Patient ID # : _____

Center: WHMC TH WH MMC BMH USF MCMC BAMC

Randomization: HFOV Conventional

date/time ___ / ___ /__ @ _____ hrs (24 hour clock)
mm dd yy

Inclusion/exclusion criteria confirmed by: _____

Inclusion Criteria:

__ 1. Age ≥ 16 years **and**
__ 2. Weight ≥ 35 kg
__ 3. P/F ratio < 200
on two consecutive ABG's
> 30 min. apart but <4 hrs apart **with**
__ 4. PEEP ≥ 10 cm H2O **with**
__ 5. bilateral infiltrates **and**
__ 6. PA wedge < 18 mmHg **or**
__ 7. no evidence of LA hypertension **and**
__ 8. ability to gain Informed Consent

Exclusion Criteria:

- FiO_2 > .80 for > 24 hours **or**
- persistent airleak **or**
- nonpulmonary terminal prognosis **or**
- intractable shock **or**
- severe COPD or asthma **or**
- enrollment in another investigation for ARDS or septic shock < 30 days

Patient Data

Gender: M F DOB: ___ /___ /___ Age: _____
dd mm yy

Height: _____ cm Wt: _____ kg (ICU Admit)

Intubation

Intubation type: orotracheal ___ nasotracheal ___ tracheostomy ___
ET diameter: ___ mm ET length: ____ cm

Number of days of mechanical ventilation prior to randomization ___.___

Were there any pneumothoraces present at time of randomization? Yes No

Air leak grade: 0 1 2 3 4

Number of days with air leak prior to randomization ___ .___

Note: This form, or the computer randomization screen should be faxed to Tom Bachman, 909 337-0830 within 48 hours of entering patient in the study.

PRE-ENTRY CLINICAL DATA

Center _____ **Patient # _____**

APACHE 2 Score _____ (worst values in first 24 hours of this ICU admission)

Diagnosis: (please check all relevant risk groups)

___ sepsis
(circle source: pneumonia • intestinal/abdominal • urinary tract • catheter • other • unknown)

___ inhalation injury
___ embolism
___ pulmonary infection
___ transfusion related
___ other (list)
_____

___ trauma (circle: chest or head)
___ aspiration
___ drug induced
___ pancreatitis
___ intravascular coag.

Ventilator Settings/ABG's - Prior to Randomization

PIP _____ PEEP _____ Mean Paw _____ I:E _____

I-Time _____ Resp Rate _____ Tidal volume _____

FiO_2 _____ Hgb _____ HCO3 _____ Base excess ____

pH _____ PaO_2 _____ $PaCO_2$ _____ SaO_2 _____

Cardiovascular Data - Prior to Randomization

BP (s/d/m) _____/_____/_____ HR _____ CVP _____

PAP _____/_____ CO _____ PCWP_____

Note: The Ventilator Settings, ABG and Cardiovascular data Prior to Randomization, should be the data most reflective of the patients status when randomized.

VENTILATOR & CLINICAL DATA - during HFOV

Center _____ Patient # _____

Scheduled date and time of reading (24 hr clock)	**_____ ___ : ___ hrs**	**_____ ___ : ___ hrs**	**_____ ___ : ___ hrs**
Actual date and time (24 hr clock)	**_____ ___ : ___ hrs**	**_____ ___ : ___ hrs**	**_____ ___ : ___ hrs**
Bias flow			
Power setting			
Delta-P			
Mean Paw			
Frequency Hz			
% I-time			
Hgb			
FiO2			
pH			
PaCO2			
PaO2			
HCO3			
SaO2			
SvO2			
heart rate			
systolic BP			
diastolic BP			
mean BP			
CVP			
Cardiac Output			
PCWP			
Air leak score (circle)	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
ET Tube Change(indicate change)			
APACHE 2 Score (Day 1,2 and 3 of treatment only)			

Note: T= 0 for HFOV is defined as when HFOV is initiated. The first data should be when the patient has stabilized or at 2 hours if still unstable. After that data, the readings are scheduled for every 8 hours for the first 72 hours of HFOV and then once per day while the patient is on mechanical ventilation. After weaning to convention ventilation these data should be reported on the equivalent "-during Conventional Ventilation" form CRF-4. This form permits the recording of the scheduled and actual protocol time.

VENTILATOR & CLINICAL DATA - during CMV

Center _____ Patient # _____

Scheduled date and time of reading (24 hr clock)	**_____ ___ : ___ hrs**	**_____ ___ : ___ hrs**	**_____ ___ : ___ hrs**
Actual date and time (24 hr clock)	**_____ ___ : ___ hrs**	**_____ ___ : ___ hrs**	**_____ ___ : ___ hrs**
PIP			
PEEP			
Mean Paw			
I:E			
Rate			
Tidal Volume (ml)			
Hgb			
FiO2			
pH			
PaCO2			
PaO2			
HCO3			
SaO2			
SvO2			
heart rate			
systolic BP			
diastolic BP			
mean BP			
CVP			
Cardiac Output			
PCWP			
Air Leak Score (circle)	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
ET Tube Change(indicate change)			
APACHE II Score (Day 1,2 and 3 of treatment only)			

Note: T= 0 for CV is defined as 1 hour after randomization. The first data is scheduled for when the patient has stabilized or at 2 hours if still unstable. After that data the readings are scheduled to occur every 8 hours for the first 72 hours of CV and then once per day while the patient is on mechanical ventilation. This form permits the recording of the scheduled and actual protocol time.

STUDY EXIT REPORT

Center _____ Patient # _____

Exit date/time ___ / ___ /__ @ _____ hrs (24 hour clock)
mm dd yy

Exit Criteria met:

___ withdrawal of informed consent

___ weaned from MV

___ 30 days from entry

___ HFOV treatment failure and physician determined potential benefit of CMV

___ death (briefly describe cause of death)

_____
_____
_____
_____

Associated Causes of Death: (please select all appropriate causes)

___ profound hypoxemia ___ multiple organ failure (≥ 3 organs)

___ sepsis ___ withdrawal of life support

___ cardiac arrhythmia ___ other: _____ (please specify)

Treatment Failure Criteria Met During Study

___ No

___ Yes ___ / ___ /__ @ _____ hrs (24 hour clock)
mm dd yy

Criteria Met

intractable hypotension (average MAP during period)

___ MAP < 50 for 1 hour

___ MAP < 60 for 4 hours

___ intractable respiratory failure (pH < 7.15 and HCO3 >19 meq/l for 6 hours)

___ oxygenation failure (OI > 42 after 72 hours of treatment)

OUTCOME REPORT - 1 Month Follow-Up

Center _____ Patient # _____

Indicate source of follow up data

___ Patient died (___ / ___ /__)
dd mm yy

___ Actual 30 day follow-up

___ Lost to follow-up

i.e. Status at discharge date of discharge (___ / ___ /__)
dd mm yy

If alive indicate respiratory status

___ No respiratory support required

___ Oxygen required - defined as requiring supplemental O2 administration to maintain an oxygen saturation of at least 90% awake without CPAP.

___ CPAP required - defined as CPAP required to maintain an oxygen saturation of 90% or greater, awake breathing room air.

___ Mechanical ventilation required - defined as being required if necessary to maintain a PaCO2 of ≤ 50 Torr during spontaneous breathing with metabolic acidosis treated (HCO3> 19 meq/L).

Other significant events

___ Weaned MV: (___ / ___ /__)
mm dd yy

___ Weaned O2: (___ / ___ /__)
mm dd yy

___ Discharged: (___ / ___ /__)
mm dd yy

___ Transferred: (___ / ___ /__)
mm dd yy

___ Extraordinary therapeutic interventions after exit ? (e.g., ECMO, iNO, HFV, other)

_____

_____

OUTCOME REPORT - 6 Month Follow-Up

Center _____ Patient # _____

Indicate source of follow up data

___ Patient died (___ / ___ /__)
mm dd yy

___ Actual 6 month follow-up

___ Lost to follow-up

___ Status at discharge date of discharge (___ / ___ /__)
dd mm yy

___ Status at 30 days

If alive indicate respiratory status

___ No respiratory support required

___ Oxygen required - defined as requiring supplemental O2 administration to maintain an oxygen saturation of at least 90% awake without CPAP.

___ CPAP required - defined as CPAP required to maintain an oxygen saturation of 90% or greater, awake breathing room air.

___ Mechanical ventilation required - defined as being required if necessary to maintain a PaCO2 of ≤ 50 Torr during spontaneous breathing with metabolic acidosis treated (HCO3> 19 meq/L).

Other significant events

___ Weaned MV: (___ / ___ /__)
mm dd yy

___ Weaned O2: (___ / ___ /__)
mm dd yy

___ Discharged: (___ / ___ /__)
mm dd yy

___ Transferred: (___ / ___ /__)
mm dd yy

___ Extraordinary therapeutic interventions after exit (e.g., ECMO, iNO, HFV, other)

_____

_____

MOAT - UNANTICIPATED EVENT REPORT

FAX 714 283-8493 or
909 337-0830
att: Tom Bachman

PATIENT NUMBER _____
SITE _____
DATE OF EVENT _____
TIME OF EVENT _____

Investigators are required to report any unanticipated events to the study sponsor within 24 hours of occurrence. This should be accomplished by filling out this form and faxing it to SensorMedics. After fax transmission this original form should be maintained with the other Case Report Forms.

These reportable events include: 1) HFOV failure, 2) study protocol violation, and 3) unanticipated adverse clinical events. (note the study Risk Analysis anticipates certain potential adverse effects that need not be reported on this form including: pulmonary overdistention, barotrauma, excess mucus, and over or under oxygenation and ventilation)

INDICATE TYPE OF EVENT

___ HFOV failure, ___ protocol violation, ___ unanticipated adverse clinical event

DESCRIBE EVENT

INVESTIGATOR SUBMITTING REPORT _____

VENTILATOR STRATEGY LOG

Center _____ Patient # _____

Date & Time (2/13 - 22:12)	Ventilator change (e.g., PEEP 12 to 15)	Reason for change (e.g., O2 sat 85%)

note: Keep with ventilator and document every significant ventilator setting change for the first three days of treatment on the assigned ventilator or until exit, whichever occurs first.

ELIGIBILITY LOG

Center _____

Date (m/d/yy)	Patient ID	P/F & PEEP (eg. 95 / 12)	Reason for not enrolling (eg, no Informed Consent, Investigator unavailable, not ARDS, HFOV unavailable)

Confounding Therapies

Center _____ Patient # _____

1. Entry through day 30 days

Treatment	Received ?	**Study Day** started**	Length	Responded ?
ECMO	yes no			yes no
iNO	yes no			yes no
Proning	yes no			yes no
Steriods *	yes no			yes no
Surfactant	yes no			yes no
HFV ***	yes no			yes no

* only Steriods for treatment of fibro-proliferative phase of ARDS need be noted. If yes, indicate below the initial dose and duration
(e.g., initial 2 mg/kg/day m-prednisolone for 14 days).

_____

** day 1 - 30 even if patient already exited from study

*** HFV used for rescue (indicate HFO or HFJ)

2. Prior to entry:

• patient immune compromised ? Y N

• extended mechanical ventilation (5 days or greater) ? Y N

If yes:

- P/F < 200 with PEEP 10 or greater for ___ . ___ days

- Bilateral infiltrates for ___ . ___ days