Ames Research Center

~~C. Cramer~~
Thornton

NASA

LR:239A-2

TO: Joe Kremin
Code: SKPL
O&C Building, Room 42730
Kennedy Space Center, FL 32899

FROM: Patricia S. Cowings, Research Psychologist,
Biomedical Research Division

SUBJECT: Human Use Protocol for SL 3 experiment #3AFT23: "A Preventive Method for the Zero Gravity Sickness Syndrome".

Enclosed are 10 copies (with associated attachments) of our Human Research Protocol for the above Shuttle Flight Experiment. I would like to request a meeting of the Human Review Committee, at their earliest convenience, to review this proposal. I will be happy to attend the committee meeting.

Until quite recently, I was under the impression that those portions of this research (i.e., Baseline Data Collection) which are to be conducted at NASA Ames Research Center would only require the approval of the Ames Human Research Evaluation Review Board. That approval, dated until 1986, is also enclosed. However, now I understand that the entire proposal must be reviewed and approved by your organization before we can begin. We have tentatively scheduled members of the SL-3 crew to attend Baseline sessions at Ames during the month of April. Consequently, anything that you might do to facilitate expediting this meeting would be greatly appreciated.

I have been informed that the Johnson Human Use Committee usually grants approvals for a period of 90 days. Because the proposed flight experiment requires periodic interaction with crewmembers beginning at L 10 months, I would like to request that your committee consider extending their approval for a period of 1 year.

Because of the time criticality of the review we have sent by copy of this letter 10 copies of our Human Research Protocol to Dr. Nachtwey, at JSC.

Thank you for your attention to this matter. If I can provide any information or materials to assist you, please do not hesitate to contact me.

Sincerely yours,

Patricia S. Cowings

Patricia S. Cowings, Ph.D.
Research Psychologist

Enclosures:
1. Protocol
2. Ames HRERB Approval
3. Enclosure 1 Vitaes
4. Enclosure 2 Human Research Consent Form
5. Enclosure 3 Diagnostic Scale Instruction Material
6. Enclosure 4 Safety Plan
7. Enclosure 5 Illustration

cc:
240A-3/W. Berry w/o enclosures
213-2/H. Finger
240A-3/C. Schatte w/o enclosures

PSCowings: 3-9-84/5724

ENCLOSURE II:

HUMAN RESEARCH CONSENT FORM

FOR

SPACE LAB 3 LIFE SCIENCES EXPERIMENT #3AFT23:

"A PREVENTIVE METHOD FOR THE ZERO-GRAVITY SICKNESS SYNDROME".

NASA-AMES

LR:239A-2 Moffett Field, California

HUMAN RESEARCH CONSENT

PART I

The series of tests for which ---------- is to serve as a subject has been explained to him in detail. The following information was included in this explanation.

A. TITLE: SHUTTLE FLIGHT EXPERIMENT #3AFT23:

A PREVENTIVE METHOD FOR THE ZERO GRAVITY SICKNESS SYNDROME

B. PRINCIPAL INVESTIGATOR: PATRICIA S. COWINGS, PH.D.

CO-INVESTIGATORS: WILLIAM B. TOSCANO, M.A.
JOE KAMIYA, PH.D.
NEAL E. MILLER, PH.D.
JOSEPH SHARP, PH.D.

C. PURPOSE:

The primary purpose of this flight experiment is to determine the extent to which zero-gravity sickness in crewmembers can be reduced by training them to control their own autonomic responses. This autonomic conditioning method is called Autogenic-Feedback Training (AFT). Three crewmen will participate (inflight) in this study as Treatment Group subjects and will receive preflight training in voluntary autonomic control. Two crewmen will receive an alternative treatment and will therefore serve as Control Group subjects for this study.

Additionally, this study will enable us to: (a) examine the relationships between physiological responses and the severity of zero gravity sickness symptoms experienced in space; and (b) develop predictive criteria for susceptibility to zero gravity sickness based on a crewmembers demonstrated ability (preflight) to learn physiological self-regulation.

D. NATURE OF TESTS OR EXPERIMENTS:

This experiment will be conducted in three phases: I. PREFLIGHT CREW PARTICIPATION REQUIREMENTS; INFLIGHT CREW PARTICIPATION REQUIREMENTS; AND III. POST FLIGHT CREW PARTICIPATION REQUIREMENTS.

During all preflight and inflight sessions listed below, your physiological responses will be monitored with the aid of an Ambulatory Monitoring System (AMS). This AMS (see attached illustration) contains a garment, transducers, biomedical amplifiers, and a cassette data tape recorder. The physiological responses to be recorded are: (a) electrocardiography, and heart rate; (b) respiration rate and tidal volume; (c) basal skin resistance and galvanic skin response; and (d) peripheral blood volume of the hand. Additional responses measured using laboratory hardware include: (a) other sites of blood volume; (b) other sites of basal skin resistance; and (c) electromyography of your forearm extensor muscles. All mesures are non-invasive with transducers attached either to the garment itself, or to skin surfaces with tape. During inflight sessions only, a triaxial accelerometer, measuring head and upper body movement, will be attached to your STS headset.

E. MANNER IN WHICH TESTS OR EXPERIMENTS WILL BE CONDUCTED:

I: PREFLIGHT CREW PARTICIPATION REQUIREMENTS

BASELINE DATA COLLECTION L 10 to L 6 mo.

NOTE: Conducted on 3 consecutive days. All crewmembers will attend these sessions, with no more than two crewmembers on any given day. Only ONE motion sickness test will be administered on any given day. All baseline data collection will be conducted at NASA ARC. These sessions include the following:

(1) Coriolis motion sickness test: The inital symptoms of motion sickness will be induced using a standard rotating chair test. Physiological responses will be monitored and the individual's symptom characteristics will be documented.

During this test, you will be blindfolded and seated in a rotating chair. Following ten minutes of resting baseline, chair rotation will be initiated at 6 rpm for a period of five minutes. During this five minute period, you will be instructed by a tape recorded voice to perform head movements (left, right, front and back) in random order at 2 second intervals. At the end of this five minute period, you will stop head movements for 30 seconds (chair rotation continues) and you will be asked a series of questions designed to determine your level of motion sickness symptoms (see attached Diagnostic Scale Instruction Material). If at this time you have no (or few) symptoms AND you report that you feel well enough to go on, we will increase the chair speed to 8 rpm and initiate a second 5-minute sequence of head movements. This procedure continues, with the chair speed increasing in 2 rpm steps every 5 minutes. This test will be terminated when: you have completed the maximum duration of this test (65 minutes), OR the experimenter requests that the test be terminated (based on your response to the diagnostic scale), OR at any time that you request it. Please keep in mind, these tests are designed to be terminated BEFORE the onset of severe nausea or vomiting. We don't want to have to clean up the room!

(2) Vertical acceleration motion sickness test: Motion sickness symptoms will be induced using the Vertical Acceleration and Roll Device (VARD) at ARC. Physiological responses will be monitored and the individual's symptoms documented.

During this test, you will be seated within an enclosed cab. Following ten minutes of resting baseline, the cab will be oscillated (+ or 2.5 ft.) at 0.33 Hz., 0.35 g. for a period of five minutes. During this five minute period, you will be instructed by a tape recorded voice to perform head movements (left, right, front and back) in random order at 2 second intervals. At the end of this five minute period, you will stop head movements for 30 seconds (oscillation of cab continues) and the diagnostic scale will be administered. If at this time you have no (or few) symptoms AND you report that you feel well enough to go on, we will initiate a second 5-minute sequence of head movements. This procedure continues until you have completed the maximum duration of this test (75 minutes), the experimenter requests that the test be terminated (based on your response to the diagnostic scale), OR you ask that the test be terminated.

(3) Resting Baseline Sessions: The subject is required to sit quietly in a reclining chair within a darkened, sound attentuated chamber while listening to tape recorded music for a period of 30 min. His physiological responses are monitored and these data are then compared to motion sickness test data for establishing an individual "stress profile". This procedure will be repeated twice. Once we have established which autonomic responses diverge from the subject's own resting baseline levels as a function of exposure to motion stimuli, we can then determine where to place emphasis in subsequent (AFT) autonomic conditioning sessions.

(4) Ambulatory Baseline: The crewmember will be required to wear an ambulatory monitoring garment and instrument package for a minimum period of 15 hours. This instrument will continuously record his physiological responses while he conducts his normal daily activities away from the laboratory.

ADDITIONAL OPERATIONAL TRAINING: L-10 to L-6 mo.

Note: Conducted on same days as Baseline Data Collection.

(1) Diagnostic Scale Administration: The crew member is videotaped while participating in Coriolis and vertical acceleration motion sickness tests. These video tapes, in conjunction with written materials, will provide the crewmember with a training-aid for learning to self-assess his own motion sickness symptoms. A standardized diagnostic scale will be used by the crewmember inflight (written 8-item checklist) to document level of malaise experienced. (See attached Diagnostic Scale Instruction Material).

(2) Instrument Package Operation: The crew member will be given an opportunity to practice procedures for donning and doffing the ambulatory monitoring garment, attaching electrodes, transducers and cable harness, and operation of the data recording hardware.

MISSION SIMULATIONS: As Scheduled by Mission Management.

Additional opportunities to practice donning and doffing of instrument package, operation of instrument package, and Inflight Time Lined Procedures (see Section II: INFLIGHT CREW PARTICIPATION REQUIREMENTS) may be obtained during scheduled mission simulations. Such opportunities will also enable the

crewmembers to make assessments of the likelihood that the ambulatory monitoring hadware will interfere with other mission activities. Procedural modificiations reccomended by crewmembers may be incorporated at this time. These sessions will be particularly valuable to Control Group subjects who will not participate in preflight autonomic conditioning, and therefore will have less opportunity to familiarize themselves with the hardware than the Treatment Group subjects.

PREFLIGHT AUTONOMIC CONDITIONING/TESTING: L-4 to L 1 mo.

NOTE: Only those crewmembers designated as Treatment Group subjects will be required to participate in this phase of the experiment. This time frame and schedule assumes that the JSC Autogenic Feedback Training Facility will be operational and available for use in support of this SL 3 experiment.

(1) Formal AFT sessions: The crewmember will be trained by the P.I. and/or a designated coinvestigator, to volitionally control his own autonomic responses during 12 Formal AFT sessions (each session = 42 min. data acquisition). Three sessions per week would be optimal. With this schedule, Formal AFT sessions can be conducted over a 4 week period. The L 4 to 2 mo. window for initiating training is suggested to allow for scheduling constraints of crew participation. The final session in this sequence should be administered no earlier than L-1 month.

(2) Self-Administered AFT sessions: The crewmember will be required to perform daily training sessions away from the laboratory (minimum of 15 minutes per session). On some of these daily sessions he will practice, without the package, the skills he has acquired in the laboratory. On at least two days (in the interval between formal AFT sessions) he will train with a duplicate flight instrument package. Data collected during these instrumented sessions (cassette tapes) must be returned to the P.I. for subsequent analysis.

(3) Training tests: A total of 3 Coriolis motion sickness tests will be administered to this crewmember as a test of his ability to suppress his symptoms using AFT. These tests will be spaced at equal intervals, and will be given on the same days as three of the Formal AFT sessions.

FINAL AFT VERIFICATION SESSION: L 7 days

A final two hour AFT session will be conducted by the P.I. and/or designated coinvestigator no earlier than one week prior to launch. This session will be conducted at NASA Kennedy Space Center (requires exclusive use of "quiet" office/room containing a table, desk chair and a reclining chair). A duplicate flight instrument package containing recorder, transducers, and feedback display will be provided by the experimenter for use during these sessions. The Final Verification Session will serve to determine the level of autonomic control retained by the crewmember at L-7 and will further strengthen his autonomic control with additional AFT and the assistance of an Investigator. This session consists of the following procedures:

Treatment Subjects only-tested individually.

(1) Resting Baseline - approx. 30 min.

(2) Crewmember performs Bidirectional autonomic control without feedback approx. 30 min.

(3) Crewmember performs Bidirectional autonomic training/practice with feedback and with the assistance of an Investigator - approx 30 min.

(4) Review of instrument package operation and diagnostic scale procedures.

Control subjects-tested simultaneously.

(1) Resting Baseline - approx. 30 min.

(2) Review of instrument package operation and diagnostic scale procedures.

DONNING OF AMBULATORY MONITORING HARDWARE: L 4 to 6 hours

NOTE: All crewmembers

The ambulatory monitoring garment, transducers, electrodes, AFS and recorder should be donned at the time the crewmember dresses for launch.

INITIATE DATA RECORDING L 10 minutes (HOLD)

NOTE: All crewmembers

At the time of the normal L -10 minute hold prior to launch, the crewmember will be required to turn on his instrument package to initiate data recording. The recorder and associated AFS hardware will be mounted to his seat during lift-off. The AFS and recorder will be removed from the seat and attached to the crewmember's belt following orbit insertion. NOTE: Evaluation is currently underway concerning the feasibility of allowing the crewmember to wear the monitoring system on a belt (i.e., strapped to his left thigh) during launch. If this procedure is permitted, it will eliminate the need for Shuttle Interface (mount on chair).

II: INFLIGHT CREW PARTICIPATION REQUIREMENTS

CONTINUOUS PHYSIOLOGICAL MONITORING: All Crewmembers.

All crewmembers participating in this experiment will be required to wear (in-operation) the ambulatory monitoring system during waking hours (approx. 15-hours). Minimum requirements are for monitoring to continue through Mission Day 5. Crewmembers may opt to continue monitoring on additional mission days and during re entry. This inflight requirement involves the following:

(1) During Post Sleep Activity period, the crew member dons the ambulatory monitoring system.

(2) At this time, a second cassette tape (each tape operates for approx 7 hours), will be removed from stowage and kept in the crewmember's flight suit pocket. The data tape must be replaced daily following 7-hours of

operation. NOTE: The Diagnostic Scale Booklet (3" x 5") and a pencil should also be removed from stowage at this time and placed in the same pocket as the data cassette tape.

(3) Battery packs must be replaced on alternate mission days (Mission days 2 and 4).

(4) Electrodes and/or transducers may be replaced (from spares in stowage) on an as-needed basis.

(5) The garment, hardware, data cassette tapes and diagnostic scale booklet should be removed and restowed (personal stowage tray) during the Pre-Sleep Activity Period, daily.

(6) In the event of hardware failure, there is no contingency for inflight repairs. Because this is to be a split shift mission, the crewmember whose instrument package has failed, is required to use the instrument package of another crewmember on the alternate shift. In this event, battery packs of the "borrowed" unit must be replaced more often. It is essential that crewmembers stow their own tapes in their personal stowage trays.

TIME-LINED DIAGNOSTIC SCALE ADMINISTRATION: All Crewmembers.

(1) All crewmembers participating in this experiment will be required to self-administer a diagnostic scale twice daily, (see attached Diagnostic Scale Instruction Material). The required information is to be written in the diagnostic scale booklet kept in the crewmember's pocket. Duration of this activity is 2 minutes.

(2) Crewmembers are required to indicate time of diagnostic scale administration by pressing the event button (once) on their ambulatory monitoring systems.

(3) This time-lined activity must occur at the same time of day (+ or - 30 minutes) on each mission day. The time of day, however, for scheduling this activity is non-critical for CONTROL GROUP SUBJECTS.

SYMPTOM-CONTINGENT DIAGNOSTIC SCALE ADMINISTRATION: All Crewmembers.

(1) All crewmembers participating in this experiment are required to indicate the occurrence of inflight symptoms AT ANY TIME DURING THE MISSION by pressing the event button (twice) on their ambulatory monitoring systems.

(2) The crewmember is then required to self administer the diagnostic scale (within no more than 10 minutes) following the onset of symptoms.

(3) CONTROL SUBJECTS ONLY are required to re administer the diagnostic scale after 30 minutes following first administration. During this 30 minute interval the crew member may continue any scheduled mission activities.

(4) The conclusion of this activity is signaled by pressing the event button (once) on their ambulatory monitoring systems.

TIME-LINED PREVENTIVE AFT: Treatment Subjects Only.

(1) Immediately following the first, daily time lined diagnostic scale administration, Treatment Group crewmembers (who recieved preflight AFT) are required to perform AFT exercises for a 15 minute period with the aid of the wrist-mounted feedback displays. No other flight activity may occur during this period.

(2) Immediately following this Preventive AFT session, these crewmembers are required to re-administer the diagnostic scale (this is the second, daily time-lined diagnostic scale administration).

(3) The time of day for administration of this session is non-critical, BUT, this session must occur no earlier than 1 hour following any inflight exercise.

SYMPTOM-CONTINGENT COUNTERACTIVE AFT: Treatment Subjects Only.

(1) Following self-administration of the diagnostic scale (see C. SYMPTOM CONTINGENT DIAGNOSTIC SCALE ADMINISTRATION:) the crewmember is required to attempt to apply AFT to counteract his symptoms with the aid of the wrist mounted feedback displays.

(2) The period for attempting to counteract symptoms will not exceed 30 minutes. During this 30 minute interval the crew member may continue any scheduled mission activities.

(3) Immediately following this 30 minute period, the crewmember is required to re-administer the diagnostic scale.

III: POST FLIGHT CREW PARTICIPATION REQUIREMENTS

All crew members participating in this experiment will be required to attend (individually) a 2-hour debreifing session within 14 days post flight. The Principal Investigator and one other co-investigator will participate in this meeting. No specific site requirements are made for this meeting.

F. DURATION:

This experiment will be a portion of the payload of Space-Lab 3, scheduled for launch in November, 1984. Crew participation in this experiment begins approximately 10 months prior to launch (each participation requirement shows the schedule within text). Preflight AFT will involve 12 training sessions, administered 3 times a week. This activity will be conducted within a 3 month window prior to launch.

G. FORSEEABLE INCONVENIENCES, DISCOMFORTS, AND/OR RISKS:

1. During motion sickness eliciting tests (preflight) there is some possibility of transient motion sickness . However, the test procedures are designed to terminate runs before the actual onset of motion sickness (severe nausea or vomiting).

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2. Some degree of disorientation and vertigo may be experienced.

3. Subjects may experience some skin irritation due to the adhesive on the surface of electrodes. The disposable electrodes to be used have been designed for long term ambulatory use.

Date	Signature of Principal Investigator
Date	Signature of NASA Medical Monitor

HUMAN RESEARCH CONSENT #3AFT23

PART II

SPACE LAB 3 LIFE SCIENCES HUMAN EXPERIMENT

I, the undersigned, do voluntarily give my informed consent for my participation as a test subject in the experiment entitled "A Preventive Method for the Zero-Gravity Sickness Syndrome" which is designed under the direction of Dr. Patricia S. Cowings, the proposer and designated Principal Investigator, and under the coordination of Dr. John Tremor, the NASA Life Sciences SL-3 Project Scientist.

The proposed human research has been explained to me to my satisfaction, prior to the execution of this Conset Form, and I understand that I may widraw this consent at any time unless as recommended by the Principal Investigator or her designee, the withdrawal is unwise, dangerous, or impossible.

If during the actual mission, the Mission Commander determines that the amublatory monitoring hardware is impeding my performance on other mission activities, then I may remove part or all of the instrumentation to complete the task in question. When the task has been completed, however, I am required to reapply and activate the continuous monitoring hardware. Inflight diagnostic scale administration and (as many as possible) of the inflight procedures must continue as proposed.

If during the mission, the Mission Commander, upon consultation with the assigned Flight surgeon, determines that participating in this experiment constitutes a risk to my health and/or safety, I may remove part or all of the continuous monitoring hardware. Inflight diagnostic scale administration and (as many as possible) of the inflight procedures must continue as proposed.

I was afforded an opportunity to ask questions concerning the experiment, and all questions asked were answered to my satisfaction. Based on the above considerations, I volunteer and agree to perform these duties as part of my employment and understand that I am considered medically qualified to participate in such tests.

I understand that in the event of physical injury resulting from the experiment and calling for immediate action or attention that NASA will provide the necessary emergency treatment. I also understand that NASA will pay any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act of the Federal Tort Claims Act.

I understand that complete investigator/crewmember privacy will be maintained at all times. My data records will be assigned identification codes, with neither my name or position title identified. No information regarding my motion sickness susceptibility, preflight training or inflight performance will be released to any sources (including the news media, NASA management and operational medicine personnel) without my written permission.

My consent to participate as a test subject in the experiment: #3AFT23,

HUMAN RESEARCH CONSENT #3AFT23

"A Preventive Method for the Zero-Gravity Sickness Syndrome" shall not be construed as a release of NASA from any future liability which may arise from, or in connection with, the above tests or experiments.

This consent form is valid for a 1-year period from the date of the signature by the subject and the Principal Investigator (which dates should be identical). The signed, dated, original consent form shall be forwarded to the SL-3 Life Sciences Project Scientist , Dr. John Tremor, NASA Ames Research Center, Mail Code 240A 3, Moffett Field, California 94035.

APPROVED:

_____ _____

TEST SUBJECT DATE

_____ _____

SL-3 PROJECT SCIENTIST DATE

_____ _____

PRINCIPAL INVESTIGATOR DATE