing.*

Key Findings

- When in the situation of being unconscious due to severe injury, nearly four out of five respondents (79.2%) said they would want to be entered into the study even if they were unable to provide consent. An even higher percentage of respondents (88.2%) said that they would want to be entered into the study if there were less than a 1 in 100,000 risk of allergic reaction. A similarly high number of respondents (79.8%) would want family members entered into the study. More than two out of three respondents (67.8%) favor including children aged 15 to 17 in the study. Given these high percentages, it is clear the community is very strongly in favor of being included in the study and of including family members and teenagers aged 15 to 17 without the requirement of consent.

- Concerns expressed by those who would not want to be entered into the study (20.8%) primarily involved a fear of the possibility of side effects, the lack of the opportunity to provide consent (15.4%), the idea that the treatment hasn't been proven effective (13.5%), and the need for more information (11.5%).

- The reasons respondents would not want family members included in the study involved the belief that patients should retain the right to provide consent (25.7%), fear of possible side effects (21.8%), the need for more information (10.9%), and the lack of proof that the treatment is effective (9.9%).

- Those who supported including children in the study (67.8%) primarily felt that age made no difference and everyone should have an equal chance of surviving. Respondents also noted that 15 to 17 year olds are a high-risk age group and may be more likely to be severely injured, but share many of the same needs as adults and deserve the opportunity because they have their whole life ahead of them and prove the effectiveness of the treatment for this age range.

- The respondents who did not think it was appropriate to include children in the study (32.2%) believed, at this age, consent should be necessary and that children in this age group are simply too young. Some felt the treatment should be proven on adults first.

- If suffering from cardiac arrest, a very high majority of the respondents (89.0%) would want to be entered into the cardiac study without providing consent. Nearly as many respondents (88.6%) also would want family members to be entered into the study, as well. Respondents show a very strong preference for participating in the cardiac study themselves and having family members participate without providing consent.

- The primary reasons respondents would not want to be entered into the cardiac study involved the fear of side effects (27.3%), the preference of dying rather than receive the treatment (23.9%), and wanting the opportunity to give consent (20.0%).

- The primary reasons respondents would not want family members to be entered into the cardiac study included fear about possible side effects (28.8%), the need for the patient to give consent (28.8%, and the need for more information (8.5%).

- If severely injured or suffered cardiac arrest, a very high majority of respondents (82.8%) said that they would not be upset if they later learned they were entered into this study.

- The top four communication channels the community uses to get information are television (88.3%), the Internet 79.0%), radio (77.8%), and newspapers (72.1%). About half the community receives information through newsletters, from their church, and through the schools.

Appendix

UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS
EXCEPTION TO CONSENT RESEARCH
Questionnaires – October, 2006

V1.0

Hello, my name is _____ calling on behalf of University of Texas Southwestern Medical Center at Dallas from Hebert Research, an independent research firm in Bellevue, Washington.

May I speak to someone who is at least 18 years of age? Thank you.

[IF NECESSARY, REINTRODUCE YOURSELF]

We would like to get your opinions about a medical study involving people who have been severely injured and another involving victims of cardiac arrest. The survey will take approximately 10 minutes. I will describe the research studies and ask for your opinions about them. You can skip any questions or stop the survey at any time. Your opinions will help guide how best to inform your community about this study. Your answers will be kept anonymous.

Is now a good time to do the survey? Thank you!

Introduction: [READ]
First, I am going to describe the research study to you.

[READ THE FOLLOWING PRIOR TO ASKING SURVEY QUESTIONS]

Different ways of treating victims of cardiac arrest and for patients with severe traumatic injuries, such as those occurring in a serious car crash, are being considered in Dallas County. Currently, very few cardiac arrest victims survive to be discharged from the hospital, and many patients with serious traumatic injuries die in the field or hospital. Researchers wish to study a different way of performing CPR for cardiac arrest victims, including a new valve that improves blood flow during chest compressions, and an experimental fluid treatment that may improve a person's chances of surviving severe injuries. The cardiac arrest victim or injured patient would either receive standard treatment or one of the experimental treatments. This is by chance, like flipping a coin, and is the only way to find out whether or not the new treatment is better than what is done now. Each of these experimental ways of treating cardiac arrest and trauma patients has shown promise in animal studies and small human studies, but more research is needed before this can be proven.

Usually, researchers ask people for consent to participate in a study. In the case of cardiac arrest and severe injuries, it is not possible to give consent because the person may be confused, unconscious, or in shock. In addition, family members may not be available to speak for them. Research studies can be performed without consent in emergencies such as this. People may be included in a study like this only after a research ethics board has approved the study in advance. Such groups, including the one at UTSW, value the opinion of citizens like you.

All of the experimental ways of treating cardiac arrest and trauma victims that are being considered have appeared safe in animal and small human studies.

Some places in the United States are currently using an approach to treating cardiac arrest that is very similar to the approach in this study. Also, the experimental fluid to be given to trauma victims in this study is currently approved for regular use in Europe. As with any treatment, however, there is always a risk of side effects that were not anticipated. There is also a chance that the studies won't result in better survival. A special committee of experts who are not involved in the studies will be set up to monitor for any unexpected events.

Now I would like to ask you a few questions about this study.

1. If you were severely injured and had a one in three chance of dying with standard treatment, would you want to be entered into the study and possibly receive this experimental treatment, even though you couldn't give consent?
   1. Yes **[GO TO Q3]**
   2. No
   3. Don't know
   4. Question refused

2. What is the reason for your concern?
   1. Fear about possible side effects
   2. Patients should not lose the right to provide consent for themselves
   3. Other _____ **[SPECIFY]**
   4. Don't know
   5. Refused

3. If one of your family members was severely injured and had a one in three chance of dying with standard treatment, would you want them to be entered into the study and possibly receive this experimental treatment, even if they or you couldn't give consent?
   1. Yes **[GOTO Q5]**
   2. No
   3. Not applicable (respondent doesn't have family members)
   4. Don't know
   5. Question refused

4. What would be the reason for your concern?
   1. Fear about possible side effects
   2. Patients should not lose the right to provide consent for themselves
   3. Other _____ **[SPECIFY]**
   4. Don't know
   5. Refused

5. If there was less than 1 in 100,000 risk of an allergic reaction, would you still want the experimental treatment given to you?
   1. Yes
   2. No
   3. Don't know
   4. Question refused

6. Injury is the leading cause of death in people ages 15 - 44 years. Injured adolescents have the same benefits and risks from the experimental fluid as adults. Do you think it is appropriate to include 15-17 year olds in this study?
   1. Yes
   2. No
   3. Don't know
   4. Question refused

7. What are your reasons for your answer? **[VERBATIM]**

8. If you suffered a cardiac arrest and had less than a 10% chance of surviving with standard treatment, would you want to be entered into the study and possibly receive the experimental treatments, even though you couldn't give consent?
   1. Yes **[GO TO Q10]**
   2. No
   3. Don't know
   4. Question refused

9. What is the reason for your concern?
   1. Fear about possible side effects
   2. Patients should not lose the right to provide consent for themselves
   3. Other **[SPECIFY]**
   4. Don't know
   5. Refused

10. If one of your family members suffered a cardiac arrest and had less than a 10% chance of surviving with standard treatment, would you want them to be entered into the study and possibly receive the experimental treatments, even if they or you couldn't give consent?
    1. Yes **[GO TO Q12]**
    2. No
    3. Don't know
    4. Question refused
    5. Not applicable (respondent doesn't have family members)

11. What would be the reason for your concern?
    1. Fear about possible side effects
    2. Patients should not lose the right to provide consent for themselves
    3. Other **[SPECIFY]**
    4. Don't know
    5. Refused

12. If you were in a severe accident or suffered a cardiac arrest and later learned that you were in this study, would you be upset?
    1. Yes
    2. No **[SKIP TO Q14]**
    3. Don't know **[SKIP TO Q14]**
    4. Question refused **[SKIP TO Q14]**

13. Why do you say that? **[VERBATIM]**

We will tell the community about this study before it begins. Please answer "Yes" or "No" whether you use the following sources to get information? **[READ 14-21]**
    1. Yes
    2. No
    3. Don't know
    4. Refused

14. Newspaper
15. Internet
16. Neighborhood Associations
17. Newsletters
18. Churches
19. Schools
20. Radio
21. Television

22. What other ways do you get health-related information that we haven't asked about? **[VERBATIM]**

23. Do you have any additional comments about giving experimental treatments to cardiac arrest victims or severely injured patients without first getting written consent? **[VERBATIM]**

DEMOGRAPHICS

I have just one more question to ask to make sure that we have a representative sampling of your community's opinions. Your answers will be kept anonymous.

24. What is your age?

THAT CONCLUDES OUR SURVEY. THANK YOU VERY MUCH FOR YOUR TIME AND COOPERATION.
POSTCODE LANGUAGE USED DURING SURVEY:
1. ENGLISH
2. SPANISH

POSTCODE GENDER:
1. MALE
2. FEMALE
DATE: _____INTERVIEWER: _____

UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS
INVESTIGACIÓN SOBRE LA EXCEPCIÓN DE CONSENTIMIENTO
CUESTIONARIO – July, 2006

V1.0

Hola, mi nombre es _____ y le estoy llamando de parte de la Universidad de Texas Southwestern Medical Center at Dallas. Yo trabajo para Hebert Research, una compañía independiente de investigación en Bellevue, Washington.

¿Podría hablar con alguien mayor de 18 años de edad? Gracias

[DE SER NECESARIO, VUELVA A PRESENTARSE]

Nos gustaría conocer su opinión sobre un estudio médico relacionado con personas que han sufrido graves heridas y otro estudio relacionado con víctimas de paro cardiaco. La encuesta llevaría aproximadamente 10 minutos. Primero le describiría los estudios que se están investigando y después le pediría su opinión al respecto. Si no quiere responder alguna pregunta, puede saltársela, y también puede detener la encuesta en cualquier momento. Sus opiniones ayudarán a guiar mejor a la comunidad sobre este estudio y todas las respuestas que nos dé serán anónimas.

¿Es este un buen momento para que pueda responder el cuestionario? ¡Gracias!

Introducción: [LEER]
Primero le voy a describir el estudio.

[LEA LO SIGUIENTE ANTES DE HACER LAS PREGUNTAS DE LA ENCUESTA]

En el condado de Dallas se están considerando distintos tratamientos para pacientes con heridas severas como las que sufren las víctimas de accidentes automovilísticos. También se está considerando otro tratamiento para personas que sufren un ataque cardiaco. Actualmente muy pocos pacientes de paro cardiaco sobreviven y muchas personas gravemente heridas mueren camino al hospital o en el hospital. Los investigadores quieren estudiar una manera distinta de dar Resucitación Cardiopulmonar a las personas que sufran un ataque cardiaco, incluyendo emplear una válvula que mejora la circulación sanguínea al presionar el pecho. También quieren probar un tratamiento con un fluido experimental que puede aumentar la posibilidad de que sobrevivan los heridos de gravedad. Las víctimas de paro cardiaco podrían recibir el tratamiento estándar o el experimental, se decidiría al azar, por ejemplo, lanzando una moneda al aire, y es la única forma de saber si este tratamiento es mejor que lo que se hace actualmente. Tanto el tratamiento para víctimas de paro cardiaco, como el tratamiento para heridos, han tenido resultados favorables en pruebas en animales y en pequeños estudios con humanos, pero se requiere más investigación para comprobar su eficacia.

Normalmente los investigadores piden el consentimiento del paciente para su participación en un estudio. Sin embargo, en el caso de víctimas de paro cardiaco y de heridas de gravedad, no es posible dar consentimiento porque la persona puede estar confundida, inconsciente o en shock. Por su parte, los familiares pueden no estar disponibles para decidir por el paciente. En este tipo de emergencias sí se pueden implementar tratamientos que se están estudiando. Se puede incluir a personas en un estudio como este, después de que un consejo sobre ética de investigación aprueba por adelantado el estudio. Los miembros de estos consejos, como el de UTSW, valoran la opinión de ciudadanos como usted.

Todos los tratamientos que se están considerando para atender a las víctimas de paro cardiaco y de heridas graves, han resultado seguros en animales y en pequeños estudios en humanos.

En algunos lugares de Estados Unidos ya se están usando tratamientos para víctimas de paro cardiaco, similares al de este estudio. Asimismo, el fluido experimental que se le daría a los pacientes gravemente heridos en este estudio, ya se aprobó para uso en Europa. Sin embargo, como con cualquier tratamiento, siempre hay un riesgo de efectos secundarios que no se habían anticipado. También pudiera suceder que el estudio no resultara en mejor posibilidad de sobrevivencia. Un comité especial de expertos que no tienen nada que ver con el estudio, se encargarían de monitorear la aparición de cualquier suceso no esperado.

Ahora me gustaría hacerle algunas preguntas acerca de este estudio.

1. Si usted sufriera heridas de gravedad y tuviera una en tres posibilidades de morir con los tratamientos convencionales, ¿le gustaría que lo incluyeran en el estudio y posiblemente recibir el tratamiento experimental, aunque no pudiera dar su consentimiento?
   1. Sí **[PASE A LA PREGUNTA 3]**
   2. No
   3. No sé
   4. No respondió

2. ¿Qué le preocupa?
   1. Temor a posibles efectos secundarios
   2. Los pacientes no deberían perder su derecho de dar consentimiento por sí mismos.
   3. Otro _____ **[ESPECIFIQUE]**
   4. No sé
   5. No respondió

3. Si un miembro de su familia sufriera graves heridas y tuviera una en tres posibilidades de morir con los tratamientos convencionales, ¿le gustaría que lo incluyeran en el estudio y posiblemente recibir este tratamiento experimental, aunque ni su familiar ni usted pudieran dar su consentimiento?

   1. Sí **[PASE A LA PREGUNTA 5]**
   2. No
   3. No aplica (el encuestado no tiene familiares)
   3. No sé
   4. No respondió

4. ¿Qué le preocuparía?

1. Temor a posibles efectos secundarios
2. Los pacientes no deberían perder su derecho de dar consentimiento por sí mismos.
3. Otro _____ **[ESPECIFIQUE]**
4. No sé
5. No respondió

5. Si la posibilidad de una reacción alérgica fuera de una en cien mil, ¿desearía aún que le aplicaran el tratamiento experimental?

1. Sí
2. No
3. No sé
4. No respondió

6. Las heridas son la causa número uno de muerte en personas de quince a cuarenta y cuatro años de edad. Los adolescentes tienen los mismos riesgos y beneficios que los adultos al aplicárseles el fluido experimental. ¿Cree usted que es apropiado incluir en este estudio a jóvenes de quince a diecisiete años de edad?

1. Sí
2. No
3. No sé
4. No respondió

7. ¿Cuál es el motivo de su respuesta? **[ANOTAR RESPUESTA TEXTUALMENTE]**

8. Si sufriera usted un paro cardiaco y tuviera menos del diez por ciento de posibilidad de sobrevivir con el tratamiento convencional, ¿le gustaría que lo incluyeran en este estudio y posiblemente recibir el tratamiento experimental, aunque no pudiera dar su consentimiento?

1. Sí **[PASE A LA PREGUNTA 10]**
2. No
3. No sé
4. No respondió

9. ¿Qué le preocupa?
1. Temor a posibles efectos secundarios
2. Los pacientes no deberían perder su derecho de dar consentimiento por sí mismos.
3. Otro _____ **[ESPECIFIQUE]**
4. No sé
5. No respondió

10. Si un miembro de su familia sufriera un paro cardiaco y tuviera menos del diez por ciento de posibilidad de sobrevivir con el tratamiento convencional, le gustaría que lo incluyeran en este estudio y posiblemente recibir el tratamiento experimental, aunque ni su pariente ni usted pudieran dar su consentimiento?
1. Sí **[GO TO Q12]**
2. No
3. No sé
4. No respondió

5. No aplica (el encuestado no tiene familiares)

11. ¿Qué le preocuparía?
    1. Temor a posibles efectos secundarios
    2. Los pacientes no deberían perder su derecho de dar consentimiento por sí mismos.
    3. Otro _____ **[ESPECIFIQUE]**
    4. No sé
    5. No respondió

12. Si usted fuera víctima de un accidente, o le diera un paro cardiaco y después se enterara de que fue incluido en este estudio, ¿se molestaría?
    1. Sí
    2. No **[PASAR A LA PREGUNTA 14]**
    3. No sé **[PASAR A LA PREGUNTA 14]**
    4. No respondió **[PASAR A LA PREGUNTA 14]**

13. ¿Por qué opina eso? **[ANOTAR RESPUESTA TEXTUALMENTE]**

Le informaremos a la comunidad sobre este estudio antes de comenzarlo. Por favor responda "sí" o "no" a si usa las siguientes fuentes de información **[LEER 14-21]**

1. Sí
2. No
3. No sé
4. No respondió

14. Periódico
15. Internet
16. Asociación de colonos
17. Boletines
18. Iglesias
19. Escuelas
20. Radio
21. Televisión

22. ¿De qué otra manera recibe información sobre salud, que no le hayamos preguntado? **[ANOTAR RESPUESTA TEXTUALMENTE]**

23. ¿Tiene algún otro comentario respecto a dar tratamiento experimental a víctimas de paro cardiaco o de heridas graves, sin obtener primero su consentimiento? **[ANOTAR RESPUESTA TEXTUALMENTE]**

DEMOGRAFÍA

Sólo me queda una pregunta que hacerle para asegurarnos que tenemos una muestra representativa de las opiniones de nuestra comunidad. Su respuesta será anónima.

24. ¿Qué edad tiene?

ESO ES TODO. MUCHAS GRACIAS POR SU TIEMPO Y COOPERACIÓN.

POSTCODE LANGUAGE USED DURING SURVEY:

1. ENGLISH
2. SPANISH

CÓDIGO DE GÉNERO:
1. MASCULINO
2. FEMENINO

FECHA: _____

ENTREVISTADOR: _____

Answers to Open-Ended Questions

Respondents who did not know or would not want to be entered into the study and possibly receive the experimental treatment without providing consent were asked:

Q2. What is the reason for your concern?

The following are the "Other" reasons provided:

- *It's experimental and you're not sure of the success rate. I don't want my life hanging in the balance of something you're just testing out.*
- *There isn't enough information yet to know if the experiment would increase my chances of survival.*
- *Will lawsuits result if I don't survive? Family suing UT; taking family member's life.*
- *I'm a paramedic. I'd rather have the treatment that is in use right now. I realize it is not always 100 percent effective, but it is at times.*
- *I'd rather have the tried and true method rather than the one that's not proven to work.*
- *I don't know what the whole procedure is and it is not clarified.*
- *Just use what means are available, instead of the experimental trial. If I die, I die.*
- *It's still somewhat experimental.*
- *It would depend on the severity of the injuries and what the injury related to or if it was a brain injury.*
- *It's new. Untested.*
- *If there is a lower probability of survival, then I would not do it. If there was a 1 in 2 chance of survival, I would say yes. If the probability was better (of survival), I would say yes.*
- *I don't want to prolong my life. When the Lord is ready for me, then I am ready.*
- *This is over my head – it's advanced information in the way it is presented for someone who is a layman; I need it in more simpler laymen's terms.*
- *It's not FDA approved. As a Christian, whatever the plan that God has for me, that's it.*
- *There should be family consent, until the study is proven.*
- *The treatment has not been approved in the U.S., by the FDA. Chances of survival have not been proven, as well.*
- *I know what the odds are with the standard treatment; the odds could be less with the experimental.*
- *I don't know enough about it.*
- *Not knowing enough about it.*
- *Some people may survive but the quality of life afterwards is questionable.*
- *Stick with the tried true.*
- *My age.*

- *If this is done by someone who is learning, I don't know if I would want them.*
- *My age.*
- *Experimental means that they don't know the outcome yet.*
- *I'd like to know more about it depending on how it affects your heart.*
- *I'm 86 years old. I don't know what I'd do. I don't think that I would want to do that. Too much else is wrong, I have a terrible back and can't get around.*
- *I'd rather stick with the old way, the standard treatment; I'm afraid of dying.*
- *Everybody has their own opinion to go along with them. Since I'm 78 and have health problems, it might be different for me.*
- *I have COPD. Doctor makes the decision.*
- *Just because it is experimental.*
- *I'm a Jehovah's Witness.*
- *The chances of survival and the success rate of previous studies.*
- *I'd rather go and die normal.*
- *They should test the standard more.*
- *I wish I knew what the percentages were vs. the standards. I know Europe is very innovative, but innovative doesn't always mean safe.*
- *There are already procedures in place that work and I don't know much about this.*
- *Fear of side effects and patients not losing right to provide consent.*
- *If there is an emergency, I think they try to start it if you could save the life. I don't know.*
- *If someone is dead, they need to stay that way. I don't believe in frenetic effort to revive someone who is already dead.*
- *At my age at 83, I have had no problems, so why take any risks?*
- *Survival and as to whether it would work.*
- *It is experimental at this point. I have a certain amount of distrust for experimental things.*
- *Integrity.*
- *I don't want to be a guinea pig.*
- *I wouldn't be able to control my own self anymore...we've seen all kinds of patients...comatose etc., and I think you would be prudent as researchers to include families, etc.*
- *Go with standard treatment—I don't want to be a guinea pig.*
- *Already in a study with Parker.*
- *I'm 86 years old and ready to go if something happens.*
- *I wouldn't want anyone else deciding what to do with my life and would prefer using a known procedure. You know what to expect afterwards.*
- *I just don't really know anything.*
- *I'd have to know more about the treatment.*
- *Hasn't been proven? I'd say no.*
- *How informed the team is at the time. How much training they have received at the time.*
- *I have a living will and if I'm critically injured, I don't want to be brought back.*

- *The unknown; there's no proof with the study.*
- *Not knowing anything about it...I think I'd rather go w/the regular treatment...*
- *I would want to be aware of the consequences. It depends on who you are talking about; the event of a living will, etc.*
- *The chances of survival with this study.*
- *Treatments are experimental, and we don't know if they will work or not.*
- *It would depend on the chances of the experimental treatment.*
- *If I have a cardiac arrest at this age of mine, it's my time to go.*
- *I'm conservative about all medical procedures.*
- *I would need to research it more on my own.*
- *Because I have severe allergies and it could kill me. I am also epileptic. When I have an allergic reaction, I go into seizures.*
- *Just don't know enough about it.*

Those who did not know or would not want family members entered into the study and possibly receive the experimental treatment without providing consent were asked:

Q4. What would be the reason for your concern?

The following were the "Other" reasons provided:

- *The consent and the side effects and would it improve your chances of not dying.*
- *It's experimental. If there is a one in three chance in the standard, what are the odds with the new one?*
- *There isn't enough information yet to know if the experiment would increase my chances of survival.*
- *I prefer to have them have the standardized treatment in use today.*
- *It is experimental; just because they have not finished studying it and the chances of survival. I would have to know what the treatment is.*
- *I don't know enough information.*
- *Still experimental.*
- *If they are lying there like my husband was, no, because he was already gone. He would be a vegetable if he lived. He could have even made it. I wish I could have left it in the hands of the doctor.*
- *I don't know the chances with the experimental treatments they would receive as opposed to the standard treatments and how they would compare.*
- *It's new and untested.*
- *They need to make their own decisions.*
- *It would be up to them and their family's decisions.*
- *It's not FDA approved. I'm not hot on being the guinea pig or be the experiment.*
- *It's more proper that family members quickly ask the odds of someone dying and if the answer is "yes" then it is okay, and the rule of thumb is the person doesn't have to give consent.*

- *It has not been approved by the FDA and there is a risk with the study itself.*
- *Chances are too slim.*
- *The odds might be less with the experimental treatment.*
- *I don't know about it.*
- *Because if they have the last chance for survival, I prefer that.*
- *When making a decision for someone else, it weighs heavier on my mind.*
- *Stick with the tried true methods.*
- *My family doesn't want to be kept alive and I respect their wishes.*
- *Experimental means not proven yet.*
- *I would need more information and the ratio of success with the experimental fluid.*
- *Would fell guilty if they died.*
- *It's experimental treatment.*
- *I'm a Jehovah's Witness.*
- *The chances of survival and the success rate of previous studies.*
- *I've lived many years. I wouldn't want to risk it on someone younger.*
- *I'd rather have them die normal.*
- *Don't know enough a about it - not enough details.*
- *If it was proved, I would try it.*
- *If someone is dead, they need to stay that way. I don't believe in frenetic effort to revive someone who is already dead.*
- *Again, it would depend on their age, everything that can be done to help the younger people is important, and with older people, it is not that important.*
- *I'd rather do the standard than risk the experimental.*
- *They are adults; they would not need consent from me.*
- *Don't want them to be a guinea pig either.*
- *Not without a family member's consent. It should be regulated with legal oversight. There should be ordered ways to compliment the work of the researchers and a committee to qualify it.*
- *I don't know what their thoughts would be or how they would react, so I'd just go with the standard treatment.*
- *It's not my life to make the decision over.*
- *I want only family members to give consent and a known procedure has better possibilities with known side effects.*
- *I'd just have to know more.*
- *They do so many experiments now - that's where I say no. I don't trust them until it is written on paper. They would have to show me what they're doing before I say "Yes".*
- *I want to know how well-trained the people are at administering the treatment.*
- *I would prefer the standard treatment; it's just fear of the unknown.*
- *Not knowing anything about it.*
- *It's better to go with the standard treatment, than to gamble with the unknown.*
- *Need more information.*
- *It's what they would want ahead of time.*

- *I'm conservative about all medical procedures.*

Q7. What are your reasons for your answer? (Referring to whether it's appropriate to include 15-17 year olds in this study.)

Those Who said it is Appropriate:

- *As long as there is parental consent, there's no difference in family members as it is getting consent from an adult. Age doesn't make a difference to me.*
- *Because a lot of the times, when they are hurt, the parents aren't going to be there anyway. Usually the parents would be upset if you didn't do everything you could.*
- *Simply because it gives them a chance.*
- *It might be the same for kids as adults.*
- *Because if there is a one in 3 chance, at least it is that chance or better in the experimental treatment.*
- *I read or saw something about this. It's where there were measures taken in car wrecks and people were upset. If it helps people survive, and how are you going to learn if you don't try? If the survival does not give a quality of life then I would say, no. If the quality of life continues, then I would say, yes.*
- *Sometimes they might need it more.*
- *They should be given a chance.*
- *Anything that will lessen the death rate will be helpful.*
- *Anyone can have a heart attack or be injured. We don't come with guarantees.*
- *They might need it, too.*
- *If the current results aren't as good as we'd like them to be, then we should go ahead and try it and we might as well try it on teenagers so we know the results in that age group.*
- *If our best odds of survival are one in three, we better look to better alternatives. If 33 percent at present time-- only 1 in 3 survive with the present treatment, look for alternatives.*
- *They deserve a chance, too.*
- *I have young children and I want to have them have opportunities; my daughter started driving at 15 and because she was driving a car, chances were high that something would happen.*
- *Well, the younger people would be healthier and strong enough to be able to fight the side effects.*
- *They have the potential, the most to gain at that age. They have their lives ahead of them. So they should be given the best chance to survive. Research in other countries also gives them a better chance.*
- *A lot of 15-17 year olds are involved in accidents.*
- *They should have the chance to survive.*
- *I feel that anything that could be done is better than the standard way.*
- *My husband had a cardiac arrest, his was terrible. He died and didn't come back from treatment.*
- *Because they would be more injured than anyone else with things like car wrecks.*

- *I would want my family to live.*
- *With adolescents and children, you don't give them the same amounts and dosages as adults because it would have a different effect on them.*
- *If they have an equal chance of getting benefits, they should do it.*
- *It sounds like a good deal if that's the only way to save people and if nothing else can be done, so be it.*
- *I don't think the physiology is all that different in 15 to 17 year olds.*
- *They're just learning to drive and are a higher risk for accidents. There seems to be an age bracket where there are more fatal accidents.*
- *Because we have more problems with the age group; a lot of them are depressed and have personality problems.*
- *Because I would have faith in the researched treatment and it would save their lives.*
- *If it gives them a better chance for survival, and even though there is a chance of an allergic reaction, they have a better chance for survival because they are still young and stronger then adults.*
- *I think with younger people the likelihood of them suffering from cardiac arrest is minimal. Of course, younger people have more stamina than the older ones so they might have a better chance of survival.*
- *Because I have a 16 year old.*
- *Because we let 16 year olds drive cars so they should also be treated as an adult. Plus, they are the ones driving more.*
- *I just think that anything that can be done to save someone's life, even experimental, should be done.*
- *There have been some of these football players dropping dead. What do they have to lose? It might bring them back. If you are going to come back and you don't have your mind, that's something else.*
- *I think it should apply to all ages. I don't think you should leave out a certain age group.*
- *If had a crisis like that, I'd be willing to try the experimental test; anybody who is injured and is going through a cardiac arrest, the majority of people, would be willing to have the experiment done on them.*
- *We should all receive any treatments that would enhance our chance for survival.*
- *If there was an accident with young people driving, the chances are high of an accident for elderly and young people, especially with teenagers.*
- *Medicine moves up the ladder each and every year. All of my kids are grown up, but if one got in a car accident and if the new stuff is coming out, he should definitely receive this new treatment.*
- *They deserve every chance to live.*
- *Studies show that they definitely take risks and have consequences.*
- *If they are gonna put it out there—if they do this deal on adults, why not give everybody a chance?*
- *They still have many years ahead of them and should have every chance possible to live.*
- *The opportunity to up their chance of survival!*

- *They are young.*
- *If you don't have a good chance for survival, it's good to try something that will help improve your chance of survival.*
- *Anything that would help you survive, I'm all for it.*
- *I think it would be right if the situation was that bad.*
- *Anything that you come up that is better for the people should be used.*
- *If I was injured and had a 1 in 3 chance of surviving with the standard treatment, why not?*
- *I am a trauma nurse and time is crucial. I think all should have a chance at any means to live.*
- *I like to give every chance to youngsters.*
- *If it is good for one group, why wouldn't it be good for the other?*
- *If it saves their life, do whatever it is.*
- *It sounded to me that the odds of dying are greater for the standard treatment. I'd want to increase my chances of survival for my family.*
- *If it were my child, I would want every possible thing done to save their life.*
- *The reason for that, if it betters their chance for survival, I think they should be included in the study.*
- *Because if there is a possibility it will help them and save their life, then why not try it?*
- *Someone at that age who is in that type of situation and if no adult happens to be around at that time, then they should go ahead and do it.*
- *It is good to use it on all people.*
- *Because I think that you've got to give them the same chance as you give everybody else.*
- *Some young people have the same illness.*
- *Because they're just as likely to be seriously injured; they're reckless!*
- *They deserve every chance to live, too.*
- *If I had teenager that was sick or hurt and there was any chance of survival even if it was experimental, I'd do anything it took to keep them alive.*
- *Because there is always room for study and without it, there is no way to know what the outcome will be.*
- *It should be for everyone.*
- *They are old enough to get every chance to live.*
- *My children are already older but I have young grandkids and they could benefit from this.*
- *I'm all for progress.*
- *If we don't try it, we won't ever find out. If it doesn't work, then they'll stop it anyhow!*
- *It's a great idea.*
- *Everyone should get a chance.*
- *If it will help them, then do it.*
- *If the outcome is better or if they are severely injured and there's a 1 in 3 chance only possible with standard treatment and the new one improves it, so be it.*

- *Might be the best way to prove the potential of the treatment.*
- *There has to be something new all the time or you will be stagnant.*
- *My reasons for trying to save a life? It would be for trying to save a life.*
- *They're the ones at most risk. They think, "I'm God and no one is going to hurt me."*
- *We all need a better way.*
- *Because they are able to tell you if they start experiencing a side effect where younger children might not be able to do that.*
- *It could happen to anybody.*
- *Give them every chance.*
- *Why not? If you're going develop new methods, you need to try it on younger people.*
- *Because of the maturity level of the 15, 16, 17 year olds, they would have a better chance with the treatment.*
- *I was brought to the hospital and pronounced dead or alive at one time, and experienced electric shock. I know first hand what it's like.*
- *Just because they are a teenager, that shouldn't have an effect on whether or not they could be in the study. As long as their parents gave permission.*
- *Yes, they're humans just like us old folks.*
- *I believe in improvement and if there's a possibility—people love life and they want to live. I had a brother die in his sleep. He had a heart attack. It runs in my family and I'm on high blood pressure medication right now.*
- *If they were seriously injured and there was a good chance of not surviving and this study helps and if the person gives consent and the person does not get hurt, it should be done.*
- *If it works, that is great.*
- *I worked in the medical field as an administrative person in a clinic. There's a need for people that are dying to have a better chance of surviving. That's the way it should be.*
- *Well, I think they ought to get a chance. I don't know.*
- *I would want to know they were getting anything possible that would save them. If the standard treatment offers no guarantees, then try something new.*
- *I try anything for my loved ones.*
- *Their bodies are about the same as well as equivalent to an older person in comparison.*
- *It should be the same. A heart is a heart.*
- *Everyone deserves a chance.*
- *Because their chance of survival might be better than someone who is older.*
- *I feel that any measure should be taken to save a life. It should be taken.*
- *We need to know.*
- *Trauma is very common in that age group.*
- *It sounds like if they don't have a good chance, that it would be better to take this other chance than to do nothing.*
- *Why not if it saves lives?*
- *They should do it to all.*

- *They should have the same rights as adults for a better quality of care. When you start reaching that legal age of maturity they can make those same decisions as the usual adults can.*
- *It's because there is a chance and until we study that, how will we know? I don't know of any other way to find out!*
- *Anything to save someone's life.*
- *The young men play sports and they like to live. They have there whole life ahead of them.*
- *It sounds like they may be on to something that would be an improvement, and increase the chances of survival.*
- *Because they are partly grown.*
- *They are trying to get a better chance and technology is advanced enough to take that chance.*
- *Fifteen to seventeen year olds have the same characteristics as full-grown people; younger people are injured just as much as full-grown people.*
- *I don't know - I would want to do everything that is possible to ensure a healthy life for myself and my family.*
- *I trust the people at Southwestern Medical with my life. And I know their history to be nationally acclaimed medical researchers.*
- *I think that anything to save as life is good. If it is proven in Europe, it is OK here. I am reluctant on young kids. The personnel should be well trained.*
- *Everyone should have a chance.*
- *Do it everyone.*
- *It should all be the same.*
- *Given the high mortality, there is much to be done in terms of improving patient outcome.*
- *I'm going to school for this. Scientific ethics would be good for research. We can't stay old forever. Try the new experiments or we'll never know. We can't stay closed minded.*
- *I have a seventeen year old and, as a parent, if I wanted my son to live, I would take any measure to insure it.*
- *Because they're driving; they are more liable for themselves. There are a lot of times they are by themselves on the way to the school. If one of then was injured and they went into shock, if they can't answer for themselves, they're incoherent.*
- *It wouldn't hurt anything.*
- *Any chance for extending their life if they have a quality of life, it depends on the extent of their other injuries, but if you can keep their heart going, it all goes ahead. But if you bring them back from cardiac arrest but other injuries happen to other parts of their body, it may not be worth it and their medical expenses are too expensive.*
- *Should be done on everyone.*
- *They should get every chance to live.*
- *The heart is the heart.*
- *I think it is a good idea.*
- *Hope--that it would be successful because they're so young.*

- *They deserve every chance to live.*
- *They need to be protected, too.*
- *Just don't know why they would be excluded.*
- *If it gives a better chance of survival; but with 1 in 3 with standard treatment, why not?*
- *Kids need to be protected.*
- *Given the number that are hurt, they deserve every chance.*
- *It should be done on everyone.*
- *Why not?*
- *Old enough to deserve a chance.*
- *There are clueless and take risks.*
- *Anything is good for them to keep them alive.*
- *I have really bad experiences, no money, no insurance. Doctors don't care if you do not have money.*
- *If that's what's available; they have so much time in front of them and if there's going to be an improvement with the fluid, they should be included.*
- *They are pretty much adults and almost grown to that level.*
- *They are the ones in the most car wrecks--street racing, hitting light poles.*
- *Give them every chance to survive.*
- *I guess if your talking about accidents and such, teenagers get into a lot more than adults and need more help with their judgment and, hell, if it works, they'd live a lot longer!*
- *Give them every chance to make it.*
- *They would be part of the test group, including the 15-17 year olds in this study.*
- *I was in a car crash, and anything that could have helped out would have been great.*
- *Everyone should have the chance.*
- *The way you explain it, I don't think age really matters as long as it helps you.*
- *If the risks are equal to better than traditional ways of saving a life, it's worth taking a risk.*
- *We have a severely disabled child and we've seen improvement with the experimental medicines our child has had. If we had been fearful and chose not to take the risk, then we would not have seen any improvement. If there is a benefit in that area, I think it should be offered to adolescents just as much as adults.*
- *Because if the benefits are preventing death from a cardiac incident, it would be okay to give to the young people.*
- *Any chance is better then basically none, in many cases, and so many die because they don't have the proper treatment.*
- *It's more a matter of saving kids. It seems like if there's a possibility of getting the percentage up-- for example if it's one out of three and with the treatment it would be two out of three, then the chances are doubled for survival.*
- *I have 18 year old boys, and I would like them to have the best chance of survival, even if the treatment is experimental. ANY chance to improve their survival is a good thing to see when dealing with younger kids.*

- *Well you never know when a young person could have a heart attack or something like that, and the doctor should give consent for them because doctor's know best.*
- *If you value the research, it's as valuable for all ages.*
- *I have teenagers around and want them to have every chance of survival.*
- *If the odds are pretty high against your survival, and the chances are that low, I'd do anything I could to survive and it'd be the same for members of my family, too.*
- *If it was going to save their life, definitely.*
- *A lot of people in that age group get severely injured where they would need it. It's not that much more of a risk when you are severely injured and if it would help them, if there's a chance, then try it.*
- *Why not?*
- *It should be OK for everyone.*
- *Too young to let die.*
- *Never too young.*
- *Should be OK.*
- *I think they deserve an opportunity to live just like anybody else.*
- *If they're at risk, they should get it.*
- *Car wrecks and kids are a large cause of traumatic injuries. Anybody that can benefit from this treatment should take part in it.*
- *To keep them alive; we have to give them every chance including an experimental one.*
- *I have children that age and think they should have every chance.*
- *I would say it would give a better chance of survival.*
- *It would be left be up to the parents and doctors. My sister fell and had a blood clot. If they took it out, she wouldn't know us. She died when the doctor said to leave her alone.*
- *If the person is going to die from their injuries, they deserve the best chance of survival, no matter who the person is, or what their age is.*
- *Every age deserves a chance.*
- *I just think for a drug to be complete, you have to include a whole gambit of ages.*
- *They would have the same chance as we would.*
- *They are as apt to survive with treatment.*
- *They probably have as good judgment as she would have.*
- *If it's an injury, I don't see why they shouldn't be included in the same group.*
- *If it is the difference between that person dying and living, then they deserve any and all chances of survival, no matter the age of the person.*
- *I guess it allows a broader study base.*
- *I believe that they need every opportunity for survival.*
- *I am for anything that is researched thoroughly that can give a chance at a low rate of dying, and I consider a low rate of dying anything less than 50%.*
- *We are not doing very well, so it's worth trying*
- *I'd want my kid to have every chance.*

- *If the person is that young, you want to give them a chance to survive so they can have a full life.*
- *If it was my kid, I'd want to keep him alive.*
- *Why not? If they drive a car at that age, then accidents do happen.*
- *They deserve as good a chance to survive as adults.*
- *15-17 yrs are in wrecks every day.*
- *It's all the same.*
- *All ages.*
- *Should be fine.*
- *A heart is a heart.*
- *It's all the same.*
- *It should be no different from adults.*
- *Because I think what your doing is research in improving the procedure and, therefore, all age groups should be involved.*
- *I think they deserve every chance.*
- *I'm combining serious injuries and cardio events. I have a son and a lot of injuries happen at that age, especially with athletics.*
- *We should try everything to save them.*
- *Because it sounds like it is increasing the possibilities of surviving.*
- *Because my mother was a cardiac patient. I lost her in June. There are so many things left to find out when you have family members who have been thru this with a heart valve. When it saves lives, to live longer, research is necessary. It doesn't mean I'm not afraid. There are a lot of conditions with diabetes where it's in an experimental stage. There's all kinds of medical situations.*
- *Medical knowledge - just knowing how many people die in cardiac arrest. There's a doctor that's already doing some of this.*
- *They are just as important as the adults.*
- *Doesn't really matter what age.*
- *They deserve the best treatment they can get.*
- *According to the information that you presented to me, it seems it will increase someone's chances for recovery.*
- *Most 15 year olds are close to full physical development.*
- *I think they deserve as much of a chance as possible.*
- *Well, you need to save them, too.*
- *It gives a wider range of results, especially since teens are responsible for a lot of the accidents today.*
- *I have a 14 year old so if there is a possibility to help him in a situation, I'd want that opportunity.*
- *Logic.*
- *I think it would be appropriate to try that,*
- *Well, if it was my child, I would want to do everything possible to help the situation.*
- *With the family's consent, yes.*

- *If they're injured and had a low chance of living under the standard treatment, then age does not make that much difference. If they're going to die, then age doesn't make that much difference. I, mean, I wouldn't give it to an infant, but I don't see why a 17 year old should be excluded.*
- *A heart is a heart.*
- *Should be fine.*
- *Should be OK.*
- *If it's safe, it's safe.*
- *I just do.*
- *They got a good chance of living. I don't know.*
- *If it is life or death, I feel it's appropriate.*
- *Because they may react as well as any adult would to the treatment.*
- *I'd rather them have a better chance of survival than not having a better chance of survival.*
- *Why not make it available to everybody?*
- *Because they have a one in three chance and they are 15 years old and why wouldn't they have this same opportunity?*
- *If the caregivers feel that this is a viable option that would be helpful, I would say yes.*
- *Because they would probably have a better chance of survival as opposed to the standard treatment.*
- *I feel everybody ought to have an opportunity. The odds are the same so it should be global for everyone.*
- *Because the younger you are the more resilient you are.*
- *It's very important that they get every chance to survive.*
- *Because if it gives them a better chance of surviving, then I think you should do it.*
- *They deserve the same chance anyone else has for receiving beneficial treatment. The younger ages could help the researchers learn something that wouldn't show up in an adult; also, they may be healthier going in.*
- *Give them every chance.*
- *This is a life and death matter. The younger they are, the more they have to live for. They should have every chance to stay alive.*
- *If there is no additional reason, then there is no reason not to include them.*
- *Age is irrelevant. Youngsters deserve every chance to survive*
- *I come from a family that is in the medical field. This sounds like a suitable study to include teenagers in, if the information is accurate.*
- *Don't know.*
- *Their bodies are a bit healthier being younger.*
- *I think children in that area probably not mature enough to decide things like that*
- *If it's good for an adult, then it should be good for an adolescent. I'm not medical expert; if my survival is one in three, and if it's an adolescent, why change my opinion, since it is something I would do myself?*
- *Should be OK.*
- *OK to save them.*

- *Well I mean you have to understand. We start with the research and I guess I think any class of demographic should be allowed to qualify for this procedure...yeah, I think that age would benefit.*
- *They should just have the right.*
- *Because, to me in my mind, there is no way to simulate cardiac arrest so the only way to do it is in a real situation.*
- *I'm a heart patient--diabetic also—I am willing to try anything that might save your life.*
- *Bodies are the same as an adult for this purpose.*
- *I would think a lot of 15-17 year olds would be involved in accidents. They would be old enough to be included (physically).*
- *So many teenagers die in auto accidents - if you can resuscitate them quickly so that they can survive, if their heart stopped at scene, then they should receive this experimental treatment. Many teenagers die in car crashes, so they would be a good source for the study.*
- *I want them to help them in this kind of situation.*
- *I don't think there's an issue of age. It's either a valid or invalid treatment and the age of the person doesn't matter and you still recover regardless of the body type unless there's some unknown factor that skews a different body reaction with adults versus young teenagers that I don't know about.*
- *Should be fine.*
- *For one thing, if the fluid they're using has been successful in Europe, it would be fine for us. I know the FDA is much slower to approve things - yes, they should go ahead and try it.*
- *If they were in a traumatic accident, the chances would be better for a healthy body.*
- *Give them the same chance as adults.*
- *They have a long life ahead of them; in other words their body can take more.*
- *I have a daughter and if that happened to her, I feel that if she had a better chance, then I would want it.*
- *Why not?*
- *You've got to test the young people; it's good to get what the reaction to the experimental drug would be.*
- *They are just small adults, so why not?*
- *It should only be a doctor's decision.*
- *Not sure.*
- *Any family would want the experiment done on them if it improved the chances.*
- *In old age, no. For young people, yes.*
- *Should be the same.*
- *Teenagers should have the right, too.*
- *I have different a look than western medicine. The conscious mind is controlling new experimental studies is another way to save lives and it is in the mind. If we believe in this, then it will help us.*
- *It should be fine.*
- *I see no reason not to.*

- *Should be the same.*
- *I just believe we should try to preserve life.*
- *I think that if it's proven effective, I see no reason to restrict it from teenagers/minors.*
- *Should be OK.*
- *It will be just be fine.*
- *They're old enough make their own decisions a little bit. If it was up to them, and there was not a parent around, then they would have the right. It's their life, too.*
- *Well, they are juveniles and they should be able to get treatment at that age, too.*
- *The advance of medicine.*
- *Being in the study gives them a chance to live.*
- *Young adults, if they're conscious and their parents aren't around, and there's got to be a decision of living and dying, they've got to be saved.*
- *They have to be severely injured.*
- *OK.*
- *I would want my child to receive every chance to survive.*
- *I believe in whatever is best for the patient to help them to survive - use it.*
- *If it improves the odds of surviving and it would offer a better chance for life, it should be done.*
- *They have a viable life, so I think at that age, I think there's a maturity level in there that should prove worthwhile.*
- *Well, they need to be helped just as bad as anybody older. I don't really have a good reason. If they have a heart attack...they need help just as bad as anybody else.*
- *I recently lost a friend in a car wreck. Age isn't a standard on treatment; even if you're just 15 or whatever; if you could benefit from something that could save you right then, then why not take the chance?*
- *Try anything in that case.*
- *They have a whole life ahead of them. Every chance is crucial.*
- *It just makes sense.*
- *Why not? If it's that large of a percentage involved in the trauma. If older people are included, then why not everybody?*
- *They deserve a chance.*
- *My daughter was injured about 10 years ago, when she was in her late 50's. She was in a serious car accident, so she wouldn't be able to give consent. It didn't take too long to get some of the family and contact. The accident happened right by church where people knew her. I had a cardiac operation where they replaced a valve. I was awake slightly and, in a matter of minutes, I heard "stay with us." That was the last I knew. I would want all the help I could get. I would have wanted my daughter to have any chance she could have.*
- *The issue is that if it's the same risk. I have personally dealt with two relatives with strokes. Anything you can do to improve a cure, you should.*
- *If it will save their lives, why not?*
- *Unless you test, you're not going to know and you have to know.*

- *Because I think that advancements of this sort will only come through experimentation and, with proper oversight, it will be acceptable in cases of this nature where consent is not available.*
- *Because they are young and we need to save them.*
- *If there's a chance of them living, even a slight chance is better then none.*
- *To preserve a life, to keep them alive as long as possible. That's the American way, that's the way we did it in WWII to keep them alive.*
- *One of my sons is in Houston and is working on a valve. He says, by the time they get there, you either do this or they die. I would say go for it. If there's a chance of dying anyway, then take whatever chance you have!*
- *If it's going to save their life, try it.*
- *They are human beings like everybody else. They got their whole life ahead of them, so it would more important than it would be for me.*
- *They react differently to drugs then the way adults do.*
- *Well because we need to find ways to allow them to stay alive, as well. We don't want to exclude any age group as long as they have a quality of life.*
- *They could be in the park playing and, then, if one of them had a cardiac arrest, they would know what to do.*
- *Because since they're young people, they have more of a chance to survive than an older person.*
- *Medical research is advanced by doing this and how else are we going to find out?*
- *In recent times, not so much in past history, but a lot of kids are not dying because of injuries, and they are putting defibrillators in the schools because kids are our future.*
- *Why not? Side effects may result because they're still growing. But they may be more likely to survive with the treatment.*
- *Because there's young people dying of cardiac arrest all the time.*
- *Anything that is progressing in the medical field is good to me.*
- *Trauma is tough to explain. I am undecided until I understand more about it.*
- *If there was a small chance of allergic reaction, I guess it would be okay.*
- *Within the parameters of the study I would feel comfortable with allowing the treatments.*
- *My reasons are I believe in experimental research especially from an institute like UTSW. I know they do a lot of research projects. I generally am in favor of that kind of thing.*
- *You have a better chance to survive if you try the experiment. Your chances of survival aren't very good. If you do die, it might help people in the future.*
- *If that treatment is going to give you the best chance for survival, then go ahead.*
- *The odds are the same for adults as they are for the minors and you're taking the same chance, they're just younger.*
- *The research is done only on the injured patients, so the chance of death is already high, so they can be included.*
- *Yes, because anything that will give a person a chance to live is a good thing.*
- *They deserve every chance to live.*

- *I should not matter the age.*
- *I don't know. It should include all ages.*
- *They deserve a chance to survive.*
- *If there is a possibility for something better for them, then they should get it.*
- *The odds are not as great for the standard way of treatment. If something comes out better then you should.*
- *They are the highest risk group for traumatic injuries. They are prone to injuries in vehicles. Athletes in this age group go with undetected heart problems.*
- *They want to live.*
- *They need the same as an older person.*

Not Appropriate

- *Not without consent. If parents give consent, it's fine. They're children, they're too young.*
- *If it were my kid...It's ethics base. I would want to give consent.*
- *Too young - not adults, not considered as adults. Not adults until age 21 - needs parents consent.*
- *They are kids. Until it's proven that it works, I don't think anything should be done with kids.*
- *I would think when they are children that they would want to do anything to save their life, but experimental treatment should just be done with those above 18. Test it on the older folks first. I just want more reassurance.*
- *Too young.*
- *It just depends on the parent. Their consent is important. Being that they are young and underage, they are still too young to make a decision. They don't know what's good or bad.*
- *Youngsters have more of a chance to live.*
- *They are not old enough possibly to make that kind of judgment call.*
- *I feel they still need to give consent.*
- *Too much of a risk.*
- *Because it is not proven to be effective. If it is used in lieu of taking chances, I would rather take what is known than what is not. And if it was something they could do along side their original treatment, then my answer would be yes.*
- *They're minors and if they were able to give consent, they would still not be old enough to give consent.*
- *I think it's too risky.*
- *Because parents make the decision.*
- *Try all possibilities before the experimental treatment.*
- *I think the study should be just for 18 and over. I don't know if a 17 year old would react the same way. It might not make a huge difference.*
- *I guess primarily they have a longer life ahead of them and if there are any side effects, if there were any side effects they would have to live with them longer than anyone older.*
- *With under age 18, there needs to be some parental permission involved.*
- *I have not been given enough information to make a decision.*

- *With the liability issues, it's easier for a parent to do a lawsuit with an experimental treatment because it would be more questionable.*
- *We should not lose our right to make a choice.*
- *Only older people.*
- *Because the side effects could be far worse than the heart attack.*
- *Older people should be used first.*
- *They are still children.*
- *Being a parent, if the hospital said they're not going to live, then I would. There's always a "what if."*
- *Not without parents' consent; should be able to have consent.*
- *It would be better if they had the parent's consent. Older ages maybe starting from 19.*
- *I feel that children are different then adults and until it's 100 percent approved by our government, it shouldn't be used on a child.*
- *Their bodies are still changing and growing.*
- *I don't think that is ready, yet. Too many people have died from it. Maybe in the future.*
- *They are too young.* [Twenty-two more respondents gave this response.]
- *They are minors and even if they are conscious, they could not give consent.*
- *Want to go with the tried and true.*
- *I think they should be adults because, I don't know, a minor has a parent that gives consent but an adult gives their own consent.*
- *They should be given every chance.*
- *The survival rate will be higher, favoring the standard procedure.*
- *A parent should be available to speak for them.*
- *I would think that they are not that involved.*
- *It needs to have parental consent.*
- *What if something goes wrong?*
- *They need to be older and understand it before they can give a yes or no.*
- *Maybe their system might be more delicate than an older person.*
- *They are too young to be experimented on.*
- *They are not adults. Being an adult, I can make those decisions but under the age of 21, you're not officially a full adult with the exception that you can vote and make that decision only.*
- *There's something about a child. I had a hard time saying yes for myself. I'm a dentist and I see the benefits to this. You are though volunteering involuntarily. I can't imagine the general person agreeing to this without there being lawsuits. I just had a baby and I can't imagine a child being a trial.*
- *We already know the outcome of the other method. With your child already compromised is it alright to take an additional risk in addition to that?*
- *If they are children, it should be a decision that their parents make.*
- *Because you are making a decision for a child that only a parent should make.*
- *Why not try it on older people first, then them?*
- *I don't think they are mature enough.*

- *Family issues are more emotional when a child is involved.*
- *I don't think experimental drugs should be used on kids; I don't think kids should be guinea pigs.*
- *No opinion.*
- *They're minors; their metabolic system is more adaptable to overcoming injuries, it's more durable.*
- *Because it's experimental. It hasn't been proven. I don't think I would want to go there unless there was some information that it would be better than the proven methods no matter what the age.*
- *Because they are minors.*
- *I would think they would not be old enough to make that decision for themselves and the parents should make the decisions for them one way or the other.*
- *Their parents need to give informed consent.*
- *Jehovah's Witnesses do not give or receive blood.*
- *Not without parental consent. If there was some kind of prior statement made, like a no resuscitation statement with the elderly, I would say yes. If the odds of survival were less than one in three, I would go with the experimental treatment.*
- *I wouldn't want to risk this on a younger person; the risks and benefits are undetermined.*
- *Because that age group has a higher chance of living without it.*
- *Enough problems, no more from experiments.*
- *I don't think they can make a proper judgment, because they are minors.*
- *I don't think that minors should be put into medical studies without consent from their parents, regardless of the circumstances.*
- *I heard on the news about how some children are allergic or not allergic to certain types of vaccinations such as flu shots and it depends on the particular health of the person if his or her body can take it or not.*
- *They are too young. It's better to study older people.*
- *I think that their bodies are different. An adult is much more likely to survive the rigors of experimental treatment than a teenager.*
- *They are under 18, and it should be the parents' decision as to whether their child is placed into any form of experimental treatment.*
- *I think as adults, I'd rather the unknown be tested on adults as opposed to young people.*
- *They are just starting life. I would be a little bit leery of it.*
- *With youth, it's dealing with a different metabolism, weight, and size. Generally, you don't know what might work, especially since those experimental tests have some kind of variations, so, there is more risk. I don't know how it's going to affect them.*
- *Don't know, because they are kids and too young.*
- *It would be because they're so young and if there were side effects, they would have a lot longer to deal with them.*
- *I don't like to study kids 15-17 year olds in case they die. If there is hope for them it would be OK but if there is no hope, I don't think they should.*
- *Basically, a large majority of studies are done on people over 18.*

- *Because they are minors.*
- *I'm not sure since they are still growing.*
- *They're not within the age to give that type of verbal consent on their own. I don't want that type of risk. I don't want anything tried new on a child.*
- *Prove the concept on adults first.*
- *No, do the study on adults first.*
- *I don't think that they would be interested in that and they have other things to do and I don't think they would be that patient.*
- *Too young. If treatment has iodine in it, it could cause me to die immediately; odds should be better here.*
- *Well, I don't really have a reason. People that young should not be in this.*
- *With parental consent, yes.*
- *Should be tried on older people first.*
- *You're still developing.*
- *They too young. If they are going to use somebody, use somebody who's older and is about to croak anyway.*
- *I just think they're too vulnerable, too young. It should not be done to a younger person.*
- *Because of the potential for side effects and the right of choice.*
- *No I don't think so for myself or my family members.*
- *The heart wouldn't be as mature at the younger age.*
- *I have a fourteen-year-old son. I wouldn't want experimental treatments being done on him with him being a minor.*
- *Not without parental consent. You get into a lot of ethical stuff. It would be okay with my kids. You have religious groups that they would turn it down. I can't think of their name. They don't believe in transfusions.*
- *Their ages, because they are not adults.*

Don't know / Refused

- *I have no kids but I would want to do anything I could to save them.*
- *None.*
- *Don't know enough about it.*
- *I feel I need to know more.*
- *It's different than experimenting on adults in general.*
- *With parental consent; it's a decision a parent should make, not a child of that age.*
- *Would want consent to be given.*
- *The family could blame UT if the kid didn't survive.*
- *I would not want to speak for someone else and I have no children.*
- *Chances of survival more remote.*
- *Minors should not be able to participate. Their lives are too delicate.*
- *Not without consent of their parents. I don't think minors should be included in any medical procedures without the consent of their parents.*
- *I again, don't know enough about it.*

- *If they should have a reaction, it would affect children more, if that were to occur.*
- *Don't know.*
- *Because it's new studies and new research; it's progress.*
- *They are so young. Their bodies aren't developed as much. You could be born with a bad heart. It seems you need more study done, it seems to me.*
- *I don't know how to answer.*
- *No opinion.*
- *None.*
- *I don't know; you have to go case by case .*
- *I don't know - if it is experimental, I prefer it to be done on an adult.*
- *If there were anything that could be done, I'd want it done. I would have to know at that time, depending on their condition.*
- *I can't speak for them.*
- *I don't know.*
- *I wouldn't know if it would be good for someone at any age. You are talking about an experimental fluid and I don't know enough about it.*
- *If the stuff is safe, if whatever you give them is safe to give them and not going to cause other problems, then it would probably be OK.*
- *I would need to know more about the fluid and the study. There's no way I can say anything otherwise.*
- *You caught me off guard. If they were older, I would say yes.*
- *Don't know.*
- *With permission only.*
- *Don't know.*
- *Too young.*
- *It would more depend how serious the injury was. The EMT would have to have good training to make that call.*
- *I would only do this with parental permission.*
- *I have mixed emotions about doing an experimental procedure on a minor without parental consent.*
- *Need more study.*
- *No comment.*

Q9. What would be the reason for your concern? (Referring to concern over being entered in the cardiac study with less than a 10% chance of surviving with standard treatment without consent.)

"Other" responses by those who said they did not know or would not want to be entered into the cardiac study:

- *Is it going to hurt me? Is it going to make me a vegetable? I'd rather preserve my quality of life.*

- *It's experimental and it's a life threatening situation, unless the odds better than the standard.*
- *I don't want to be resuscitated.*
- *There is no need to suffer because the chance of survival is so low.*
- *I'd rather have the standardized one proven to work rather than the one in experimentation.*
- *I was upset because I didn't die from my last heart attack. I got depressed and I found out that that was the normal deal for men. My cardiologist showed me a study.*
- *I don't know the percentage of survival of the other treatments.*
- *The treatment is new and untested.*
- *I have had a heart attack in the past. I would want to be informed of the results before I would want it for myself.*
- *I don't want to prolong my life.*
- *You have no control if you don't give your consent.*
- *I don't want to be the guinea pig. It's a situation where you don't know what to do until you're in that situation.*
- *Stick with the tried true methods.*
- *At my age, I'm 82, I don't think that's a consideration. Someone who would have more of a benefit should have it.*
- *I'm 86 years old. I don't know what I'd do. I don't think that I would want to do that. Too much else is wrong, I have a terrible back and can't get around.*
- *There's not that much experience with it and I don't want to be a guinea pig.*
- *I have a heart problem already; my heart blew up.*
- *Chances aren't good for a good quality of survival.*
- *Because it's not proven.*
- *I have a DNR; I've had a severe heart attack.*
- *I have a DNR.*
- *Need to know more about any experimental treatment.*
- *If I am beyond a survivable functioning state, no.*
- *Again, not at my age, but in the lower ages, I would want to do everything possible.*
- *I don't want to be experimented on.*
- *If there is no hope for that person, I don't think it is right to do the study.*
- *You rather die a natural death in this situation and also for religious reasons.*
- *If I had a severe accident, I want a greater then 10% chance to live, because I feel my life would not be a good one after that.*
- *I want to give consent at all times.*
- *I'd have to know more about the chemicals. I have a religious blood-related belief. Just from a religious standpoint. I wouldn't worry about an allergic reaction.*
- *I don't trust that theory.*
- *I'm a registered nurse and from my nursing experience, if I have a cardiac arrest I just want to be let go. There are neurological effects and I don't want to be kept alive.*

- *I don't know how you'd determine the risks/odds ...so if you were taken to the hospital then I agree to the experimental treatment--you don't have any percentage rates.*
- *I need more information.*
- *If it's my time to go, then it's my time to go. If it happens, it happens. I don't want to be saved.*
- *I could go into an emergency room and they could kill me if they could not contact my doctor. I carry this list that is two pages long. It's stuff I am allergic to.*

Q11. What would be the reason for your concern? (Referring to concern over a family member being entered in the cardiac study with less than a 10% chance of surviving with standard treatment without consent.)

"Other" responses by those who did not know or would not want family members admitted to the cardiac study:

- *If they recover normally, then yes. If the side effects were not life altering and they could continue a normal life. If it would harm and there's no full recovery, then no.*
- *Because there is so low a chance of survival there is no need for additional suffering.*
- *I would rather have the standard treatment proven to work that's in use to day.*
- *I don't know the percentages of the other treatments.*
- *They are more than 50 per cent gone. I don't know then.*
- *They need to make their own decision.*
- *Older patient/family member may have DNR.*
- *It would have to be up to them.*
- *It's not approved.*
- *I don't know enough about it.*
- *Stick with the tried and true methods.*
- *With the experienced person it's all right. If it's somebody who is learning, I would like more study before you learn on me.*
- *My parents are my only family and like I told you, when its time to go, it's time to go!*
- *I can say yes without the approval of my husband. The younger ones shouldn't.*
- *Should be case by case.*
- *I don't want them to be the guinea pigs.*
- *It would be up to the parents.*
- *Depends on the age.*
- *Quality of life and if they were going to be a vegetable.*
- *I'd rather go with proven treatments.*
- *My mother-in-law was on life support; it was ridiculous.*
- *Don't know what it is - need to know more about it.*
- *If they are beyond a survivable, functioning state, no.*

- *It would depend on the age of the person as to whether to take such a chance. With older people, it is not as important.*
- *I wouldn't want them to be experimented on.*
- *If there is no hope for them, I don't think it is right to do the study. If there was a higher chance of survival with the study, then research might be OK.*
- *The 10% chance is too low.*
- *It's hard to make decisions for other people.*
- *I hadn't talked to them beforehand to see if they'd be willing to do it.*
- *I would want family to give consent at all times.*
- *I'd be OK with that if I knew what the treatment was.*
- *I don't want nobody in that study.*
- *I believe in the shock treatment that they currently use.*
- *I need more information.*
- *They have to make the decision themselves.*

Q13. Why do you say that? (Referring to the reasons why they would be upset if they experienced a severe injury and later learned they were in the study.)

Those who would be upset to discover they were in the study:

- *Not sure.*
- *If I'm going to die and it's the last chance, then do it, otherwise use other alternatives. I don't want to be a guinea pig.*
- *I think it would be because it was given without my consent.*
- *Because I wouldn't want to be experimented on. If I knew more about it, I might change my mind—what the different processes are, the different medication, the different techniques used. I would want to see the research on it.*
- *Because I would just be upset.*
- *I still want to give consent first.*
- *Possibly initially, but then I would get over it. Obviously, the benefits would be there because I would be alive. It would be the consent portion that was against my wishes.*
- *I do not know enough about the study.*
- *It doesn't bother me.*
- *I would be happy to be alive.*
- *I would want to have it be my choice. I do not like the idea of being a research project.*
- *Because I don't want that and I don't want to end up on life support.*
- *Because I had turned it down originally and it would be going against my wishes.*
- *I don't agree because I had said no earlier.*
- *I would feel that the person should be entitled or be found out from the family if you involuntarily participate or might feel mildy upset.*
- *My privacy would be invaded. I would feel used.*
- *They saved me.*
- *They helped me.*

- *They saved my life.*
- *Wouldn't know what you were doing at the time, would like them to help me.*
- *They did it without permission.*
- *Happy to be alive.*
- *I'm alive.*
- *Too young.*
- *I might not have made that decision. When in a study you're a guinea pig. When I was in a study one time, I had a bad deal with it; I was in a blind study for taking estrogen or for post-menopausal, where I ended up with a cyst on my left ovary. The doctor watched it and it didn't appear to be cancerous. The Dr. came back and conferred with my male partner, and said I should receive a hysterectomy—he wanted to take whole kit and caboodle. I said I'll think about it. I'm still doing fine.*
- *Because they didn't get my consent.*
- *I was alive, so that's good.*
- *Don't know why.*
- *There is a possibility. If none of my family members would know about the treatment. Nurses kill people, give people shots.*
- *I'd be grateful.*
- *If I survived I'd be happy.*
- *I didn't give consent.*
- *It would depend on what the doctor would say about it.*
- *I do not know enough about it. I want to stay alive.*
- *I would only be upset if I wasn't healed. I would be upset if they did this without permission and I wasn't healed.*
- *Because I didn't agree to it.*
- *Because I am a Jehovah's Witness. A living will tells everything.*
- *I want to be able to die in such a situation.*
- *Not sure how I would feel.*
- *If I didn't know more about it, I would be upset.*
- *I am a nervous 71-year-old woman when it comes to those types of things.*
- *Because you're alive.*
- *Because quality of life is dependent upon functioning adequately, if in a quadriplegic state, God forbid that, I would be enthusiastic.*
- *If you are better, it would be OK.*
- *If there were side effects that wouldn't have been if I hadn't had had it, I would be upset.*
- *Simply because I would want them to whenever possible do whatever is possible to bring me back to survive.*
- *Losing my rights.*
- *Because it worked.*
- *They didn't ask.*
- *Well, I know it's contradictory according to my answers, but, giving it further thought, it really doesn't make much sense given my former answers. If knowing*

that standard treatment would not work, I would not be upset. That was chosen for me first without getting the standard treatment. I don't think anybody wants to be a guinea pig without their knowledge.

- *If it was unapproved medical treatment without my consent, I would be upset.*
- *Need to know more information.*
- *I like to choose what to do with my body.*
- *With my nursing background, a patient is always complaining and the paramedics do the best they can for the patient. I would rather be let go.*
- *I'd want to have other treatment options...but if they gave me this treatment to keep me stay alive, I wouldn't be upset at all.*
- *If my quality of life were poor and I were handicapped I would be upset but I don't know about long term ...if I were in a vegetative state I wouldn't be happy about that but I wouldn't know—that's the risk I take so ...I guess it would apply more if a family member were the one making the decision on your behalf...so initially I'd hate to see my sister in a vegetative state...but eventually you think we did everything we could to save her life...maybe some disappointment but even if that person passed on we did the right thing and the burden that would create for the family long term ...but that's the risk you take in this situation, anyway.*
- *If I didn't get this new experimental treatment, then, yes I would be upset. I want a chance to survive.*
- *I don't want to ever be in this situation. If I had only a 10 percent chance of living at the sight, I would go ahead and do it. I work for a surgeon.*
- *Cause if the chances are revealed to be less, then I'd be upset.*
- *Not if it didn't mess me up.*
- *Don't like people doing things without permission.*
- *I'd be thankful.*

Q23. Do you have any additional comments about giving experimental treatments to cardiac arrest victims or severely injured patients without first getting written consent?

- *Again, it is one of those personal choices but science and medicine have come a long way.*
- *Again, only as long as the appropriate panels have signed off on it and communicated it to the public and the panels are medical and ethical.*
- *Any possible way to save people is worthwhile.*
- *Anything that could help someone in the future is a good idea.*
- *As long as they have conducted as much of the study as can be done under controlled conditions BEFORE applying it to field medicine, then that is OK.*
- *As much research as possible is necessary for the safety factor.*
- *Because of the fact that they may not be able to answer for themselves or before they're deceased, if the standard procedure as it currently exists may or may not work, this probably should happen.*
- *It is best to try anything that looks promising.*
- *I can't judge for others.*

- *Do what you can do.*
- *I don't think it's a good idea.*
- *It is ethically suspect--hard to say how I'd respond until in that situation.*
- *Go ahead and do what you have to do.*
- *I have a problem with not getting consent.*
- *Have to think about it.*
- *I am against it and I really think to take advantage of someone who cannot defend themselves is wrong.*
- *I basically feel that anything that could help them survive is worth the chance of doing it.*
- *I can't imagine it being ethically passed. I see the advantages but I can't see the general public accepting it. Our world is consent, consent, consent. If there's no consent given, I can't imagine the public being okay with it.*
- *I could never do what you're suggesting but I have to make the decision up front.*
- *I could see where some people might be upset over it, if there's no opportunity to say aye or nay. As long as there's no other way and it didn't make somebody paralyzed, and that person was alive and healthy, they should probably be excited to be involved in an experimental treatment and they survived.*
- *I do about the study - you need to get the government involved and get away from the medical exclusive groups and get with community leaders.*
- *I don't know. We never had any problem in our family on either side, so I don't think about it. Yes, if they needed some kind of treatment to help their life.*
- *I don't have a problem with it.*
- *I don't have a problem with that.*
- *I don't know enough about the experimental procedures, so I wouldn't give it to them.*
- *I don't really like the idea of someone else making the decision if I'm not capable of doing so myself.*
- *I don't really understand what we're talking about; I don't know what the treatment is or the technique. I know what the standard is because my husband went through that. I'd like to read about it though.*
- *I feel that you should try everything.*
- *I guess it would be okay if it is going to work or had a good chance of working.*
- *I have a lot of questions because I don't know what it is. I can't adhere to something I don't understand.*
- *I hope it works.*
- *I hope that the city of Dallas will approve it.*
- *I nearly had a heart attack and I would have done anything to stay alive.*
- *I really don't have anything else to say.*
- *I think everyone should be willing to try a new way to do things. If the old way doesn't work, then maybe the new one will.*
- *I think if the likelihood of survival is increased, it seems to me to do the thing to do – if they're incapacitated, do everything to keep them alive. It is like a Good Samaritan – you can't fault them for trying. Same is true in a medical emergency.*

- *I think improvement in that area should be pursued. If a person has indicated they do not want to be resuscitated or kept alive, that should be honored.*
- *I think it is a good idea.*
- *I think it is a very personal thing. My feeling is if I had one of my family members in that situation, I would want to try anything so they have every chance they can.*
- *I think it should be put out to the general public that it's a possibility before it takes place. Some people might not want to do that – also, to lower the liability of the people at the hospital. I don't know.*
- *I think it's dangerous in a way; there are people who would have lots of problems with it. There are people whom, if you did this, and that person died, they would sue you.*
- *I think it's good if it's public information. So that the community knows it's a possibility they will get treated with it before it's put to use.*
- *I think it's kind of an iffy situation, but if it's been approved, why not see how it goes?*
- *I think that it should always be allowed.*
- *I think that this is a very good thing to try.*
- *I think that we have to be hoping for any breakthrough that can be available.*
- *I think the person on the scene that is qualified has to make that decision.*
- *I think they should get consent because it is a study, and that people should know what possible side effects there are with different animals that were studied.*
- *I think we should think of ways to save lives.*
- *I think you should get consent.*
- *I think you're going about it the right way; just going through and doing a survey and getting public feedback.*
- *I want them to know it is a good idea.*
- *I would just come out and say, and just tell people about the program and let people make up their minds. I would just tell the people and not sound like I was selling it.*
- *I would like to talk to close members of the family.*
- *I would love to know about what experimental procedures they are doing.*
- *I would never ever be in favor of that. I'm giving an 82-year-old point of view. I've had a beautiful, productive life and my family is very solicitous and attentive. I'm happy with where I am in my life.*
- *I would want the person giving this experimental treatment to be trained to do so.*
- *If I had less than a 10 percent chance of living, then try anything!*
- *If it can insure a quality life after treatment, that would make a difference.*
- *If it helps, it needs to be done as soon as possible.*
- *If it was provided by someone who is accredited like if you were in an airplane and you had no control over the situation.*
- *If the experimental treatment is the best option at the time, it is something they should do, if the conventional treatment is not a good option.*
- *If the experimental treatments are believed to be helpful so much that the researchers would willing to receive them, and if the emergency caregivers are free from liability should things go wrong, then I'm fully in favor of them.*

- *If the person is really knowledgeable about this, I would go ahead and do this.*
- *If the victim was conscience, they should know the pros and cons of the study. Same thing if a guardian was making the decision; letting the guardian know the pros and cons of the study so they can make a decision for the victim.*
- *If you can't get consent at the time, you do what you have to do.*
- *If you're about to die and don't have a good chance of living with the standard treatment, and most people want their loved ones to live, I think the experimental treatment is okay without the consent.*
- *I'm in favor of research and I believe that everything medically is well-tested.*
- *I'm all for it, I just about lost my dad with the standard procedure.*
- *I'm aware of many treatments today. What we've thought was not safe we have discovered to be effective.*
- *I'm for anything that will help.*
- *I'm for trying things to develop ways of helping people; I'm pro stem cell research.*
- *In life threatening situations everyone deserves every chance to survive.*
- *In most of the cases it would be too late anyway, but there is no reason why a person could not carry a card that would enable permission to be known.*
- *This is infringement on patient rights on whether or not they want the treatment.*
- *Is it more expensive to do the studies than what is done currently?*
- *It depends on the quality of life afterwards. They have to have some certain quality of life. If they turn out perfectly fine afterwards then I approve that it should be done. If the outcome is that they just survive their life only but they are in a vegetable state or they suffer on a continuous basis, then I don't approve of it.*
- *It is a good thing - anything should be used to prolong human life.*
- *It is always better for the person receiving this experimental treatment to know...make the decision themselves...they are receiving this because it's better than the regular treatment in the hospital.*
- *I think that it's great.*
- *It would be really nice to try one and if it does not work, go back to the standard. It's a good idea to let the county publicize that the experiment was being done.*
- *It would take power of attorney of my kids to do it; they have power attorney over me. My daughter has the authority to take me off life support.*
- *It's best, I think if you can get written consent. Without written consent, you would be running into...It smacks too much like the Nazis, an experiment they carried out in concentration camps. They had no written consent. I just don't like the idea of having this done without a lot more information.*
- *It's good; it's a next step.*
- *It's kind of unethical to give treatment without their consent.*
- *It's their better chance to survive, versus no treatment or standard treatment.*
- *It's up to the doctor's discretion. They should decide if there's a higher chance for people to survive with the experimental treatment.*
- *I've stood at my son's bedside and anything that was done for him, we were thankful for!*
- *Life or death situations would be the only circumstance that I would do this.*

- *Make it more knowledgable to people so they're not freaking out, the more it's talked about, the more people are aware of it. They should do this with all kinds of education levels. The basic person should know what you're talking about.*
- *Making decisions for others including family is ethically hard for me.*
- *My immune system is weakened because of cancer. I've been in trial studies for endometriosis and allergies. I'm not eligible for some studies.*
- *My only concern is what the patient's wishes would be. I had a family member who just passed away a year ago, and in a cardio event, he would not have wanted it. He was ready to go.*
- *My opinion on that would be I'd have to see the stints. I don't know what the stints are. I'm not sure what fluids you're talking about. I'd have to know more about them.*
- *No - I just wish everybody success.*
- *No added comments.*
- *No and I mean my mother just passed away and we would have been happy for anything experimental to be used...when the odds are complete I think anything would be useful...so I think everyone would want something to be useful.*
- *No because you have a choice between living and dying and you can't make it if you are unconscious. And it is a way that society can help.*
- *No, but we need this type of study to improve things overall.*
- *No, I don't have anything else to say.*
- *No, I really don't.*
- *No, I think you've covered everything.*
- *No, my mother died at 40 years old from cardiac arrest and I've doubled her age. I'm 85 but feel like 40.*
- *No, sir. There is no time. Family members are far away. It's not practical because they are far way and hard to contact.*
- *I have no trust in the doctors.*
- *No, but a 10% chance of survival is too low to be giving the experiment.*
- *No, it depends on what would give the person the best odds or chances of survival.*
- *No, it is important for you to do this, I think It's good, we should always be prepared.*
- *No, you and I have exhausted this topic already.*
- *No. I have no problem with that.*
- *No. If it were a family member that was out of town and someone else could be accessed, then I'd let them make the decision.*
- *No. If you are that bad off, and there's a chance that this will help, then go for that!*
- *No. Under the circumstances it would be the doctor's discretion. What else are you going to do?*
- *None other than I would like to learn more about it.*
- *Not unless it is impossible to get consent. It's better to save a life.*
- *Nothing, except that it sounds wonderful if it comes to be!*

- *One of my neighbors when I was a kid actually did give consent. Friends and neighbors should be able to give consent if nobody else is around.*
- *Personally, I have a problem with it - I would not want experimental treatment that I did not consent to.*
- *Possibly the length of the study—there should be a period of time lapse before the treatment is applicable.*
- *Put on a vehicle license that shows advance permission.*
- *The circumstances you read were emergency situations where no one can give consent. I'm good with that.*
- *The Do Not Resuscitate rule is the biggest concern.*
- *The family should have the final say--what the family wants.*
- *The FDA needs to be involved on a timely basis.*
- *The fluid appears to be promising if it is approved in Europe. If they've shown due diligence, it's okay. You can't determine the effectiveness of a procedure without doing it on people.*
- *The general public doesn't know the treatment for major trauma. It's not right to experiment with medicine and treatment without consent. I think it should be done in a researched environment not in the field.*
- *The liability issues and the proven track records of Europe would be my concerns.*
- *The only thing I would say is when people go into the doctors, they should be asked these questions. They should put this on their medical records. That would be the choice that they picked and they would do that.*
- *The only way that medical science moves forward is to do studies..*
- *The person that is not expected to survive should want this kind of treatment.*
- *The person that is their caregiver could do it.*
- *The research should not lead to the advertising of drugs. That leads to a deterioration of the respect for medical research. If this is a result, it's a mistake to fund it (this research). If it's funded by a pharmaceutical company, it's marketing and of no value.*
- *The study just needs to be understood and reasonably public. It would require significant monitoring and not understating the side effects.*
- *There may be lawsuits if treatment was given without consent. The more people know about it, the less they'll be skeptical.*
- *There's not always the opportunity to get consent; the best chance for life is what you should do.*
- *There's the Good Samaritan law. Also, if you want to keep someone alive, you can buy your own little pads to give a person a shock. They have those at the airport. Also, there are pacemakers with a defibrillator where if it would stop, there is an automatic shock, which is what Cheney has. There really is a lot of stuff out there occurring without informed consent, anyway.*
- *They did it to me. They gave me a TPA without my consent and they give it to people who have clots and I refused to consent for it because I was doped up with morphine.*

- *They need to hit the news media to say they're implementing the procedure. The latest technology. Don't surprise them with it; keep them informed. That would mean less of a problem with lawsuits.*
- *I think that what is best is what is appropriate.*
- *To me, I wouldn't want it but I can't speak for both sides. I'd never been in that predicament so I really can't say.*
- *Try everything and anything to save a life if they are doing everything. Try every possible avenue. Includes experimental treatment.*
- *It is up to the individual themselves.*
- *We need to be better informed on this study.*
- *We need to educate the population before doing this.*
- *Well, OK, let me ask you this. If someone is in a car wreck and suffering from a heart attack and the regular treatment would give them a 90% chance of survival...no added factors...I do think it's a good idea. I don't think I'd have any qualms about this treatment.*
- *We're living longer today; we used to live until we were 55 and now I'm 77 so I think this is wonderful.*
- *What I would like to know is what is in the experimental fluids and the public should be well educated that this exists and if it really does increase their survival rate. Some people with cardiac arrests don't survive, however most of them do.*
- *What is cardiac arrest? I don't know.*
- *When considering the risk, my opinion is that most people would get anything that might save their lives.*
- *When it comes out here it needs more protection. People should wear a tag that would say they did not want to participate.*
- *When it is not feasible to get consent by the patient or their family, it only makes sense to give them the best possible treatment, which may include the use of promising experimental procedures.*
- *When you get to a certain age point, you don't want to experiment. I'm glad it's available, though.*
- *Whenever you're been knocked out, the doctor does whatever he sees fit to do...when I went to the hospital a few years ago, he, the doctor, said to sign this. So, I signed it and we did the same thing in WWII to preserve a life. You just don't let people die.*
- *Would be willing to try.*
- *Yeah, where consent can't be gotten there should be oversight to regulate what occurs so nothing 'Frankensteinish' can occur.*
- *Yes. You have to start somewhere. At some point in time the CPR we use now had to begin. I think the ethics of it though are that the people that are doing it need to stop it before more damage is done.*
- *You have to get in touch with the age group.*
- *You need to be sure to let everyone know exactly what the projects are about.*
- *You need to do everything that you can.*