

## 6. Study Site Information

<b>SITES:</b>	<b>IRB's:</b>	<b>Key Dates/Info:</b>
<p><b>1.</b> Wilford Hall Medical Center Lackland AFB, TX 78236-5300 <b>PI</b> Stephen Derdak DO</p>	<p>Darlene Castro Clinical Research Div. AF Medical Operations Office Surgeon General Bolling AFB,DC 20332</p>	<p>IRB Approval: 8/5/97 First subject: 10/26/97 Patients enrolled: 20</p>
<p><b>2.</b> The Toronto Hospital 200 Elizabeth Street Toronto, Ontario M5G2C4/Canada <b>PI</b> John Granton, MD</p>	<p>M Elvis Medical Research Directorate CCRW 2-814 The Toronto Hospital 200 Elizabeth Street Toronto, Ontario M5G2C4, Canada</p>	<p>IRB approval: 7/7/97 First subject: 12/11/97 Patients enrolled: 21</p>
<p><b>3a.</b> The Wellesley Hospital 160 Wellesley St. East Toronto, Ontario M4Y1J3, Canada <b>PI</b> Thomas Stewart MD</p>	<p>E Keystone Research Institute The Wellesley Hospital 160 Wellesley St. East Toronto, Ontario M4Y1J3, Canada</p>	<p>IRB approval: 8/28/97 First subject: 12/4/97 Patients enrolled: 5 ICU closed and study terminated: 6/1/98</p>
<p><b>3b.</b> Mount Sinai Hospital 600 University Avenue Toronto, Ontario M5G1X6/Canada <b>PI</b> Thomas Stewart, MD</p>	<p>Bill Wilson Mount Sinai Hospital 600 University Avenue Toronto, Ontario M5G1X6/Canada</p>	<p>IRB approval: 10/13/98 First subject: 8/25/98 Patients enrolled: 14</p>
<p><b>4.</b> Maine Medical Center 22 Bramhall Drive Portland, ME 04102 <b>PI</b> Sandy Bagwell, MD</p>	<p>D Hayes MD MMC-Research Institute 125 John Roberts Road Suite 5 S. Portland, ME 04106</p>	<p>IRB approval: 6/25/97 First subject: 1/28/98 Patients enrolled: 15</p>
<p><b>5.</b> Bronson Medical Center 252 E. Lovell Street Kalamazoo, MI 49007-5345 <b>PI</b> Bill Shillingwall DO</p>	<p>Robert Hume MD Bronson Medical Center 252 E. Lovell Street Kalamazoo, MI 49007-5345</p>	<p>IRB approval: 8/14/97 First subject: 3/14/98 Patients enrolled: 1 Study terminated: 10/30/98</p>

**SITES:****6.**

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**Key Dates/Info:**

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IRB Approval: 7/8/98  
First subject: 10/8/98  
Patients enrolled: 11

IRB approval: 10/13/98  
First subject: 3/16/99  
Patients enrolled: 17

IRB approval: 8/21/98  
First subject: 3/30/99  
Patients enrolled: 7

IRB approval: 8/7/99  
First subject: 5/20/99  
Patients enrolled: 27

IRB approval: 1/27/99  
First subject: 11/1/99  
Patients enrolled: 10

List of Patients and Outcomes
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patid	vent	EXIT	status30	status6m	IHTTxF	newPTX	DurHFO	DurMV
1.01	0	2	0	0	0	0	2.7	9
1.02	1	2	0	0	0	0		2
1.03	1	3	2	0	0	0		88
1.04	0	5	3	3	0	1	13	23
1.05	1	5	3	3	0	0		0.1
1.06	1	5	3	3	0	1		1.1
1.07	1	3	2	0	0	0		60
1.08	0	2	2	0	0		5	26
1.09	0	2	0	0	0	0	6	13
1.1	1	5	3	3	0			3.3
1.11	0	2	2	3	0	0	2	27
1.12	1	5	3	3	0	0		18
1.13	1	5	3	3	1			3.4
1.14	0	2	2	0	0		3.5	23
1.15	0	5	3	3	0		0	0
1.16	0	3	2	0	0	0	5	53
1.17	1	6	2	0	0	0		22
1.18	0	5	3	3	0	0	5	5
1.19	0	5	3	3	0		0.9	0.9
1.2	1	5	3	3	0	0		8
2.01	1	2	0	0	0	0		10
2.02	1	3	2	3	0	0		39
2.03	0	3	2	0	0	0	26	39
2.04	1	2	0	0	0	0		18
2.05	0	3	2	0	0		2.5	57
2.06	1	2	0	0	0	0		6
2.07	0	4	3	3	0	0	4	6
2.08	0	1	3	3	0	0	0.75	5
2.09	1	5	3	3	0	0		6
2.1	1	3	2	3	0	1		31
2.11	0	5	3	3	0	0	3	7
2.12	1	5	3	3	0	0		5
2.13	0	3	2	0	0	0	5	30
2.14	1	2	0	0	0	0		19
2.15	0	2	2	0	0	0	4	29
2.16	1	6	2	2	0	0		180
2.17	0	5	3	3	0	0	4	14
2.18	0	3	2	0	0	0	1	133
2.19	0	5	3	3	0	0	1	21
2.2	1	6	3	3	0	0		12
2.21	0	3	2	0	0	0	8	41
3.01	1	1	3	3	0	0		4
3.02	0	3	2	0	0	0	13	50

List of Patients and Outcomes
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3.03	1	5	3	3	0	0		18
3.04	0	5	3	3	0	0	5	27
3.05	1	5	3	3	0	0		18
3.06	1	5	3	3	0	0		3
3.07	0	3	2	3	0	1	30	36
3.08	0	2	0	0	0	0	3	7
3.09	1	3	2	2	0	1		182
3.1	0	5	3	3	0	0	3	10
3.11	1	5	3	3	0	0		2.5
3.12	1	5	3	3	0			1.1
3.13	1	1	3	3	0	1		1.5
3.14	0	5	3	3	0		4	10
3.15	1	5	3	3	0	0		2.75
3.16	0	2	0	0	0	0	1.7	2.3
3.17	1	1	2	3	0			30
3.18	0	5	3	3	0	0	1.5	1.5
3.19	0	5	3	3	0	0	11	11
4.01	0	2	0	0	0	0	9	18
4.02	0	6	2	3	0	0	0.3	42
4.03	0	2	0	0	0	0	3	7
4.04	1	5	3	3	0	0		23
4.05	1	5	3	3	0			12
4.06	1	2	0	0	0	0		18
4.07	0	3	2	0	0	0	11	57
4.08	1	5	3	3	0	0		4
4.09	1	3	2	0	0	0		43
4.1	0	5	3	3	0			6
4.11	0	6	3	3	0	0	0.5	4
4.12	1	5	3	3	0	0		0.1
4.13	1	3	2	3	0	0		34
4.14	0	3	2	0	0	0	2.3	85
4.15	0	5	3	3	0		3	13
5.01	0	4	0	0	0	0	10.4	22
6.01	0	3	2	3	0	1	14.5	33
6.02	1	2	0	0	0	0		10
6.03	1	5	3	3	0	0		8
6.04	0	5	3	3	0	0	16	23
6.05	0	2	2	0	0	0	4	8
6.06	1	5	3	3	0			28
6.07	0	3	2	3	0	1	7	38
6.08	1	2	0	0	0	0		22
6.09	1	1	3	3	0			8.9
6.1	0	2	0	0	0	0	5.2	11.2
6.11	0	2	2	0	0	0	11.5	25

List of Patients and Outcomes
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7.01	1	3	0	0	0			14
7.02	0	4	3	3	0		7	8
7.03	0	3	2	0	0		6	31
7.04	1	2	0	0	0			4
7.05	0	2	0	0	0	0	11	19
7.06	1	5	3	3	0	0		0
7.07	1	2	0	0	0	0		6
7.08	0	2	2	0	0	0	12	16
7.09	0	5	3	3	0	0	6	6
7.1	1	2	2	0	0	0		7
7.11	1	5	3	3	0	0		0.8
7.12	1	5	3	3	0	0		5
7.13	1	2	0	0	0	0		10
7.14	1	5	3	3	0	0		18
7.15	0	2	0	0	0	0	8	14
7.16	0	2	2	0	0	0	10	23
7.17	1	5	3	3	0	0		30
8.01	1	1	2	3	0	0		44
8.02	0	2	0	0	0	0	5	12
8.03	1	2	0	0	0			13
8.04	0	2	0	0	0	0	5	10
8.05	0	2	2	0	0	0	3.7	10
8.06	1	5	3	3	0			0.4
8.07	0	3	2	3	0	0		38
9.01	0	2	0	0	0	0	3.5	11.5
9.02	1	5	3	3	0	0		1.4
9.03	1	2	0	0	0	1		15
9.04	0	4	2	0	0	0	4.8	30
9.05	0	2	0	0	0	0	2.5	24
9.06	1	2	0	0	0	0		20
9.07	0	5	3	3	0	0	3	3
9.08	1	5	3	3	0	0		19
9.09	0	1	0	0	0	0	2	10
9.1	1	5	3	3	0	0		4.3
9.11	1	2	0	0	0	0		5
9.12	0	2	2	0	0	0	4	32
9.13	0	5	3	3	0	0	1.5	1.5
9.14	1	5	3	3	0	0		4.3
9.15	1	5	3	3	0			30
9.16	0	3	2	0	0		16	35
9.17	1	2	2	0	0	0		62
9.18	0	5	3	3	0	0	2.3	2.3
9.19	1	2	0	0	0	0		17
9.2	0	2	3	3	0	1	10	23

List of Patients and Outcomes
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9.21	0	5	3	3	0	0	3.3	3.3
9.22	1	2	0	0	0			23
9.23	1	1	0	0	0	0		24
9.24	0	2	2	0	0	0	3.4	29
9.25	1	2	2	0	0	0		28
9.26	0	2	0	0	0		2.7	16
9.27	0	5	3	3	0		3.7	5.8
10.01	0	3	2	0	0	0	4	74
10.02	0	5	3	3	0	0	3	16
10.03	1	5	3	3	0	0		4
10.04	1	1	3	3	0	0		9
10.05	1	5	3	3	1	0		2
10.06	0	2	2	3	0	0	1.7	11
10.07	0	2	2	0	0	0	13	24
10.08	1	6	2	0	0	0		22
10.09	1	1	2	0	0	0		42
10.1	0	5	3	3	0	0	4.2	4.2
Explanation of Header Codes								
patid	First digit	center						
vent	0=HFOV	1=CMV						
status30	2= respiratory support, 3= death							
status6m	2= respiratory support, 3= death							
IHTTxF	1= treatment failure intractable hypotension							
newPTX	1= new air leak							
DurHFO	days of HFO							
DurMV	days of mechanical ventilation (CV+HFO)							

This is a log of events reported by the sites on the "Unanticipated Events" Case Report Form, as well as events identified while reviewing the patient data packets. The Adverse Events CRF indicates that only HFOV FAILURES , PROTOCOL VIOLATIONS and UNANTICIPATED ADVERSE EVENTS should be reported.

Date	Pat #	Vent	comment
10/27/97	1.01	HF	mucus plug during CV, also diarrhea, skin problem noted
11/2/97	1.02	CV	patient bagged during transport, no exacerbation
11/4/97	1.02	CV	patient extubated early due to mucus plug
12/31/97	3.02	HF	after 8 hrs HFO, patient returned from OR and left on CV
1/16/98	3.03	CV	Only enrollment and outcome data available
3/14/98	5.01	HF	Only enrollment & outcome data available
2/11/98	4.02	HF	Patient withdrawn after 8 hours because no ARDS
3/26/98	2.03	HF	unable to ventilate, resolved with removal of ETTube mucus plug
4/1/98	1.02	CV	post op MI & block 5 months after study exit
4/18/98	2.05	HF	false alarm (pressure sensor failure) day 3, switched to CV
5/9/98	1.04	HF	driver overheated day 2, placed on 2nd HFO without de-sat
5/11/98	1.04	HF	Right main stem mucus plug with desat , resolved with suctioning
8/14/98	1.05	CV	cardiac arrest unrelated to study at 3hrs
8/18/98	1.06	CV	cardiac arrest from tension pneumothorax day 1, successful CPR
8/18/98	2.08	HF	exit for neurological evaluation day 1
8/19/98	1.06	CV	heart failure (DNR) day 4
8/19/98	1.07	HF	undetected leak in circuit, uneventful switch to CMV
9/21/98	3.09	CV	entry delayed because of in hospital transport
12/26/99	4.05	CV	Assist control cmv during transport
1/5/99	4.05	CV	Assit control mode after TxF-RespAcid day 7
1/25/99	1.09	HF	desat during ETT change
2/22/99	1.13	CV	after TxF (RespAcid & Hypotension) day 3, short HFO rescue attempt
4/19/99	1.15	HF	patient cardiac arrest at 20 minutes, prior to initiation of HFO
4/26/99	8.02	HF	written Informed Consent not received at time of randomization
5/28/99	7.03	HF	patient taken off HF @ 6 hrs, returned to HF after 48 hrs
6/16/99	9.03	CV	patient left in SIMV but at 10 cc/kg for first 3 days
6/21/99	8.03	CV	on day 3 patient switched to SIMV from PCV
7/26/99	3.06	HF	patient enrolled with high wedge, but ARDS present
7/26/99	3.06	HF	patient removed from HF early because of hyperventilation
7/26/99	9.04	HF	patient to OR on CMV twice

10/14/99	4.11	HF	Attending switched patient to CMV on day 1 without Tx failure criteria met
12/15/99	2.15	HF	Uneventful early wean to CMV on day 4
7/3/00	4.12	CV	Patient switched to another CMV strategy (PCV) because of bradycardia
8/31/00	10.07	HF	Unexplained episode of arrhythmia and hypotention, perhaps related to low pH
11/11/00	9.27	HF	PEEP <10 at entry, had grade2 airleak & OI 23 so ARDS was severe, just low PEEP re:Air leak
11/19/00	9.27	HF	2 days after wean to CMV, rapid rise in ICP and death, likely due to head trauma
11/24/00	7.16	HF	Patient circuit lost pressure, patient switched to CMV and later returned to HF unevenfully