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Thermoregulation During Spaceflight

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National Aeronautics and
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Ames Research Center
Moffett Field, California 94035-1000

SPACE ADAPTATION RESEARCH PROGRAM

TITLE: THERMOREGULATION DURING SPACEFLIGHT

DATE SUBMITTED:

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ADDITIONAL INFORMATION IF NEEDED:

SUMMARY

The purpose for this flight proposal is to investigate human thermoregulatory parameters during excercise in microgravity. The hypothesis to be tested is that microgravity-adopted astronauts will exhibit accentuated increases in their core temperatures (excess hyperthermia) during exercise because of altered heat loss responses due to reduced sweating and/or accentuated vasodilation. The specific aims are (a) to compare core and skin temperature responses during moderate exercise before flight and inflight; (b) to determine whether the hypothesized inflight excessive hyperthermia is due to increased heat production, reduced sweating, impaired peripheral vasodilation, or to some combination of these factors; and (c) to determine whether heat production at an exercise load of 60% of the maximal working capacity is similar preflight and inflight. It is expected that the astronauts will exhibit excessive hyperthermia during exposure to microgravity which will be caused by decreased sweating and decreased skin blood flow.

A. PROGRAM DESCRIPTION:

1) Hypothesis: Microgravity-adapted astronauts will exhibit excess hyperthermia during exercise because of altered heat loss responses due to reduced sweating and/or vasodilation.

2) Introduction: Little information is available for determining the effects of microgravity exposure on human thermoregulation. Leach et al. (1978) have suggested that there is a decreased sweat loss during exercise in microgravity and possible reduced insensible heat loss. Presumably, an increased "sheeting" of sweat on the surface of the body reduces convective as well as evaporative heat loss during exercise in microgravity. Spaceflight is associated with a developing hypohydration. Results from numerous ground-based studies have shown that hypohydration results in reduced sensitivity and elevated core temperature threshold for the onset of both skin blood flow and sweating heat loss responses. To date, there have been no direct measurements of skin blood flow or sweating responses during exercise in astronauts in microgravity.

3) Specific Aims:

a) To compare core and skin temperature responses in astronauts during moderate exercise before flight and in microgravity.

b) To determine whether the excess inflight hyperthermia is due to altered heat production, impaired vasodilation, impaired sweating, or to some combination of these factors.

c) To determine whether heat production at a moderate level of oxygen uptake (60% of preflight peak oxygen uptake) is similar preflight and inflight.

4) Rationale/Justification: Humans, with their normal core temperatures of 37° C (98.6° F), are closer to their upper lethal limit of core temperature (42° C or 107.6° F) than to their lower lethal limit of 27° C (80.6° F). Astronauts undergoing EVA would more likely have problems with excess heating than with enhanced cooling because of their physical work (exercise) performance. Any countermeasure effective for reducing heat production and/or increasing heat dissipation should

allow for higher work rates for longer periods of time. Also, understanding the relationship between heat production and evaporative heat loss will be required for accurate estimations of drinking water requirements during long-duration spaceflight.

5) <u>Background</u>: To date there have been no published accounts of heat maladies suffered by astronauts; i.e., heat exhaustion or heat stroke. The capacity of the environmental control system in the Space Shuttle is more than adequate to accommodate the crew's heat dissipation load, even when heavy exercise is performed periodically during orbital missions. The same was true during the Apollo and Skylab missions (Waligora and Horrigan 1975, 1977).

Because of the limitation of heat removal capacity of the extravehicular (EVA) suit, the upper limit of energy utilization during EVA in the Gemini, Apollo, and Skylab flights was 225-300 kcal/hr; this corresponds to an oxygen uptake of 0.8 to 1.0 liter/min during light exercise. The average EVA time was about 6 and 4 hr for Apollo and Skylab astronauts, respectively (Waligora & Horrigan 1977). Total heat removal capacity of the Space Shuttle-Space Station EVA suit is 2,513 kcal (10,000 BTU) and maximal rate of heat dissipation is about 503 kcal/hr (2,000 BTU/hr). The average steady-state range is about 213 kcal/hr (850 BTU/hr), which is somewhat lower than the 225-300 kcal/hr range of earlier suits. Vorobyev et al. (1986) reported mean energy expenditures of 198-294 kcal/hr for two cosmonauts during 170-175 min. of EVA; their average oxygen uptake was about 0.7 liters/min. The upper limit of heat removal of our suit (503 kcal/hr) is approximately equivalent to an oxygen uptake of 1.7 liters/min., a level about half the peak oxygen uptake (peak VO_2) of 3.4 liters/min. (45 ml O_2/min/kg body wt.), the average level for the total astronaut corps. Constant work at 50% of the peak oxygen uptake, i.e., at 1.7 liters/min., can be endured for about 5 hours of EVA. Constant work at 50% of the peak level will result in an equilibrium level of body core temperature of $38.0 \pm 0.1^\circ$ C (100.4° F), an optimal level for efficient work performance.

Since the rate of rise and final equilibrium level of body core temperature is directly proportional to the absolute exercise load (Greenleaf 1979), it is clear when astronauts work at loads greater than 503 kcal/hr (50% peak VO_2) that all metabolic heat will not be removed, suit ambient temperature will increase, and thus body temperature will rise above 38° C. The level of non-steady state hyperthermia depends on a number of factors including exercise intensity and duration, level of physical fitness, muscle groups involved, the size of the lean body mass, and the degree of microgravity deconditioning of the astronauts. The last factor involves the level of hydration and the efficiency of cardiac function which determine if sufficient blood is available to supply sufficient nutrients to working muscles as well as providing adequate perfusion of deep and especially peripheral veins to transport body heat for dissipation.

If we assume the average, normal body core temperature to be 37.0° C (98.6° F), death can ensue when body temperature falls below 27° C (80.6° F) and when it exceeds 42° C (107.7° F); i.e., with a drop of 10° C but with an increase of only 5° C. Thus overheating is more critical than overcooling. The lower limit of core temperature for the onset of heatstroke is between 41.1° C and and 42.0° C (Shibolet et al. 1976), but cases of classical heatstroke have been reported with core temperatures of 40.6° C (105.1° F) (Leithead and Lind 1964). The rate of heat exchange is also important. Unacclimatized men resting in a hot, humid environment (42° C, 90% relative humidity) are near their limit of tolerance and consciousness with rectal temperatures of 38.5° C (Convertino et al. 1980). But during intense isotonic exercise, rectal temperatures in the heatstroke range have been recorded with no adverse symptoms or lasting effects. Robinson (1963) measured rectal temperatures of 40.0° C and 41.1° C in two champion runners after a 3-mile race, and Pugh et al. (1967) observed rectal temperatures of 41.1, 40.5, and 40.2° C in the first, third, and fourth place finishers, respectively, after a marathon race. In normal ambient conditions, heat exhaustion and physical debilitation usually occur before heatstroke occurs. Under conditions in which heat flow away from the skin is reduced, such as in workers wearing impermeable clothing or astronauts wearing a suit with inadequate heat removal capacity, skin temperature rises resulting in a reduced core to skin temperature gradient. Under such conditions heat cannot be adequately removed from the core and symptoms of heat stress may occur even at core temperatures as low as 38° C (Tanaka et al. 1978, Smith 1980). Clearly, the absolute level of core temperature cannot be used to determine the physiological state of astronauts or when heat exhaustion is likely to occur.

All of these considerations, prognostications, and measurements have been applied to and performed on normal, healthy subjects on Earth. Jauchem (1988) has reviewed the effects of various environmental stressors including acceleration and hypergravity, hypogravity and weightlessness, hyperoxia and hypoxia, radiofrequency radiation, vibration, and circadian rhythm changes, and concluded that all of them influence body temperature to some degree. There is a close relationship between body fluid-electrolyte-osmotic parameters, cardiovascular (peripheral blood flow) heat dissipation mechanisms, and exercise thermoregulation in eugravity. There appear to be adaptive changes in fluid-electrolyte and cardiovascular parameters in microgravity. Therefore it is reasonable to assume changes in exercise thermoregulatory function will occur in microgravity-adapted astronauts. The major questions are (a) whether there is a unique effect of adaptation to microgravity per se on thermoregulation; (b) if so, will this effect adversely influence astronauts' performance and well-being; and (c) if so, can appropriate countermeasures be implemented?

Thermoregulatory studies conducted on astronauts in microgravity have, in general, produced either indirect data (Leach et al. 1978) or have been performed under inadequately controlled environmental conditions (Novak et al. 1980). Conclusive results have not been obtained. Instructive results have come from controlled studies of exercise thermoregulation after prolonged bed rest (Fortney 1987, Greenleaf and Reese 1980) and water immersion (Greenleaf et al. 1985). The excessive increases in esophageal (Fortney 1987) and rectal (Greenleaf and Reese 1980) temperatures during submaximal exercise after 12-14 days of horizontal bed rest have been attributed mainly to reduced conductive heat loss via enhanced peripheral vasoconstriction responses that were not the result of reduced plasma volume and were the result of reduction in sweating and evaporative heat loss (Fortney 1987, Greenleaf and Reese 1980). The rectal temperature response to exercise in air after immersion deconditioning is also higher than the pre-immersion level (Greenleaf et al. 1985), similar to the response after bed rest. While resting rectal temperature is increased post-immersion, it has also been reported to be unchanged from ambulatory levels (Greenleaf and Reese 1980) or to be increased above control levels (Fortney 1987) after bed rest deconditioning. The reason for this discrepancy is not clear and is currently being investigated at Ames.

B. EXPERIMENTAL DESIGN AND METHOD:

1) Overall Design: The overall study design involves a comparison of the thermoregulatory responses of 8 male astronauts during exercise in a ground-based environmental chamber to those on 10-14 day flights. Measurements of core and skin temperatures, local sweating, forearm blood flow, and oxygen consumption will be measured at a constant exercise level (60% preflight peak VO_2) during exercise tests (ET) conducted 3 times preflight, 3 times inflight, and 2 times postflight. Since thermoregulatory responses are dependent upon relative exercise intensity, exercise capacity (VO_2 peak) will be measured 3 times preflight, two days before the end of the flight, and once post-flight. The ET will be conducted in an environmental chamber at a temperature and humidity characteristic of the Shuttle middeck (77° F, 30-35% relative humidity). Because of the roughly 24-hr fluctuations in cabin ambient conditions during flight (see appendix 1 for examples of ambient cabin conditions), the ET will be scheduled for approximately the same time of the astronaut's activity day—approximately 3 hr after waking and 2 hr after breakfast. Exercise tests will be done in duplicate preflight, 3 times inflight (flight days 2, 5, and the day before scheduled landing) and 2 times at least 30 days postflight. Thermoregulatory responses will be assessed during each 60-min. ET from measures of core and skin temperatures, local sweating responses, forearm blood flow and heat production calculated from the exercise oxygen consumption.

2) Core Temperature: Core temperature will be measured using two separate techniques—rectal temperature for the steady state response, and ear canal-tympanic membrane temperature for the initial transient temperature response. The rectum is the site most often used to assess core temperature during long-duration steady-state exercise. The limitations of the rectal measurement site are that it takes 50-60 min. to reach equilibrium and it may be influenced by local muscle heat production during leg exercise. Ear-canal temperature measurement is an indirect method to estimate brain temperature. It is fast-responding and an accepted method to measure transient core temperature responses which are essential for the identification of an altered sweating or skin blood flow reflex response. Esophageal temperature will be measured with soft, disposable thermocouples (Mallinckrodt Anesthesia Products). Thermometer pills (Human Technologies, Inc.) will be evaluated preflight using volunteers to determine whether they might be used in place of the rectal temperature site for measurement of steady-state core temperature.

3) Forearm blood flow and sweating responses: Both vasodilation and sweating heat loss responses are effected via reflex nervous responses. To determine the effector reflex responses, forearm blood flow and sweat rate are plotted as a function of the rise in core temperature during the first 10-20 min. of exercise. The slopes of these relationships are an indication of the sensitivity of the reponses, while the core temperature at which sweating or vasodilation begins is the threshold of the responses (Nadel et al. 1977). Changes in sensitivity are thought to reflect changes in the function of the peripheral, afferent nervous system, while changes in threshold are interpreted as a central neural change in the thermoregulatory system (Fortney and Vroman 1985, Nadel et al. 1977). We predict there will be both central and peripheral modifications in heat loss responses upon exposure to microgravity; threshold changes in the central nervous system changes will be caused primarily by changes in body hydration, and changes in the peripheral nervous system by the postulated sheeting of sweat on the surface of the skin.

4) Oxygen Consumption: Heat production can be calculated by the method of indirect calorimetry (Newburgh 1949) from measurements of oxygen consumption and respiratory exchange ratio (VCO_2/VO_2). Oxygen consumption will be measured twice during each ET test—after 50 and 60 min. of exercise. The subject will breathe through a large-bore two-way breathing valve with the expired air directed through an ultrasonic flowmeter for measurements of ventilation. The expired gases will then go into a mixing chamber from which aliquots of the gas will be sampled and analyzed for percent oxygen and carbon dioxide. Samples of the cabin air will be taken immediately before each oxygen consumption determination for measurement of the inspired percentages of oxygen and carbon dioxide. All determinations will be performed in duplicate. If a gas analyzer is not available by the time of the flight, aliquots of the cabin air and expired air will be stored in small gas cylinders to be analyzed after the flight.

C. CREW TRAINING:

Approximately two months before flight, one 1-hr and one 2-hr training sessions will be required to familiarize the crew with the ET and peak VO_2 tests (Table 1). All ET and peak oxygen tests will be conducted on an electrically-braked cycle ergometer with the crewmen in the supine position to minimize orthostatic effects on the cardiovascular system. Then, as close as possible to launch, two peak VO_2 tests and two ET tests will be performed. Each ET will include 60 min. of a constant-load exercise, plus 30 min. for calibrating the equipment and instrumenting the crew. The load on the cycle ergometer will correspond with that required to produce an oxygen uptake of 60% of each crewperson's preflight peak oxygen uptake. The ET will be conducted at least 2 hr after a meal (breakfast) with the crew abstaining from all drugs—including alcohol, nicotine, and caffeine—for 24 hr prior to each test.

1) Preflight: One 1-hr and one 2-hr exercise training sessions two months preflight. Then two preflight ET and two preflight peak oxygen tests will be done as close as possible to launch, allowing at least 2 days between the ET tests for complete recovery from the exercise.

2) Inflight: Three ET tests (total time required = 90 min./test) on flight days 2, 5, and one day before reentry. One peak oxygen test two days before reentry.

3) Postflight: One peak oxygen test approximately 28 days postflight. If this value is not back to preflight levels, it will be repeated 15 days later and the postflight ET tests also postponed. Two ET tests will be performed on postflight days 30 and 32, unless a longer delay is required for return of the peak VO_2.

4) Flight Equipment: An electrically-braked supine cycle ergometer will be used for all exercise tests, and the ET may be done in place of a usual daily exercise bout. Measurements to be taken during the 30 min. resting (instrumentation) pre-exercise period and during exercise are: rectal temperature (or stomach temperature with a thermometer pill), ear-canal temperature, 6 skin temperatures, heart rate from the electrocardiogram, and rate of sweating from chest hygrometer capsules, forearm blood flow measured during baseline and twice/minute during the first 20 min. of exercise. Oxygen consumption will be measured once, two days before reentry. Backup or actual flight ET and peak oxygen equipment should be used for all pre- and post-flight testing.

D. MEASUREMENT DEVICES AND EQUIPMENT:

1) Body Temperature Measurements: Rectal, skin, and ear-canal thermocouples and/or thermistors interfaced with a continuous recording system; e.g., Yellow Springs instruments thermistors connected to a Science/Electronics Physiological Squirrel Monitoring System. If proven accurate, Cortemp thermometer pills may be substituted for the rectal temperature site (Human Technologies, Inc., St. Petersburg, FL). The ear-canal-tympanic membrane thermocouples have cotton ends for comfort (Mallinckrodt Anesthesia Products, St. Louis, MO).

2) Oxygen Consumption Measurements: Ventilation will be measured with an ultrasonic flowmeter (GHG Electronic, Switzerland). Gas samples will be analyzed either postflight (MGA medical gas analyzer), or inflight, with a middeck gas analyzer for oxygen and carbon dioxide (to be developed in the Space Biomedical Research Institute). In either case, before aliquots are taken, they will be sampled from a gas mixing chamber (Meer Instruments, La Jolla, CA).

3) Local Sweat Responses: Dew point hygrometry system to be developed by Boeing.

4) Forearm Blood Flow: Measured using the System for Venous Occlusion Plethysmography developed for SLS-1 (Engineering Development Laboratories, Newport, VA).

5) Exercise Device: An electronically-braked cycle ergometer which will provide accurate graded exercise levels with little upper body movement which is necessary to insure the forearm blood flow measurements are free of movement artifact.

6) Cabin temperature, humidity and air flow: Standard thermistor, humidity sensor, and hot-wire anemometer (Appendix 1).

7) Heart Rates: Standard inflight electrocardiograph used during other inflight exercise protocols.

E. EXPECTED RESULTS:

We expect that the astronauts will exhibit excessive increases in their core temperatures during exposure to microgravity. The higher core temperatures may be due to decreased sensitivity of both skin blood flow and sweating responses to the increased core temperature.

F. SUPPORTING FACILITIES:

1) Preflight: Johnson Space Center's environmental physiology heat chamber.

2) Inflight: Shuttle middeck.

3) Postflight: Johnson Space Center's environmental physiology heat chamber.

G. REFERENCES:

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H. BIOGRAPHICAL SKETCHES:

See appendix 2 at end of proposal.

I. BUDGET:

(Please note the equipment needed for this study is most likely redundant with equipment needed for other DSO or EDO projects). Therefore, some of these costs may be shared, and once developed, this equipment will be available for other studies.

1) No additional salaries are required.

2) Equipment (duplicate flight and ground-based equipment):

Development of Dew Point Hygrometry Sweat System	50K
Evaluation of Thermometer Pills	1K
Mixing Chamber	10K
Development of gas analyzer	50K
Ultrasonic flowmeter	15K

Yellow Springs Thermistors and Data Storage System	10K
Development of Cycle Ergometer	30K
Purchase of System for Venous Occlusion Plethysmography	30K
Cabin temperature, humidity and air flow sensors.	2K

3) Other direct costs:

Subject costs for ground-based studies and validations	10K

4) Travel costs:

Travel and housing for Dr. Greenleaf from Ames to JSC (12 trips/$1000)	12K

5) Other costs:

Data analyses and publication costs	10K

6) Overhead costs: none

TOTAL COSTS:	230K

J. CURRENT AND PENDING SUPPORT:

1) John Greenleaf:

a) FY 1990 RTOP funds. "Fluid and Electrolyte Shifts during Deconditioning: Rehydration and Exercise Thermoregulation"; 90K.

b) FY 1991 RTOP funds; 90K (year three).

2) Suzanne Fortney:

a) FY 1990: Directors discretionary funds. "Plasma Volume and Orthostatic Intolerance"; $60K.

b) FY 1990 RTOP funds. "Mechanism of Orthostatic Intolerance During Bedrest of Varying Duration"; $50K.

c) FY 1991 Directors discretionary funds (last year); $60K.

d) FY 1991-1994 RTOP submission. $100K annually.

K. PROVISIONS FOR USE OF HUMAN TEST SUBJECTS:

The investigations proposed will be reviewed by the Johnson Space Center Human Research Policy and Procedures Committee, and the Ames Research Center Human Research Experiments Review Board. If approved, the study will conform with the principles of the Helsinki Code of the World Medical Association.

Table 1. Crew Time Requirements

	VO_2 Peak	Exercise Test (ET)
*Preflight	Training Session (1hr) Preflight Measure (1 hr) Preflight Measure (1 hr)	Training Session (2 hr) Preflight Test (2 hr) Preflight Test (2 hr)
Inflight	Inflight Measure (1 hr) (L-3)	Inflight Tests (2 hr/ea) (D2, D5, L-2)
Postflight	Postflight Measure (1 hr) (L + 38)	Postflight Tests (2 hr/ea) (L + 30, L + 32)
Total Time	5 hr	16 hr

*Preflight training sessions should occur within 60 days of the flight. Preflight VO_2 peak or ET tests should occur as close as possible to the launch, with the ET tests done on separate days, sparated by at least 2 days.

APPENDIX 1: CABIN TEMPERATURE (°F) VARIABILITY DURING SHUTTLE FLIGHTS.

	A	B	C	D	E
1	MISSION			ON-ORBIT, °F	
2	STS	ORBITOR	STS	CT MAX	CT MIN
3	1	co	1	80.2	75.0
4	2	co	2	82.5	70.0
5	3	co	3	81.5	73.0
6	4	co	4	82.0	68.0
7	5	co	5	80.0	75.0
8	6	ch	6	78.0	72.0
9	7	ch	7	76.0	69.0
10	8	ch	8	80.0	72.0
11	9	co	9	83.0	68.0
12	10	ch	41B	83.0	70.0
13	11	ch	41C	79.0	68.0
14	12	dis	41D	78.0	72.0
15	13	ch	41G	91.0	73.0
16	14	dis	51A	85.0	73.0
17	15	dis	51C		
18	16	dis	51D	83.0	76.0
19	17	ch	51B	83.5	74.0
20	18	dis	51G	89.0	80.0
21	19	ch	51F	92.0	76.0
22	20	dis	51I	82.0	72.0
23	21	atl	51J		
24	22	ch	61A	80.0	73.0
25	23	atl	61B	84.0	74.0
26	24	co	61C	86.0	80.0
27	25	ch	51L		
28	26	dis	26R	89.0	72.0
29	27	atl	27R		
30	28	dis	29R	82.0	71.0
31	29	atl	30R	84.0	72.0
32	30	co	28		
33	31	atl	34	89.0	69.0
34	32	dis	33		
35					
36	mean all			83.2	72.6
37	±SD all			±4.1	±3.2

APPENDIX 2: BIOGRAPHICAL SKETCHES

BIOGRAPHICAL SKETCH

Give the following information for key professional personnel listed on page 2, beginning with the Principal Investigator/Program Director. Photocopy this page for each person.

NAME	TITLE	BIRTHDATE (Mo., Day, Yr.)
John E. Greenleaf, Ph.D.	Research Scientist	Sept. 18, 1932

EDUCATION *(Begin with baccalaureate or other initial professional education and include postdoctoral training)*

INSTITUTION AND LOCATION	DEGREE (circle highest degree)	YEAR CONFERRED	FIELD OF STUDY
University of Illinois, Urbana	B.S.	1955	Physical Education
New Mexico Highlands Univ., Las Vegas	M.A.	1956	Physical Education
University of Illinois, Urbana	M.S.	1962	Physiology
University of Illinois, Urbana	Ph.D.	1963	Environ. Physiology
Karolinska Institute, Stockholm	Postdoc	1966-1967	Human Physiology

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government Public Advisory Committee. List, in chronological order, the titles and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. DO NOT EXCEED TWO PAGES.

Research Scientist, NASA Ames Research Center	1963-1966
Swedish Medical Research Council Senior Post-Doctoral Fellow	1966-1967
Research Scientist, Space Physiology Branch, NASA Ames Research Center	1967-present

HONORS:

George Huff Scholarship Award (U. Ill. 1954, 1955); Phi Epsilon Kappa, 1954; NSF pre-doctoral fellowship, 1962; NIH pre-doctoral fellowship, 1962-63; NASA special achievement award, 1973; NASA post-doctoral fellowship – Warsaw, 1973, 1974, 1977; NIH post-doctoral fellowship – Warsaw, 1980; Aero. Med. Asso. Harold Ellingson Award, 1981, 1982; Co-editor Int. J. Biometeorol., 1966-75; Editorial boards: J. Appl. Physiol., 1976-78; Aviat. Space Environ. Med., 1985-present.

PUBLICATIONS:

Greenleaf, J.E., Carol J. Greenleaf, D.H. Card and B. Saltin. Exercise temperature regulation in man during acute exposure to simulated altitude. Journal of Applied Physiology 26:290-296, 1969.

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Ekblom, B., C.J. Greenleaf, J.E. Greenleaf and L. Hermansen. Temperature regulation during continuous and intermittent exercise in man. Acta Physiologica Scandinavica 81:1-10, 1971.

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Greenleaf, J.E. Temperature regulation during isotonic exercise. Acta Physiologica Polonica 24:supplement 6:67-75, 1973.

DO NOT TYPE IN THIS SPACE—BINDING MARGIN

Greenleaf, J.E., S. Kozlowski, K. Nazar, H. Kaciuba-Uscilko and Z. Brzezinska. Temperature responses of exercising dogs to infusion of electrolytes. Experientia 30:769-770, 1974.

Greenleaf, J.E., B.L. Castle and D.H. Card. Blood electrolytes and temperature regulation during exercise in man. Acta Physiologica Polonica 25:397-410, 1974.

Kozlowski, S., H. Kaciuba-Uscilko, J.E. Greenleaf and Z. Brzezinska. The effect of thyroxine on temperature regulation during physical exercise in dogs. In: Temperature Regulation and Drug Action. Edited by P. Lomax and E. Schonbaum. Basel:Karger, 1975. pp. 361-366.

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Kaciuba-Uscilko, H., Z. Brzezinska and J.E. Greenleaf. Effect of propranolol on thyroxine-induced changes in body temperature and metabolism during exercise in dogs. Acta Physiologica Polonica 27:33-38, 1976.

Sobocinska, J. and J.E. Greenleaf. Cerebrospinal fluid [Ca^{2+}] and rectal temperature response during exercise in dogs. American Journal of Physiology 230:1416-1419, 1976.

Nielsen, B. and J.E. Greenleaf. Electrolytes and thermoregulation. Presented at the Third International Symposium on the Pharmacology of Thermoregulation, Sept. 14-17, 1976, Banff, Canada. Drugs, Biogenic Amines and Body Temperature. Edited by K.E. Cooper, P. Lomax and E. Schonbaum. Basel:Karger, 1977. pp. 39-47.

Greenleaf, J.E., V.A. Convertino, R.W. Stremel, E.M. Bernauer, W.C. Adams, S.R. Vignau and P.J. Brock. Plasma [Na^{+}], [Ca^{2+}], and volume shifts and thermoregulation during exercise in man. Journal of Applied Physiology: Respiratory, Environmental and Exercise Physiology 43:1026-1032, 1977.

Greenleaf, J.E., P.J. Brock, J.T. Morse, W. Van Beaumont, L.D. Montgomery, V.A. Convertino and G.R. Mangseth. Effect of sodium and calcium ingestion on thermoregulation during exercise in man. In: New Trends in Thermal Physiology. Edited by Y. Houdas and J.D. Guieu. Paris:Masson, 1978. pp. 157-160.

Greenleaf, J.E. Thresholds for Na^{+} and Ca^{++} effects on thermoregulation. In: Effectors of Thermogenesis. Edited by L. Girardier and J. Seydoux. Experientia Suppl. 32:33-44, 1978.

Greenleaf, J.E. Hyperthermia and exercise. In: International Review of Physiology, Volume 20, Environmental Physiology III. Edited by D. Robertshaw. Baltimore:University Park Press, 1979. pp. 157-208.

Greenleaf, J.E. and R.D. Reese. Exercise thermoregulation after 14 days of bed rest. Journal of Applied Physiology: Respiratory, Environmental and Exercise Physiology 48:72-78, 1980.

Kozlowski, S., J.E. Greenleaf, E. Turlejska and K. Nazar. Extracellular hyperosmolality and body temperature during physical exercise in dogs. American Journal of Physiology 239 (Regulatory Integrative and Comparative Physiology 8):R180-R183, 1980.

Greenleaf, J.E., W. Van Beaumont, P.J. Brock, L.D. Montgomery, J.T. Morse, E. Shvartz and S. Kravik. Fluid-electrolyte shifts and thermoregulation: Rest and work in heat with head cooling. Aviation, Space and Environmental Medicine 51:747-753, 1980.

Sciaraffa, D., S.C. Fox, R. Stockmann and J.E. Greenleaf. Human acclimation and acclimatization to heat: a compendium of research – 1968-1978. NASA Technical Memorandum 81181, August 1980. 102 p.

Greenleaf, J.E., B. Kruk, H. Kaciuba-Uscilko, K. Nazar and S. Kozlowski. Hypothalamic, rectal, and muscle temperatures in exercising dogs: effect of cooling. Medicine and Science in Sports and Exercise 14:126, 1982. Abstract.

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Kruk, B., H. Kaciuba-Uscilko, K. Nazar, J.E. Greenleaf and S. Kozlowski. Hypothalamic, rectal, and muscle temperatures in exercising dogs: effect of cooling. Journal of Applied Physiology 58:1444-1448, 1985.

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Kaciuba-Uscilko, H., B. Kruk, K. Nazar, J.E. Greenleaf and S. Kozlowski. Progressive enhancement of body temperature response to consecutive exercise bouts of the same intensity in dogs. Acta Physiologica Polonica 36:165-174, 1985.

Spaul, W.A., R.C. Spear and J.E. Greenleaf. Thermoregulatory responses to heat and vibration in men. Aviation Space and Environmental Medicine 5:1082-1087, 1986.

DO NOT TYPE IN THIS SPACE—BINDING MARGIN

BIOGRAPHICAL SKETCH

Name	Title	Birthdate
Suzanne M. Fortney	Research Physiologist	August 6, 1950

Education

Instit. and Location	Degree	Yr Conferred	Field of Study
Univ. of Missouri, St. Louis	BA	1972	Biology
St. Louis University	Ph.D.	1979	Physiology
Yale University	PDF	1978-1981	Environ. Phys.

Research Experience

1988-Present	Research Physiologist, NASA Johnson Space Center
1987-1988	Assoc. Professor, Johns Hopkins Univ. (Dept. Environ. Physiology)
1981-1987	Assistant Professor, Johns Hopkins Univ. (Dept. Environ. Physiology)

Publications (Selected)

Beckett, W.S., N.B. Broman, D. Nigro, J.E. Wilkerson and S. M. Fortney. Effects of prolonged bedrest on lung volume in normal individuals. J. Applied Physiol. 61: 919-925, 1986.

Fortney, S.M., N.B. Vroman, W.S. Beckett, S. Permutt and N.D. LaFrance. Effect of exercise hemoconcentration and hyperosmolality on exercise responses. J. Appl. Physiol. 65: 519-524, 1988.

Fortney, S.M., W.S. Beckett, A.J. Carpenter, J. Davis, H. Drew, N.D. LaFrance, J.A. Rock, C.G. Tankersley, and N.B. Vroman. Changes in plasma volume during bedrest: effects of menstrual cycle and estrogen administration. J. Appl. Physiol. 65: 525-533, 1988.

Lightfoot, J.T., S. Febles, S.M. Fortney. Adaptation to repeated presyncopal lower body negative pressure exposures. Aviat. Space Environ. Med. 60: 17-22, 1989.

Hilton, F.J. Giordano, and S. Fortney. Case Report-Vasodepressor syncope induced by lower body negative pressure. Aviat. Space Environ. Med. 60: 61-63, 1989.

Miescher, M. and S.M. Fortney. Responses to dehydration and rehydration during heat exposure in young and older men. Am J. Physiol. 257: R1050-R1056, 1989.

Lightfoot, J.T., R.P. Claytor, D.J. Torok, T.W. Journell, and S.M. Fortney. Ten weeks of aerobic training do not affect lower body negative pressure responses. J. Appl. Physiol. 67: 894-901, 1989.

Fortney, S.M., K.H. Hyatt, J.E. Davis, and J.M. Vogel. Changes in body fluid compartments during a 28-day bedrest. In Press: Aviat., Space, Environ. Med., 1990.

Fortney, S.M. Development of lower body negative pressure as a countermeasure for orthostatic intolerance. Submitted to J. Clin. Pharmac., July 1990.

Lightfoot, J.T., F. Hilton, and S.M. Fortney. Repeatability and protocol compatibility of presyncopal symptom limited LBNP exposures. In press: Aviat. Space Environ. Med., 1990.

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Rock, J.A., S.M. Fortney. Medical and Surgical Considerations for Women in Spaceflight. Obstet. and Gynecol Survey (39(8): 525-535, 1984.

Vroman, N.B., W.S. Beckett, S. Permutt, S. Fortney. Effect of positive pressure breathing on the cardiovascular and thermoregulatory responses to exercise. J. Appl. Physiol.: Respirat. Environ. Exercise Physiol. 58: 876-881, 1985.

National Aeronautics and
Space Administration

Lyndon B. Johnson Space Center
Houston, Texas
77058

Reply to Attn of:

12/17/90

To: John E. Greenleaf, Ph.D. (ARC/NASA) and
Suzanne M. Fortney, Ph.D. (SD5/NASA)

From: Steven F. Siconolfi, Ph.D (SD5/NASA)

Subject: DSO "Thermoregulation during Spaceflight"

I understand, that as a co-investigator, my primary role in this project will be to assist in the collection and analysis of all exercise data.

Biographical Sketch

Name	Title		Birthdate
Steven F. Siconolfi, Ph.D.	Research Physiologist		4 October 1952
Institution	**Degree**	**Year**	**Field of Study**
Springfield College, Springfield, MA	BS	74	Physcial Education
Springfield College, Springfield, MA	MS	76	Exercise Physiology
Kent State Univ. Kent, OH	PhD	82	Exercise Physiology

Previous Experience

1989-present	Adjunct Professor of Exercise Physiology,Health and Human Performance University of Houston Clear Lake, Houston, TX 77058
1985-88	Associate Professor of Exercise Physiology,Exercise Physiology Section Movement Sciences Laboratory,Springfield College,Springfield, MA 01109
1987-88	Exercise Physiology Consultant, National YMCA Certification Programs in Fitness
1984-85	Visiting Assistant Professor of Exercise Physiology,Purdue University, West Lafayette, IN
1983-84	Adjunct, Assistant Professor of Physical Education, Human Performance Lab, University of Rhode Island, Kingston, RI
1980-84	Exercise Physiologist and Director, Human Performance Lab, Department of Cardiology, The Memorial Hospital, Pawtucket, RI 02860
1979-80	Teaching Fellow at Kent State University
1977-80	Basic Coordinator of the Fitness KSU Program (an adult physical fitness program).
1977-80	Instructor at YMCA Physical Fitness Specialist Workshop at Kent State University.
1975-77	Physical and Fitness Director, Hamilton YMCA, Hamilton, OH
1974-75	Laboratory Instructor for Physiology of Exercise at Springfield College.
1974-75	Research Fellow at Springfield College

Selected Publications

Siconolfi, S.F., R.A. Carleton, J.P. Elder, P.A. Bouchard (1983). Hypotension after exercise and relaxation. *Clinical Sports Medicine*, ed. Robert C. Cantu. Collamore Press, Lexington, MA, chpt 11.

Siconolfi, S.F., T.R. McConnell (1987). Hemodynamic adaptations to exercise training in cardiac patients: The role of exercise intensity and program duration. (Symposiums proceedings of NEACSM-1984). The Exercising Adult, 2nd edition. ed Robert C. Cantu, MacMillan Publishing Company, Chapter 10, pp 117-126.

Siconolfi, S.F. (1982) The estimate of percent change in total peripheral resistance during exercise and recovery. Journal of Cardiac Rehabilitation. 2:291-296.

Siconolfi, S.F., E.M. Cullinane, R. A. Carleton, P.D. Thompson (1982). A modification of the Astrand-Rhyming protocol to estimate $\dot{V}O_{2MAX}$ for use in epidemiologic studies. Medicine and Science in Sports and Exercise. 14: 335-338.

Carleton, R.A., S.F. Siconolfi, M. Shafique, P. Bouchard (1983). The delayed appearance of angina pectoris during low-level exercise. Journal of Cardiac Rehabilitation. 3:141-148.

Cullinane, E.M., S.F. Siconolfi, A. Saratelli, P.D. Thompson (1982). Acute decrease in serum triglycerides with exercise: Is there a threshold for an exercise effect? Metabolism. 31:844-847.

Siconolfi, S.F., C.E. Garber, J.R. McGhee (1984). Increased exercise tolerance in cardiac patients without peripheral resistance changes. Journal of Cardiac Rehabilitation. 4:391-394.

Siconolfi, S.F., C.E. Garber, G.D. Baptist, F.S. Cooper, R.A. Carleton (1984). Circulatory effects of mental stress during exercise in cardiac patients. Clinical Cardiology. 7:441-444.

Siconolfi, S.F., C.E. Garber, T.M. Lasater, R. A. Carleton (1985). A simple, valid step test for assessing $\dot{V}O_{2MAX}$ in epidemiologic studies. American Journal of Epidemiology. 121:382-390.

McGhee, J.R., S.F. Siconolfi, P. Bouchard, R.A. Carleton (1985). Increased work capacity in patients on Beta-blocker therapy. Journal of Cardiac Rehabilitation.

Sinning, W.E., D. Dolny, L. Cunningham, A. Racaniello, S.F. Siconolfi, J. Sholes (1985). Validity of "generalized" equations for body composition analysis in male athletes. Medicine and Science in Sports and Exercise. 17:124-130.

Rowlands, T.W., Delaney, B.C. & Siconolfi, S.F. (1987). The athletes heart in pre-pubital children. Pediatrics. 79:800-804.

Gardner, A.W., Poehlman, E.T., Sedlock, D.A., Corrigan, D.L., Siconolfi, S.F. (1988). A longitudinal study of gross efficiency in males during steady-state exercise. Journal of Gerontology. 43:R22-R25.

BIOGRAPHICAL SKETCH

Harold J. Guy

Date of Birth: [redacted]. **Citizenship:** United States

Address: 4021 Alicia Dr., San Diego, CA 92107

Degrees and Qualifications:

M.B.Ch.B. (graduate degree in Medicine), Otago University, 1963
B. Med. Sc. (degree in Medical Science, Pharmacology) Otago University, 1963
M.R.A.C.P. (Member, Royal Australasian College of Physicians), 1972
F.R.A.C.P. (Fellow, Royal Australasian College of Physicians), 1976
Licensed Physician #A42714 - State of California, Expires 11/30/91

Appointments:

1966 -	Resident in Internal Medicine & Cardiology, University of Otago, New Zealand
1967 -	Pilot Training, Royal New Zealand Air Force (RNZAF)
1968-70-	Flight Surgeon, RNZAF Medical Officer, NZ Services Med Team, Viet Nam Medical Officer, RNZAF Airbourne Rescue Team
1971-72-	Resident in Internal Medicine, Christchurch Hospital, NZ
1972-74-	Postdoctoral Fellow, RNZAF Overseas Study Grant: Pulmonary Physiology at University of California, San Diego
1974-81-	Lecturer, Senior Lecturer in Medicine, University of Otago, NZ; Director, Pulmonary laboratory; Attending Pulmonary Physician; Physician, Intensive Care Unit; Physician, Hyperbaric Facility, Christchurch Hospital
1981-82-	Sabbatical leave at University of California, San Diego
1982- -	Specialist, Section of Physiology, Department of Medicine, UCSD, Co-Investigator, NASA Experiment 198, Pulmonary Function in Microgravity, ESA D2 experiment, Pulmonary Function in Microgravity, Pulmonary Gas Exchange, Ventilation & Blood Flow in Microgravity
1985- -	Clinical Assistant Professor, Department of Medicine, UCSD
1985-87-	Attending physician, UCSD Medical Center
1987- - present	Attending physician, VA Medical Center

Relevant Publications:

Guy, H.J., R.A. Gaines, P.M. Hill, P.D. Wagner and J.B. West. Computerized, non-invasive tests of lung function: A flexible approach using mass spectrometry. Am. Rev. Respir. Dis. 113:737-744, 1976.

West, J.B., H.J. Guy and D.B. Michels. Effects of weightlessness on pulmonary function. The Physiologist 25:S21-24, 1982.

Nichol, G.M., D.B. Michels and H.J.B. Guy. Phase 5 of the single breath washout test. J. Appl. Physiol.: Respirat. Environ. Exercise Physiol. 52(1):34-43, 1982.

Tomioka, S., S. Kubo, H.J.B. Guy, and G.K. Prisk. Gravitational independence of single breath washout tests in recumbent dogs. J. Appl. Physiol. 64(2): 642-648, 1988.

Tomioka, S., S. Kubo, H.J.B. Guy, and G.K. prisk. The influence of collateral ventilation on single breath washout curves. J. Appl. Physiol. 64(1): 429-434, 1988.

Guy, H.J., G. K. Prisk and J. B. West. Pulmonary function in microgravity: Spacelab 4 and beyond. Acta Astronautica 17(10): 1139-1143, 1988.

Guy, H.J.B., and G. K. Prisk. Heart-lung interactions in aerospace medicine. In Heart-Lung Interactions in Health and Disease. Vol. 42, eds. S.M. Scharf and S.S. Cassidy. New York, N.Y., Marcel Dekker, Inc., pp. 519-563, 1989.

Work in Progress:

Guy, H.J.B., G.K. Prisk, A.R. Elliott and J.B. West. Maximum expiratory flow-volume curves during short periods of microgravity. Submitted to Journal of Appl. Physiol.

Poole, D.C., W. Schaffartzik, D.R. Knight, T. Derion, M.G. Ziegler, H. Guy, R. Prediletto, and P.D. Wagner. Slow component of oxygen uptake kinetics is located principally in exercising limbs. Submitted to Med. Science Sports & Exercise.

Honors, Awards and Memberships:

Honors and Awards:

Honorary RNZAF Physician to the Governor General of New Zealand, 1981

Member of:

Undersea Medical Society
American Society for Gravitational & Space Biology
Aerospace Medical Association
Aerospace Medical Association, Space Medicine Branch
Aerospace Human Factors Association
International Society for Aerosols in Medicine
Discipline Implementation Team (DIT) of the Exercise Countermeasures Project for the Extended Duration Orbiter (EDO)
New Zealand Medical Association
New Zealand Thoracic Society
New Zealand Physiological Society

New Zealand Medical Physics & Biomedical Engineering Society

Correspondent in Gravitational Physiology: International Union of Physiological Sciences

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MEMO 91/006

TO: ARC/NASA/John E. Greenleaf, Ph.D.
SD5/NASA/Suzanne M. Fortney, Ph.D.

FROM: SD5/KRUG/Alan D. Moore, Ph.D.

DATE: January 25, 1991

SUBJECT: Collaboration in the proposed SDO entitled "Thermoregulation During Spaceflight"

My primary role as a scientific collaborator in the proposed study shall be to participate in the collection, quality assurance, and interpretation of the exercise data. Attached is a "mini-vita" that should meet your documentation requirements.

ADM/hmg

Attachment

BIOGRAPHICAL SKETCH

Name	Title	Birthdate
Alan D. Moore, Jr.	Senior Research Scientist	June 25, 1958

Education

Institution/Location	Degree	Year Conferred	Field of Study
Campbell Univ., Buies Creek, NC	BS	1980	Biology
Virginia Tech, Blacksburg, Virginia	MS	1983	Exercise Physiology
Virginia Tech, Blacksburg, Virginia	Ph.D.	1987	Applied Research

Experience

1989-Present	Senior Research Scientist, KRUG Life Sciences, NASA Johnson Space Center
1987-1989	Assistant Professor, University of Houston, Dept. of Health and Human Performance
1980-1987	Graduate Research Assistant and Fellow, Virginia Tech, Dept. of HPER

Current Professional Certifications

1990	American Heart Association-Advanced Cardiac Life Support (ACLS)
1988	American College of Sports Medicine (ACSM) Preventive and Rehabilitative Exercise Program Director
1983	ACSM Preventive and Rehabilitative Exercise Specialist
1981	ACSM Preventive and Rehabilitative Exercise Test Technologist

Publications and Presentations (Selected)

Franke, W. D., Moore, A. D., and Herbert, W.G. (1990). Usefulness of continuous wave Doppler measures as indicators of exercise-induced alterations in myocardial contractility. Journal of Cardiopulmonary Rehabilitation, 10: 323.

Franke, W. D., Herbert, W. G., & Moore, A. D. (1988). Can the CW Doppler PkA or PkV response provide valid indications of alterations in myocardial contractility during exercise testing? International Journal of Sports Medicine, 9 (2): 148.

Herbert, W.G. & Moore, A. D. (1986). Significance of systolic blood pressure changes near graded exercise test endpoints. Medicine and Science in Sports and Exercise, 18 (2) (Supplement), S68.

Herbert, W. G., Sebolt, D. R., Wright, J. N. , & Moore, A. D.(1982). Seasonal changes in anaerobic performance capacity of college wrestlers after repetitive weight reduction. Medicine and Science in Sports and Exercise, 14 (2), 118-119.

Herbert, W. G., Sebolt, D. R., Bradley, H. R., Moore, A. D., & Robbins, F. L. (1982). A polynomial regression method for estimation of anaerobic threshold from exercise ventilation. Abstracts of Research Presentations, Annual SEACSM Meeting.

McCraw, R. L., Sebolt, D. R., & Moore, A. D. (1988). How useful is a CW Doppler measure (SVI) as an indicator of exercise-induced changes of stroke volume? International Journal of Sports Medicine, (1988), 9 (2): 148.

Moore, A. D., Charles, J. B., Frey, M. A., Gotshall, R.A., & Siconolfi, S.F. (1990). Pressure time index: It's use during orthostatic stress. The FASEB Journal, 4(3): A569.

Moore, A. D., Charles, J. B., Harris, B.A., Bungo, M.W., & Siconolfi, S.F. (1990). Does bedrest produce changes in orthostatic tolerance comparable to space flight? Medicine and Science in Sports and Exercise, 22(2) (Supplement), S37.

Moore, A. D., Barrows, L., Rahsid, M. & Siconolfi, S.F.(1990). Evaluation of non-invasive cardiac output methods during exercise. Aviation, Space, and Environmental Medicine 61(5): 488.

Moore, A. D., Smalling, R.W., Morrow, J.R. & Sease, D.R. (1989). Doppler echocardiography during exercise: is it a useful clinical tool for the detection of coronary artery disease? Medicine and Science in Sports and Exercise, 21(2) (Supplement), S12.

Moore, A. D., & Herbert, W. G. (1988). Response of Doppler measures to changes in cardiac contractility during exercise. Medicine and Science in Sports and Exercise, 20(2), S52.

Moore, A. D., Herbert, W. G., Payne, J. M., & Sebolt, D. R. (1987). Reproducibility of Doppler indices of left ventricular function during cycle graded exercise. Journal of Cardiopulmonary Rehabilitation, 7(10), 499.

Moore, A. D., Herbert, W.G., Hinkle, D. E., & Sebolt, D.R. (1983). Do small incremented bike and treadmill GXTs yield similar estimates of anaerobic threshold? Abstracts of Research Presentations, Annual SEACSM Meeting.

SECTION II

PROTECTION OF HUMAN SUBJECTS.

I. *Justification.* Explain briefly why human subjects are required.

II. *Requirements and Selection Criteria.* Describe in detail all subject selection procedures. Include source of subject population, recruitment methods, and schedules for subject briefing sessions. List all selection and exclusion criteria such as age, sex, smoking history, physical condition, and special requirements such as current Air Force class III physical examination results, and history of drug allergies. Any other special health-related testing requirements must be clearly indicated.

III. *Confidentiality.* Briefly describe the procedures employed to maintain confidentiality of subject identity and results.

IV. *Risks and Hazards.* Describe all anticipated hazards from the procedures (especially biological sample collections, new diagnostic procedures and treatments), materials (radioactive substances etc.), or any other experiment-related conditions, including immediate, delayed, or long-term effects. Include assessment of degree of risk (minimum, reasonable, or high) and proposed acceptable risk-benefit ratio.

V. *Safety precautions.* Describe details of medical intervention procedures in the event of adverse reaction. Include information on the availability of a physician and medical facilities during and after the study, any post-experiment medical check up requirements, and precautionary measures to avoid any complications (immediate and delayed) that are experiment related.

VI. *Subject information and Consent.* Include all the necessary information concerning the study that will be explained to the subjects at the briefing session. Clearly state subject rights such as freedom to withdraw from the study, workmen's compensation coverage, confidentiality, and remuneration policy. Attachments must include a duly filled Consent form (JSC Form 1416 or 1416A, Revised August 1990) approved by the institutional Human Use Committee and Subject Information Handout.

A. Subject Briefing. Describe briefly the information that will be covered during the briefing session. Include a list of personnel that will attend the briefing and the procedures that will be explained or demonstrated at the briefing.

B. Subject Information Handout. Attach a handout that clearly states in simple language all the procedures employed in the study, hazards and risks involved, safety precautions during and after the study, benefits and coverage, subjects' rights and remuneration, and any post-experiment instructions.

B. Consent Form. Include Appropriate form for minimum (1416) or reasonable risk (1416A) recommended by the Human Research Policy and Procedures Committee that is duly filled with information regarding the study and the investigator.

NASA HUMAN RESEARCH
REASONABLE RISK
INFORMED CONSENT FORM

1. I, the undersigned, do voluntarily give my informed consent for my participation as a test subject in the following research study, test, experiment, or other evaluation procedure:

NAME OF EXPERIMENT ______________________

TRAINING TOUR NUMBER ______________________

FLIGHT TO WHICH ASSIGNED ______________________

NAME OF DESIGNATED PRINCIPAL INVESTIGATOR ____________

NAME OF RESPONSIBLE NASA PROJECT SCIENTIST ____________

I understand or acknowledge that:

(a) This procedure is part of an experiment approved by NASA.

(b) I am performing these duties as part of my employment with ____________.

(c) This research study has been reviewed and approved by the JSC Human Research Policy and Procedures Committee (HRPPC) which has also determined that the protocol involves reasonable risk to the subject.

(d) "Reasonable risk" means that the risks of harm anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine tests, but that those risks are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

(e) The research procedures were explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered to my satisfaction.

(f) I am medically qualified to participate in the investigation.

(g) I may withdraw from the investigation at any time unless, as recommeded by the Principal Investigater or his/her designee, such withdrawal would be dangerous or impossible.

(h) In the event of physical injury resulting from this study and calling for immediate action or attention, NASA will provide or cause to be provided, the necessary treatment. I also understand that NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA or any third party from any future liability which may arise from, or in connection with, the above procedures.

(i) The confidentiality of any data obtained as a result of my participation as a research subject in this study shall be maintained, so that no data may be linked with me as an individual. However, if a "life-threatening" abnormality is detected, the Investigator will notify me and the JSC Flight Medicine Clinic. Such information may be used to determine the need for care or medical follow-up, which, in certain circumstances, could affect my aeromedical flight status.

2. I, the undersigned, the Principal Investigator of the experiment desigated above, certify that:

   (a) I have accurately described the procedure to the test subject.

   (b) The test setup involves reasonable risk to the test subject. All equipment to be used has been inspected and certified for safe and proper operation.

   (c) The test subject is medically qualified to participate.

   (d) The test protocol has not been changed from that orginally approved by the JSC HRPPC.

APPROVED:

Test Subject	Date
Principal Investigator	Date
Project Scientist	Date

(1) A detailed description of the experiment or investigation will be attached to this consent form. The Principal Investigator is responsible for formulating this document, which should be in layman's terms such that the subject clearly understands what procedures will be required and the risks associated therewith.

(2) This form is valid for a 1-year period from the date of signature by the Principal Investigator and the test subject (which dates should be identical). A signed, dated copy of this form with attachments must be forwarded to the JSC Human Research Policy and Procedures Committee, Mail Code SA, Lyndon B. Johnson Space Center, Houston, Texas 77058.

NASA HUMAN RESEARCH
MINIMAL RISK
INFORMED CONSENT FORM

1. I, the undersigned, do voluntarily give my informed consent for my participation as a test subject in the following research study, test, experiment, or other evaluation procedure:

NAME OF EXPERIMENT ____________________

TRAINING TOUR NUMBER ____________________

FLIGHT TO WHICH ASSIGNED ____________________

NAME OF DESIGNATED PRINCIPAL INVESTIGATOR __________

NAME OF RESPONSIBLE NASA PROJECT SCIENTIST __________

I understand or acknowledge that:

(a) This procedure is part of an experiment approved by NASA.

(b) I am performing these duties as part of my employment with ____________.

(c) This research study has been reviewed and approved by the JSC Human Research Policy and Procedures Committee (HRPPC) which has also determind that the protocol involves minimal risk to the subject.

(d) "Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are no greater than those ordinarily encountered in daily life or during the performance of routine tests, but that those risks are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

(e) The research procedures were explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered to my satisfaction.

(f) I am medically qualified to participate in the investigation.

(g) I may withdraw from the investigation at any time unless, as recommended by the Principal Investigator or his/her designee, such withdrawal would be dangerous or impossible.

(h) In the event of physical injury resulting from this study and calling for immediate action or attention, NASA will provide or cause to be provided, the necessary treatment. I also understand that NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA or any third party from any future liability which may arise from, or in connection with, the above procedures.

(i) The confidentiality of(.y data obtained as a result of my participation as a research subject in this study shall be maintained, so that no data may be linked with me as an individual. However, if a "life-threatening" abnormality is detected, the investigator will notify me and the JSC flight Medicine Clinic. Such information may be used to determine the need for care or medical follow-up, which, in certain circumstances, could affect my aeromedical flight status.

2. I, the undersigned, the Principal Investigator of the experiment desigated above, certify that:

(a) I have accurately described the procedure to the test subject.

(b) The test setup involves minimal risk to the test subject. All equipment to be used has been inspected and certified for safe and proper operation

(c) The test subject is medically qualified to participate.

(d) The test protocol has not been changed from that orginally approved by the JSC HRPPC.

APPROVED:

Test Subject	Date
Principal Investigator	Date
Project Scientist	Date

(1) A detailed description of the experiment or investigation will be attached to this consent form. The Principal Investigator is responsible for formulating this document, which should be in layman's terms such that the subject clearly understands what procedures will be required and the risks associated therewith.

(2) This form is valid for a 1-year period from the date of signature by the Principal Investigator and the test subject (which dates should be identical). A signed, dated copy of this form with attachments must be forwarded to the JSC Human Research Policy and Procedures Committee, Mail Code SA, Lyndon B. Johnson Space Center, Houston, Texas 77058.

DE\ MINATION, FINDINGS AND AUTHORI TION

Title of Research: Thermoregulation During Spaceflight

Principal Investigator(s): John Greenleaf, SL:239-7

File Number: H.R. 97

Based upon my examination of the Protocol for the above-entitled research, staff analysis and recommendations concerning the same including medical and legal review, as well as my independent examination of the File annexed I hereby find and determine:

1. That the research requires the use of human test subjects, and cannot feasibly be accomplished through the use of animals or by other means;

2. That the importance of the objective of the research outweighs the inherent risks to the human test subjects who may be involved, and that said subjects will not be unnecessarily exposed to risk of injury, discomfort, or inconvenience;

3. That the record contains evidence of satisfactory procedures for obtaining from each test subject his voluntary, and his informed, consent and that each test subject or his survivors would receive adequate compensation in the event of misadventure on the basis of federal, state, or private insurance compensatory plans as more particularly detailed and described in the File annexed.

Effective this date, the above entitled research is authorized and the Principal Investigator(s) herein may proceed with the same subject to the following conditions:

A. This Authorization is valid until May 31, 1992 and the research may not continue beyond this date unless additional written authorization from me is received.

B. All test subjects will receive a physical examination by a licensed physician prior to participation in the research and a physical examination upon termination of their participation in the research and in the event any medical impairment is disclosed the same shall be reported promptly and in writing to the test subject, to the ARC Chief, Institutional Operations Office, and to the Chief Counsel with an information copy to me.

Date: 5/29/91

Dale L. Compton, Director

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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John E. Greenleaf and Suzanne M. Fortney (Johnson Space Center, Houston, Texas 77058-3696)

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12a. DISTRIBUTION/AVAILABILITY STATEMENT

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13. ABSTRACT *(Maximum 200 words)*

The purpose for this flight proposal is to investigate human thermoregulatory parameters during excercise in microgravity. The hypothesis to be tested is that microgravity-adopted astronauts will exhibit accentuated increases in their core temperatures (excess hyperthermia) during exercise because of altered heat loss responses due to reduced sweating and/or accentuated vasodilation. The specific aims are (a) to compare core and skin temperature responses during moderate exercise before flight and inflight; (b) to determine whether the hypothesized inflight excessive hyperthermia is due to increased heat production, reduced, sweating, impaired peripheral vasodilation, or to some combination of these factors; and (c) to determine whether heat production at an exercise load of 60% of the maximal working capacity is similar preflight and inflight. It is expected that the astronauts will exhibit excessive hyperthermia during exposure to microgravity which will be caused by decreased sweating and decreased skin blood flow.

14. SUBJECT TERMS

Temperature regulation, Heat, Exercise hyperthermia

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