

September 15, 1993

707555

Note to Files:

On September 14, 1993, Dr. Susan Rose called to confirm that she approved of the procurement of the research services involving human subjects from Midwest Research Institute of Kansas City, Missouri. This was in response to previous correspondence that had forwarded the procurement package to her for review.

*Harold Clark*  
Harold Clark

cc: Steve Morrell

REPOSITORY OAK RIDGE OPERATIONS (ORO)  
COLLECTION ENERGY PROGRAMS DIV., ER-11  
BOX No. Active Records Gathered for Human  
Radiation Exp. P.T.  
FOLDER \_\_\_\_\_

1021999

42800

SEP 08 1993

ER-111:Clark

**APPROVAL OF PROCUREMENT BY MARTIN MARIETTA ENERGY SYSTEMS, INC.**

Susan Rose, Office of Health and Environmental Research, ER-72, HQ/GTN

The operating contractor in Oak Ridge has proposed the attached procurement of research services involving human subjects from Midwest Research Institute of Kansas City, Missouri. Based on a letter from Dr. Katherine Duncan of the Department of Health and Human Services to John McKelvey of Midwest Research Institute (copy attached), it appears that the company has the approval of the National Institute of Health for their Multiple Project Assurance (Number M-1051), effective July 1, 1991, through June 30, 1996. We are recommending that the procurement proceed based on conversations with Imre Gyuk, EE-141, that this Multiple Project Assurance approval meets the criteria for such research by the Department of Energy. If this is not the case, please advise this office immediately.

Also included for your information is a copy of the procurement package which includes the following:

1. Approval by the Oak Ridge National Laboratory Committee on Human Studies
2. Assurance of Compliance with HHS Regulations for the Protection of Human Research Subjects for Midwest Research Institute
3. Project Assurance Certificate for the subject project
4. Volunteers' Informed Consent
5. Screening Information Form
6. Description of study and other miscellaneous information

1022000

X-10 SITE OFFICE  
 4500N  HFIR  
LOG NO. 009532  
FILE CODE 42200

Susan Rose

- 2 -

SEP 08 1993

If you have any questions, please call Harold Clark at 615/576-0823. When replying, please refer to 93-1351.

*Martha J. Kass*

Martha J. Kass, Acting Director  
Energy Programs Division

Attachments

cc w/attachments:  
Irme Gyuk, EE-141, HQ/FORS  
Steve Morrell, AD-42, ORO  
Paul Gaily, ORNL

HClark:6-0823:as:6-3666:08/31/93:1351.as

Concurrence
Rtg Symbol
ER-111.....
Initials/Sig
HC <i>HC</i>
Date
9/3/93
Rtg Symbol
ER-111
Initials/Sig
GLR <i>GLR</i>
Date
9/3/93
Rtg Sym ol
ER-11
Initials/Sig
MJK <i>MJK</i>
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1022001

# memorandum

DATE: September 8, 1993

REPLY TO  
ATTN OF: ER-111:Clark

SUBJECT: **APPROVAL OF PROCUREMENT BY MARTIN MARIETTA ENERGY SYSTEMS, INC.**

TO: Susan Rose, Office of Health and Environmental Research, ER-72, HQ/GTN

The operating contractor in Oak Ridge has proposed the attached procurement of research services involving human subjects from Midwest Research Institute of Kansas City, Missouri. Based on a letter from Dr. Katherine Duncan of the Department of Health and Human Services to John McKelvey of Midwest Research Institute (copy attached), it appears that the company has the approval of the National Institute of Health for their Multiple Project Assurance (Number M-1051), effective July 1, 1991, through June 30, 1996. We are recommending that the procurement proceed based on conversations with Imre Gyuk, EE-141, that this Multiple Project Assurance approval meets the criteria for such research by the Department of Energy. If this is not the case, please advise this office immediately.

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5. Screening Information Form
6. Description of study and other miscellaneous information

1022002

Susan Rose

- 2 -

September 8, 1993

If you have any questions, please call Harold Clark at 615/576-0823. When replying, please refer to 93-1351.

*Martha J. Kass*

Martha J. Kass, Acting Director  
Energy Programs Division

**Attachments**

cc w/attachments:  
Irme Gyuk, EE-141, HQ/FORS  
Steve Morrell, AD-42, ORO  
Paul Gaily, ORNL

1022003



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892Building 31  
Room 5B-59  
301/496-7005

April 30, 1991

John McKelvey  
President and Chief Executive Officer  
Midwest Research Institute  
425 Volker Boulevard  
Kansas City, Missouri 64110

Re: Assurance #M-1051

Dear Dr. McKelvey:

The Department of Health and Human Services (HHS) has approved the renewal of your Multiple Project Assurance dated April 18, 1991, submitted by your institution in compliance with the requirements for the protection of human subjects (45 CFR 46).

Your new Assurance will become effective on July 1, 1991, and retains the same identification number of M-1051. The approval period is for five years. Therefore, it will expire on June 30, 1996, and a new Assurance is to be negotiated with the Office for Protection from Research Risks (OPRR) prior to that date. Please reference your Multiple Project Assurance number with all future correspondence to this office.

Your Institutional Review Board (IRB) has been assigned identification number 01. This IRB number, along with your Assurance number, will be required in certain forms (e.g., PHS-2590) and other correspondence.

The Assurance defines the relationship of your institution to HHS since it sets out your responsibilities and the procedures that will be used by your institution to protect human subjects. Among the most important elements of the Assurance are the reporting requirements to this office and your agreement to disseminate the content of this Assurance to those individuals at your institution who are in any way associated with human subject research.

1022004

Page 2 - John McKelvey

A copy of the approved Assurance is enclosed, as is a blank format sheet to facilitate the future reporting of changes in your IRB membership.

If I can be of further help, please contact me.

Sincerely,

  
Katherine Duncan, M.D.  
Adjunct Medical Officer  
Division of Human Subject  
Protections, OPRR, OD

Enclosures

KD/nz

1022005

**MARTIN MARIETTA****MARTIN MARIETTA ENERGY SYSTEMS, INC.**POST OFFICE BOX 2002  
OAK RIDGE, TENNESSEE 37831-8501

AUG 19 1993

Mr. W. A. Mynatt, Chief  
Acquisitions Branch  
Department of Energy  
Oak Ridge Operations Office  
Post Office Box 2001  
Oak Ridge, Tennessee 37830-8501

Dear Mr. Mynatt:

Advance Notification of Unusual Procurement

Martin Marietta Energy Systems, Inc. (Energy Systems), proposes to enter into a cost, reimbursement-type subcontract with Midwest Research Institute, Kansas City, Missouri, to perform research in "Physiological Responses of Electric and Magnetic Fields in Humans." This is work covered by DOE Regulations at 10CFR 745 and DOE Order 13003.

The anticipated total estimated cost, including fixed fee, is \$370,000.

Energy Systems does not plan to seek competitive offers on this requirement. We have attached the noncompetitive justification and approval from the ORAU / ORNL Committee on Human Studies. We have also attached Midwest's Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects and their Certification and Volunteers' Informed Consent and supporting documents.

Sponsoring Division,  
Plant and Business Unit: Energy Division, ORNL

Requisition and B & R Numbers: SN602 AK 0400000

ORNL Technical Representative: Paul C. Galley (574-0419)

DOE Technical Contact: Harold Clark (576-0823)

This subcontract will not be approved until we have received approval of the Research on Human Subjects.

If you have any questions or require further information, please contact me or Shannon Bridges, the subcontract administrator, at 576-1426.

Sincerely,



R. L. Waters, Jr., Manager  
Socioeconomic and Administrative  
Support Programs

RLW:SEBridges:rtc

Attachments: As stated

c: File - RFP No. SN602-85 - RC

1022006

# JUSTIFICATION FOR SOLE SOURCE OR RESTRICTED COMPETITION PROCUREMENT

Complete and submit this form with the purchase requisition or Form UCN-1127 when total estimated cost is \$5,000 or more. This form is not required when estimate is less than \$5,000; however, you must show "no sub" on the requisition and provide on request sufficient information to enable the buyer to verify that there is no acceptable alternate. Sole source will often delay an award rather than speed an award.

A. Requisition No. or Form UCN-1127 No. SN602 Plant X-10

If work for others and over \$1,000,000, attach ORO Work for Others Review Committee Proposal Information Form OR F4300.

B. Check One:  Sole Source Specific Vendor is Midwest Research Institute  
 No Substitution (Must be manufacturer's product specified from any vendor.)  
 Restricted Competition (Give reasons for restriction and list sources below.)

Estimated Total Cost: \$ 370,000.

Brief description of supplies or services: Physiological Studies on responses to electric and magnetic fields in human.

Justification: Reasons given must be factual; personal preference is not sufficient. Attach additional pages if necessary.

A. State why you have selected this source or this manufacturer's product or restricted competition. Identify any unique minimum requirements which only this source can supply and describe why they are important to your work. Describe background investigations, reviews, literature searches, and/or market surveys done by you, your associates, Purchasing, etc. Identify other sources considered and why they were rejected.

Please amplify on any of the following elements which are applicable to your selection of this source: (1) Exclusive capability; (2) Prior experience; (3) Facilities and equipment; (4) Schedule requirements; (5) Excess costs; (6) Other qualifications.

B. If source selected is an educational institution, describe how the institution was selected from among other universities.

C. Outline the procurement history of this requirement, if any. Do you expect follow-on sole source?  YES  NO If yes, describe. Buyer may contact you to discuss options.

Midwest Research Institute has conducted studies of physiological responses to electric and magnetic fields in humans for several years. These studies have been sponsored by the Electric Power Research Institute and the U.S. Department of Energy. The exposure facility for this research produces uniform, low intensity fields over a large area and has been extensively characterized by the ORNL EMF quality assurance team and researchers from the U.S. National Institute of Standards and Technology. This exposure facility at Midwest Research Institute is the only controlled, whole-body human exposure facility in the United States.

Task 1 of the proposed subcontract involves analysis of data collected by Midwest Research Institute under a previous grant from the U.S. Department of Energy. The research team has ready access to all the data and is familiar with the details of this work. They are therefore in the best position to analyze the data quickly and cost-effectively.

Tasks 2 and 3 of this project involve new experiments which require the use of the whole-body EMF exposure system described above. This facility is the only one of its kind in the United States. Construction of such a facility is very expensive and characterization and verification of the fields in the system requires an extended period of measurements and testing. Because the proposed subcontract does not include funds for design, construction, and characterization of a new facility, Midwest Research Institute is the only organization capable of meeting the subcontract requirements.

*Approval recommended SE Arjun 4/23/93 Approval E.C. Badler 8/12/93*

PREPARED BY: NAME Paul Galley 32885 <i>Paul C. Galley</i>	BUILDING 3147	MAIL STOP 6070	PHONE 4-0419	DATE 6/9/93
APPROVED BY: DEPARTMENT HEAD OR HIGHER AUTHORITY <i>[Signature]</i> G. E. Courville	DIVISION Energy 15			DATE

**ORAU/ORNL COMMITTEE ON HUMAN STUDIES**

**TO:** Dr. Paul Galley  
**FROM:** *William Calhoun*  
Dr. William Calhoun, Chairman, Committee on Human Studies  
**RE:** COMMITTEE ACTION ON YOUR PROPOSAL  
**DATE:** June 29, 1993

Your proposal, "Effects of Electric and Magnetic Fields on Humans" has been reviewed and approved at our last meeting June 25, 1993 without changes.

Progress reports on all active projects are requested during our fall and spring meetings. You will be notified of our next meeting to be held in the fall 1993.

/mvt

1022008



**ASSURANCE OF COMPLIANCE WITH  
HHS REGULATIONS FOR THE PROTECTION  
OF HUMAN RESEARCH SUBJECTS**

**April 18, 1991**

**Midwest Research Institute  
425 Volker Boulevard  
Kansas City, Missouri 64110**

1022009

Institutional Endorsement and HHS Approval

A. Authorized Institutional Official

Signature: *[Signature]* Date: 4/18/91  
 Name: John McKelvey  
 Title: President & Chief Executive Officer  
 Address: Midwest Research Institute  
425 Volker Boulevard  
Kansas City, Missouri 64110  
 Phone: 816/753-7600, Extension 203

B. Primary Contact (Indicate if same)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
 Name: Same as above  
 Title: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 Phone: \_\_\_\_\_

C. HHS Recommending Official

Signature: *[Signature]* Date: 4/29/91  
 Name: Katherine Duncan, M.D.  
 Title: Adjunct Medical Officer  
 Address: NIH, OPRR - 9000 Rockville Pike  
Bldg. 31, Room 5B59  
Bethesda, MD 20892  
 Phone: (301) 496-7005

D. Effective Date of Assurance 7/1/91

E. Expiration Date of Assurance 6/30/96

F. HHS Approving Official

Signature: *[Signature]* Date: 4/30/91  
 Name: F. William Dornel, Jr., J.D.  
 Title: Dir., Div. of Human Subject Protections  
Office for Protection from Research  
Risks, OER

**MIDWEST RESEARCH INSTITUTE**

**Assurance of Compliance with HHS Regulations for  
Protection of Human Research Subjects**

Midwest Research Institute, hereinafter referred to as "institution," hereby gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended) as specified below.

<b>Institutional Endorsement and HHS Approval</b>	<b>11</b>
<b>I. Statement of Applicability, Principles, and General Policies</b>	<b>1</b>
<b>II. Implementation</b>	<b>6</b>
<b>III. Addendum - March 28, 1986</b>	<b>24</b>
<b>IV. Addendum - April 18, 1991</b>	<b>26</b>
<b>Exhibit A - The Belmont Report</b>	<b>28</b>
<b>Exhibit B - Title 45, Code of Federal Regulations, Part 46 Protection of Human Subjects</b>	<b>37</b>
<b>- Clarification: Emergency Medical Care OPRR Report Number 91-01</b>	<b>56</b>
<b>Exhibit C - Form 441, Alcohol, Drug Abuse, and Mental Health Administration</b>	<b>60</b>
<b>Exhibit D - Quarterly Surveillance Form</b>	<b>63</b>
<b>Exhibit E - Membership of the Midwest Research Institute Human Subjects Committee</b>	<b>65</b>

The original document defining this institution's Multiple Projects Assurance was approved on July 1, 1982. The document was revised as indicated in Section III and reapproved on July 1, 1986. Current changes in institutional policies and procedures are addressed in Section IV. A revised membership list of the Midwest Research Institute Human Subjects Committee is provided in Exhibit E.

Changes summarized in the addenda of March 28, 1986, and April 18, 1991, are noted in the margins of the text by an asterisk (\*).

**MIDWEST RESEARCH INSTITUTE**

425 Volker Boulevard  
Kansas City, Missouri 64110  
Telephone (816) 753-7600  
Telefax (816) 753-8420

June 21, 1993

Paul Gailey  
Oak Ridge National Laboratory  
P.O. Box 2008, MS 6070  
Oak Ridge, TN 37831

**Subject: MRI Proposal "Effects of Electric and Magnetic Fields on Humans"**

Dear Mr. Gailey:

I have enclosed a copy of Midwest Research Institute's documentation of the Human Subjects Committee review and approval in connection with the proposed study under consideration by Oak Ridge. Please include this in your file for the record.

Sincerely,

**MIDWEST RESEARCH INSTITUTE**

A handwritten signature in black ink, appearing to read "R. Donaldson", written in a cursive style.

Robert Donaldson, Director,  
Contracts and Facilities Services

RD:mw

Enclosure

1022012

**MIDWEST RESEARCH INSTITUTE  
INTEROFFICE MEMORANDUM**

June 18, 1993

**TO:** Bob Donaldson  
**FROM:** Gene Podrebarac  
Chairman, MRI Human Subjects Committee  
**SUBJECT:** MRI Project No. RA-111  
Neurobehavioral Effects of EMF Exposures

\*\*\*\*\*

- TASK 1:** Effects of EMF Exposure on Cardiovascular Functions
- TASK 2:** Magnetic Field Exposure Effects on EEG Measure of Human Sensory and Cognitive Functions

The above proposed studies are an extension of studies previously approved by the Committee. The new studies will use previously approved procedures at exposure levels the same as presently used. The Committee was sent the appropriate background information, statement of work, volunteer informed consent form and the Form ADM 441 for review. The Committee members were requested to document (by mail) their approved, disapproval or request for review of the proposed study at a convened meeting of the HSC.

The Committee unanimously approved the activity plan and informed consent form.

Please call me if you have any questions.

MRI HSC Assurance Identification No: M1051  
IRB Identification No. 01

*Eugene G. Podrebarac*

Eugene G. Podrebarac, Ph.D  
Chairman, HSC

*June 18, 1993*

Date

CC: Dr. Charles Graham  
RA-111 File

1022013



3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (from Form 202)

According to 21 CFR 312.121, if an application is made to HHS regarding certification and involving use of an investigational new drug or device, additional information is required. In addition, according to 21 CFR 312.11(a)(2), 30 days must elapse between date of receipt by FDA of Form FD-157: 148 use of the drug, unless the 30 day delay period is waived by FDA.

3a. INVESTIGATIONAL NEW DRUG EXEMPTION (if more than one is approved, list others below under NOTES)

SPONSOR NAME

DRUG NAME

DATE OF END OF 30-DAY EXPIRATION OR WAIVER

NUMBER ISSUED

3b. INVESTIGATIONAL DEVICE EXEMPTION:

SPONSOR NAME

DEVICE NAME

Unless notified otherwise by FDA, under 21 CFR 812.2(b) (1) a sponsor is deemed to have an approved IDE if: (1) the IRB has agreed with the sponsor that the device is a non-significant risk device; and (2) the IRB has approved the study. (Check applicable box.)

The IRB agrees with the sponsor that this device is a non-significant risk device.

OR

The IDE application was submitted to FDA on (date) \_\_\_\_\_ Number issued \_\_\_\_\_.

NOTES:

PROJECT NO. 1111-05

## VOLUNTEERS' INFORMED CONSENT

I, \_\_\_\_\_ residing at

\_\_\_\_\_ hereby acknowledge and certify to the following:

1. I hereby volunteer and consent to be a subject in a research study sponsored by the Department of Energy and directed at Midwest Research Institute (MRI), by Dr. Charles Graham and Mr. Harvey D. Cohen. I understand this study will determine if exposure to magnetic fields at levels (200 mG) found in the home and workplace has any effect on human physiology and performance. I understand there are no known health risks associated with the brief periods of exposure I may experience.

I understand my participation will involve coming to MRI for a brief familiarization session, and then for an all-morning exposure test session. The familiarization session will last about an hour. I will complete various questionnaires, have recording sensors attached to my chest and arm to measure physiological activity (heart rate, blood pressure, respiration, etc.), and I will practice the procedures for taking these measures several times. I understand these procedures and measures are not painful or hazardous to my health.

I will then come to MRI for an exposure test session lasting from 8 am to about 12:30 pm. I am aware that this study includes a comparison group that will not be exposed to the magnetic fields, and that during my test session the fields may or may not be turned on. On arrival at the lab, I will complete the questionnaires and have the recording sensors attached as in the familiarization session. I will then remain seated in the exposure facility for the rest of the morning (reading material will be provided). At intervals, the measures I practiced earlier will be taken.

I agree to not use alcohol for 24 hours prior to the test session. I know this is a basic research study not designed to benefit me personally, and that I will receive a total of \$50.00 for my participation if I complete all study requirements; if not, I will be paid \$5.00 for each hour of scheduled participation.

2. I have been given, in my opinion, an adequate explanation of the nature, duration, and purpose of the experiment, the means by which the experiment will be conducted, and any possible inconvenience, hazards, discomfort, risks, and adverse effects on my health which could result from my participation.

OVER

1022016

3. I understand my questions concerning procedures which affect me will be answered fully and promptly by either Dr. Charles Graham, Principal Investigator, or by Dr. Eugene Podreberac, Chairman of the MRI Human Subjects Committee, which reviewed and approved this study (816/753-7600).

4. I understand that I have the right to withdraw my consent and to discontinue participation in this experiment at any time without prejudice regardless of the status of the experiment and regardless of the effect of such withdrawal on the objectives and results of the experiment; and I also understand that my participation in the experiment may be terminated at any time by the investigator in charge of the project.

5. I agree that any information obtained from me, by MRI, or its authorized representatives, in connection with this study may be utilized by MRI in publications and reports without identifying me.

6. I hereby certify that the medical-history information that I provide to MRI is complete and correct to the best of my knowledge, and that I have informed MRI staff of all serious or chronic medical problems that I now have or have had.

7. If I am injured as a result of participation in this study, MRI will pay for immediate emergency medical treatment. Beyond its emergency care payment, it is MRI's policy to pay for only those costs for which MRI is legally responsible.

8. My age is \_\_\_\_; The date of my birth is \_\_\_\_\_, 19\_\_.

I am executing this Volunteer's Consent as my free act and deed.

Today's date is \_\_\_\_\_, 19\_\_

Executed in the presence of each other

\_\_\_\_\_  
Signature of Volunteer

\_\_\_\_\_  
Signature of Experimenter

Accepted; ID \_\_\_\_\_

DOE 111-03  
SCREENING INFORMATION

Interviewer: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_ Phone: (H) \_\_\_\_\_ (W) \_\_\_\_\_

Address: \_\_\_\_\_

\*Age: (18-35) \_\_\_\_\_ Sex: \_\_\_\_\_ Birthdate: \_\_\_\_\_ Height: \_\_\_\_\_

Weight: \_\_\_\_\_ Educational level/Major \_\_\_\_\_

Source: \_\_\_\_\_

Have you participated in research studies before? \_\_\_ No \_\_\_ Yes  
(describe) \_\_\_\_\_

Do you work nights? \_\_\_ No \_\_\_ Yes\*  
(describe) \_\_\_\_\_

In the last six months, have you taken any medication regularly?  
\_\_\_ No \_\_\_ Yes\* (describe) \_\_\_\_\_

Do you now take any medication? \_\_\_ No \_\_\_ Yes\*  
(describe) \_\_\_\_\_

Do you smoke cigarettes or use tobacco? \_\_\_ No \_\_\_ Yes  
(describe) \_\_\_\_\_

Are you on any type of special diet? \_\_\_ No \_\_\_ Yes  
(describe) \_\_\_\_\_

Do you have any chronic health problems? \_\_\_ No \_\_\_ Yes\*  
(describe) \_\_\_\_\_

Has a doctor ever told you that you had any problem with your heart  
or blood pressure? \_\_\_ No \_\_\_ Yes\* (describe) \_\_\_\_\_

OVER

Have you ever had surgery?  No  Yes  
(describe) \_\_\_\_\_

Have you ever had any kind of head injury which made you unconscious,  
even for a few seconds?  No  Yes (describe) \_\_\_\_\_

Have you ever had any seizures or attacks?  No  Yes\*  
(describe) \_\_\_\_\_

Do you have any allergies?  No  Yes (describe) \_\_\_\_\_

In the last 3 months, have you been sick at all?  No  Yes  
(describe) \_\_\_\_\_

Not even a cold or the stomach flu or something like that?  No  
 Yes (describe) \_\_\_\_\_ Bed?  How long? \_\_\_\_\_

Since this study runs only in the morning, is any particular morning better  
than another for you?  
\_\_\_\_\_  
\_\_\_\_\_

Do you have any questions?

OK, good. I'll get back in touch with you as soon as we have reviewed  
this information and worked out a schedule. When is a good  
time to call you back? \_\_\_\_\_

Reviewed by: \_\_\_\_\_ on \_\_\_\_\_  Accept  Reject

\*possible reason for exclusion from participation: IF DOES NOT MEET  
CRITERIA, INFORM VOLUNTEER OF THAT FACT, ASK IF NAME SHOULD BE KEPT  
ON LIST FOR STUDIES WHICH DO NOT REQUIRE THE PARTICULAR RESTRICTION;  
DO NOT CONTINUE WITH SCREENING

1022019

## ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

## PROTECTION OF HUMAN SUBJECTS

<b>PROJECT TITLE:</b>	FURTHER STUDIES OF 60-HZ EXPOSURE EFFECTS ON HUMAN FUNCTION	<b>PROJECT NO.</b> RA-111
<b>CHARACTERISTICS OF GROUP(S):</b>	<p>Describe the characteristics of the group(s) to be used: <i>(If additional space is needed for an item, use a separate sheet)</i></p> <p>(a) Sex, race or ethnic group, age, range, etc. Men between the ages of 18 and 35</p> <p>(b) Affiliation of subjects, e.g., institutions, hospitals, general public, etc. Local colleges, universities, research institutes, general public</p> <p>(c) Subjects' general state of health <i>(mental and physical)</i> No physical or mental disease, nonsmoker</p>	
<b>SPECIAL GROUPS:</b>	<p>If human subjects are either children, mentally incompetent, or legally restricted groups, give explanation as to:</p> <p>(a) The necessity for using these particular groups N/A</p> <p>(b) Why adult "normal" groups cannot be used <i>(specifically)</i> N/A</p>	
<b>TYPE OF CONSENT:</b>	<p>What precautionary measures will be taken to insure the protection of human subjects on physical, psychological, social, legal and other issues?</p> <p>(a) Type of consent to be obtained <i>(written or oral)</i> Oral at time of recruitment. Written obtained prior to first session.</p> <p>(b) How and where will permission be recorded By principal investigator or designate at MRU</p> <p>(c) If subjects are minors or mentally incompetent, describe how and by whom permission will be granted N/A</p>	
<b>CONFIDENTIALITY OF DATA:</b>	<p>What precautions will be taken to safeguard identifiable records of individuals? These questions also apply if you are using secondary sources of data</p> <p>(a) Consider the long range use of data <i>(by you and others)</i> Individuals will not be identified in project publications and reports, and consent forms will be destroyed 3 yrs after project completion.</p> <p>(b) Immediate use of data <i>(by you and others)</i> All data will be number coded; access to data with ID information will be limited to project staff.</p> <p>(c) Describe specific procedures to be used to provide confidentiality of data Same as (a) and (b) above.</p>	

1022020

<b>RISKS TO SUBJECTS:</b>	<p>Describe in detail any physical, psychological, social, legal, economic or other risks you can foresee, both immediate and long range:</p> <p>(a) <b>Immediate risks</b> The risks are minimal. The procedures and exposure conditions have been approved for use in previous studies. No known health risks are associated with the brief exposure conditions planned. Heart rate changes seen in previous studies have been within the normal range.</p> <p>(b) <b>Long range:</b> There are no long-term risks associated with the proposed procedures.</p> <p>(c) <b>Rationale for the necessity of such risks</b> In our previous research, exposure to 60-Hz magnetic fields was associated with changes in heart rate. In this study we will determine if exposure also induces changes in other important cardiovascular parameters (e.g., ECG, blood pressure) and if some people are more responsive than others.</p> <p>(d) <b>Alternatives that were or will be considered</b> Studies performed in the work environment.</p> <p>(e) <b>Why alternatives may not be feasible</b> Inadequate control over exposure and monitoring conditions.</p>
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<b>NON-BENEFICIAL RESEARCH:</b>	<p>"Non-Beneficial Research" is defined as research involving physiological and psychological investigations of a person, his body or surroundings, which is devoid of therapeutic purpose to that person. If you plan to conduct this type of research and feel that there are no other methods available for obtaining the information needed, please describe:</p> <p>(a) <b>What other methods were or will be explored</b> See (d) and (e) above.</p> <p>(b) <b>The extent of the risks (Describe in detail any physical, psychological, social, legal and other risks you can foresee, both immediate and long range)</b> The risks are minimal.</p> <p>(c) <b>The importance of the knowledge gained.</b> The public is continuously exposed to 60-Hz magnetic fields in the home and workplace. It is important to determine if such exposure has effects on the cardiovascular system, and if individuals differ in their response to exposure.</p> <p>(d) <b>Why you feel the value of the information to be gained outweighs the risks.</b> The risks are minimal compared to the importance of identifying potential risks in the large population.</p>
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**ADDITIONAL COMMENTS:**

Signature	Date
-----------	------

## TEL-SCRIPT FOR DOE SUBJECTS

Thanks for calling. Let me tell you about the study we are doing. This study is funded by the Department of Energy. We want to find out if physiological activity like heart rate, blood pressure and respiration is affected by exposure to magnetic fields similar to those you would find in your home or at work.

To be in the study you need to be able to come to MRI for a morning session lasting from 8 am to about 12:30 pm. We ask that you not use alcohol for 24 hours prior to the session. On arrival at the lab, you will complete some questionnaires and have recording sensors attached to your chest and hand. You will remain seated in the facility all morning, and at different times we will ask you to sit quietly with your eyes closed so that we can record some physiological measures. When we are not taking measurements, you are free to sit quietly and read.

Not all people will be exposed to the fields in this study; for those who are exposed there are no known health risks associated with the brief periods of exposure we will be using. Probably the major benefit, aside from being in an interesting study, is that you will be paid for your participation. You will receive \$ 50.00 for completing the session.

Do you have any questions?  
(answer questions)

Would you like to participate in this study?

IF NO - OK, I can understand that \_\_\_\_ (rephrase reason). We sometimes have studies which do not involve \_\_\_\_; would you like me to keep you on the list so that we can call you if a study like that comes up?

IF YES - good. I need to ask you a few questions to make sure you meet all the criteria for the study. Do you have a few more minutes now? (If not, arrange time for call back).

GO TO SCREENING INFORMATION FORM

1022022

# MIDWEST RESEARCH INSTITUTE

## MEN NEEDED FOR RESEARCH PROJECT

MEN IN GOOD HEALTH BETWEEN THE AGES OF 18 AND 35 ARE NEEDED FOR A HALF-DAY RESEARCH STUDY. THE AIM OF THE STUDY IS TO FIND OUT IF EXPOSURE TO MAGNETIC FIELDS AT LEVELS COMMONLY FOUND IN THE HOME OR WORKPLACE HAS ANY SHORT-TERM INFLUENCE ON HEART RATE OR BLOOD PRESSURE. PARTICIPANTS WILL COME TO MRI FOR ONE MORNING SESSION LASTING FROM 8AM TO AROUND NOON.

**PAYMENT IS \$50.00.**

**FOR INFORMATION CALL:**

**753-7600**

**DON RIFFLE (EXT 341) OR JOB McCLERNON (EXT 674)**

1022023

**FURTHER STUDIES OF 60-HZ EXPOSURE EFFECTS ON HUMAN FUNCTION****MRI Project No. RA-111****For****Department of Energy****INTRODUCTION**

Our laboratory studies with human volunteers have repeatedly shown that exposure to 60-Hz electric and magnetic fields has an influence on heart rate. Continuous exposure to the fields slows the heart; intermittent exposure can result in both speeding and slowing. These effects appear to be due more to the magnetic field than to the electric field. People also seem to differ in their response to exposure, and we have found that a person's resting heart rate prior to exposure can be a significant predictor of how they will respond when exposed.

The effects found on heart rate may be a reflection of more important effects occurring elsewhere in the cardiovascular system. We believe it is most important to identify the underlying control mechanisms responsible for the cardiac effects we have seen. The study described here involves making detailed measurements of electrocardiographic activity, blood pressure and respiration during exposure to magnetic fields. The results will help us understand how (or if) exposure influences the electrical potentials generated by the heart or the timing of significant events in the heart cycle, and they will provide preliminary data on the other measures.

The proposed procedures and exposure conditions are similar to those approved for use in our previous studies. The research will be performed in the 60-Hz Human Exposure Test Facility at MRI by staff of the Biobehavioral Sciences Section, headed by Dr. Mary R. Cook. Dr. Charles Graham and Mr. Harvey D. Cohen will serve as co-principal investigators. We request approval of the activity plan and consent form for the study described below.

### STUDY DESCRIPTION

**Human Subjects:** Sixty, healthy young men (aged 18 to 35, no chronic disease or disability, nonsmoker) will be recruited from local colleges, universities, research institutes and the general public for paid participation in the study. Written informed consent will be obtained prior to participation.

**Experimental Design and Procedures:** Subjects will participate initially in a brief 1-hr session to become familiar with the physiological recording procedures, and to provide baseline cardiovascular data. They will complete self-rating scales designed to measure mood and alertness. Vital signs (blood pressure, temperature, pulse) will be recorded. Recording sensors will be attached to the chest and arm to measure the electrocardiogram (ECG), heart rate, blood pressure, respiration, and oxygen saturation. Measures will be taken several times to allow the subject to become familiar with the recording procedures. Subjects with blood pressure or ECG irregularities will not be continued in the study.

Subjects will then be assigned at random to either a sham exposure group (30 men), or a magnetic field exposure group (30 men). Individual differences in heart rate will be equally represented in each group. Each subject will come to MRU for a morning (8 am to 12:30 pm) exposure test session. They will be instructed to eat balanced meals and to not drink alcohol for 24 hours before the session. After collection of self-report and vital sign data, the physiological recording sensors will be attached as in the familiarization session. The subject will then sit reading in the exposure facility for three hours. For subjects in the sham exposed group, the magnetic field will not be turned on during this period. For subjects in the field-exposed group, exposure to the magnetic field will be intermittent. Exposure will comprise alternating 45-minute "field-on" and "field-off" periods. During "field-on" periods, the magnetic field will cycle on and off every 15 seconds. During "field-off" periods, the generating equipment will not be turned on. Magnetic field strength will be 200 mG. The study will be performed double blind, and physiological measures will be obtained at multiple matched points throughout sham and field exposure.

The field exposure conditions in this study are the same as those approved for use in our previous studies. The physiological recording procedures have also been approved for use in previous studies and present no risk to human subjects.

DOE 111-05  
VOLUNTEER EXCLUSION CRITERIA

**EXCLUDE VOLUNTEERS:**

- \* IF THEY ARE NOT 18 TO 35 YRS OF AGE.
- \* IF THEY ARE NOT MALE.
- \* IF THEY WORK NIGHTS (AFTER 10 PM).
- \* LOOK UP ANY PRESCRIBED MEDICATION IN PDR, CHECK WITH PI.
- \* IF THEY HAVE TAKEN MEDICATION REGULARLY IN THE LAST 6 MONTHS.
- \* CHECK CHRONIC HEALTH PROBLEMS WITH PI.
- \* IF THEY HAD BRAIN SEIZURES OR ATTACKS.
- \* IF THEY HAVE HEART OR BLOOD PRESSURE PROBLEMS.

1022026

1111-05

INTERCOM INSTRUCTIONS  
CARDIAC MEASUREMENT TASK

HI (SUBJECT NAME). CAN YOU HEAR ME OK? GOOD.

WE WILL BE TAKING A BASELINE MEASUREMENT IN THE NEXT FEW MINUTES. SO GET YOURSELF INTO A RELAXED AND COMFORTABLE POSITION IN THE CHAIR.

KEEP YOUR BACK FLAT AGAINST THE CHAIR AND YOUR FEET STRAIGHT OUT ON THE FOOTSTOOL. DURING THE MEASUREMENT, BE SURE YOUR EYES ARE CLOSED AND YOUR ARMS ARE RESTING COMFORTABLY ON THE ARMS OF THE CHAIR. TRY NOT TO PUT ANY PRESSURE ON THE FINGER SENSORS (MONITOR/CORRECT POSITION IF NEEDED).

WE'LL RECORD FOR ABOUT 3 MIN - THEN GIVE YOU A SHORT BREAK - AND THEN RECORD FOR ANOTHER 3 MIN. I'LL TELL YOU WHEN WE ARE READY TO START.

DURING 30-SEC BREAK

OK (NAME). THAT ENDS THE FIRST MEASUREMENT. TAKE A LITTLE BREAK. I'LL LET YOU KNOW WHEN WE ARE READY TO START AGAIN.

AFTER 2ND CM3

OK (NAME). EVERYTHING LOOKS FINE. WE GOT A GOOD RECORDING. YOU CAN READ AND RELAX NOW. I'LL GET BACK TO YOU IN ABOUT A HALF AN HOUR.

1022027

**RA-01115-05****ELECTRODE PLACEMENT and CHANNELS**

<u>ELECTRODE NUMBER</u>	<u>LOCATION</u>
4	Index finger
5	Ring finger
6	Upper right chest
8	Upper left chest
9	Left clavicle
10	Right clavicle
11	Left lower chest

---

<u>CHANNEL BECKMAN</u>	<u>FUNCTION</u>	<u>LEAD SELECTOR</u>	<u>PREAMP</u>
1	HR	nc	.05V/mm
2	Finger pulse	nc	.2V/mm
3	ECG II	10-11	.1mV/mm
4	Respiration	nc	.5mv/mm
5	Skin Conductance	5-6	1mv/mm
6	ECG I	10-9	.1mV/mm
7	ECG III	9-11	.1mV/mm
8	Marker	nc	.5V/mm

1022028

**Notice:**

Preliminary approval has been received for this proposed work from the ORNL Human Subjects Committee (see attached letter from the chairman). Paperwork is now submitted to the committee for final approval, and the approval documentation will be forwarded to contracting as soon as it is received.

1022029

MRI  FAX



MIDWEST RESEARCH INSTITUTE

425 Volker Boulevard, Kansas City, Missouri 64110-2299

Telephone (816) 753-7600  
FAX (816) 753-8420

Date 30 Aug 93

To HAROLD CLARK - DOE

From H.D. COHEN

0	3	3	4	-		-	
---	---	---	---	---	--	---	--

Overhead #, or Project, Task + Sub-Task

This transmission consists of 3 pages (including cover)

Receiving Facsimile Telephone Number (615) 574-9275

Verification Telephone Number ^

MRI Facsimile Machine: RAPICOM 610 (816) 753-8420 GROUP III

MRI Verification: (816) 753-7600 Ext. 361

**MESSAGE:**

*Paul Gouley ask me to send this to you.*

*H.D. Cohen*



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892Building 31  
Room 5B-59  
301/496-7005

April 30, 1991

John McKelvey  
President and Chief Executive Officer  
Midwest Research Institute  
425 Volker Boulevard  
Kansas City, Missouri 64110

Re: Assurance #M-1051

Dear Dr. McKelvey:

The Department of Health and Human Services (HHS) has approved the renewal of your Multiple Project Assurance dated April 18, 1991, submitted by your institution in compliance with the requirements for the protection of human subjects (45 CFR 46).

Your new Assurance will become effective on July 1, 1991, and retains the same identification number of M-1051. The approval period is for five years. Therefore, it will expire on June 30, 1996, and a new Assurance is to be negotiated with the Office for Protection from Research Risks (OPRR) prior to that date. Please reference your Multiple Project Assurance number with all future correspondence to this office.

Your Institutional Review Board (IRB) has been assigned identification number 01. This IRB number, along with your Assurance number, will be required in certain forms (e.g., PHS-2590) and other correspondence.

The Assurance defines the relationship of your institution to HHS since it sets out your responsibilities and the procedures that will be used by your institution to protect human subjects. Among the most important elements of the Assurance are the reporting requirements to this office and your agreement to disseminate the content of this Assurance to those individuals at your institution who are in any way associated with human subject research.

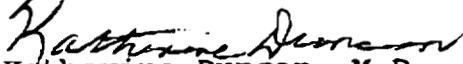
1022031

Page 2 - John McKelvey

A copy of the approved Assurance is enclosed, as is a blank format sheet to facilitate the future reporting of changes in your IRB membership.

If I can be of further help, please contact me.

Sincerely,

  
Katherine Duncan, M.D.  
Adjunct Medical Officer  
Division of Human Subject  
Protections, OPRR, OD

Enclosures

KD/nz

1022032

OPTIONAL FORM NO. (7-80)

FAX TRANSMITTAL

# of pages >

To: *Martha Kass*  
 From: *Steve Morrell*  
 Agency: *Kill Site etc*  
 Phone #: *6-0709*  
 X #: *4-9275*  
 Fax #: *6-9189*

IN 7540-01-317-7388 5099-101 GENERAL SERVICES ADMINISTRATION

EXPEDITE ★ ★ ★ ★ ★

PROPOSED MMES PROCUREMENT

ASSIGNED SPECIALIST: *Steve Morrell*  
 EXPIRATION OF REVIEW PERIOD: *9/7/93*

*8/27/93*

THE ATTACHED ADVANCE NOTIFICATION DESCRIBES A PROPOSED MMES PROCUREMENT AND HAS BEEN SUBMITTED FOR DOE'S CONTRACTUAL AND PROGRAMMATIC REVIEW. PLEASE REVIEW THE ATTACHED DOCUMENT AND INDICATE YOUR CONCURRENCE WITH THE PROPOSED SUBCONTRACT ACTION. IF YOU DO NOT CONCUR IN THIS ACTION, PLEASE INDICATE YOUR COMMENTS IN THE SPACE PROVIDED BELOW. SINCE THE CONTRACTOR WILL INITIATE THE PROPOSED SUBCONTRACT ACTION WITHIN TEN DAYS UNLESS ORO RESPONDS WITH NEGATIVE COMMENTS, IT IS IMPERATIVE THAT YOU PROMPTLY REVIEW THE DOCUMENT AND RETURN IT TO THE ORO PROCUREMENT AND CONTRACTS DIVISION.

DESCRIPTION OF ACTION

*\$1,370,000*

*Advance Notice - Midwest Research Institute*

*SN602-*

ADDRESSEE	DIVISION	CONCURRENCE	DATE
<i>Martha Kass</i>	<i>Energy Programs</i>		
<i>Steve Morrell</i>	<i>P&amp;CD</i>		
<i>Jennifer Fowler</i>	<i>OCC</i>		

RETURN TO: AD-421 ORO PROCUREMENT AND CONTRACTS DIVISION

COMMENTS:

*We need to be extra careful on this one: It deals with research on human subjects. I understand that the topic is covered by DOE Order 1300.3.*

DISTRIBUTION: BLUE - FILE  
 CANARY - MMES  
 PINK - CLERK 2  
 WHITE - CLERK 1

IF NONCONCURRENCE, CO SIGNATURE

*603278*

**MARTIN MARIETTA****ARTIN MARIETTA ENERGY SYSTEMS, INC.**POST OFFICE BOX 2002  
OAK RIDGE, TENNESSEE 37831-8501

AUG 19 1993

Mr. W. A. Mynatt, Chief  
Acquisitions Branch  
Department of Energy  
Oak Ridge Operations Office  
Post Office Box 2001  
Oak Ridge, Tennessee 37830-8501

Dear Mr. Mynatt:

Advance Notification of Unusual Procurement

Martin Marietta Energy Systems, Inc. (Energy Systems), proposes to enter into a cost, reimbursement-type subcontract with Midwest Research Institute, Kansas City, Missouri, to perform research in "Physiological Responses of Electric and Magnetic Fields in Humans." This is work covered by DOE Regulations at 10CFR 745 and DOE Order 1300.3.

The anticipated total estimated cost, including fixed fee, is \$370,000.

Energy Systems does not plan to seek competitive offers on this requirement. We have attached the noncompetitive justification and approval from the ORAU / ORNL Committee on Human Studies. We have also attached Midwest's Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects and their Certification and Volunteers' Informed Consent and supporting documents.

Sponsoring Division, Plant and Business Unit:	Energy Division, ORNL
Requisition and B & R Numbers:	SN602                      AK 0400000
ORNL Technical Representative:	Paul C. Galley (574-0419)
DOE Technical Contact	Harold Clark (576-0823)

This subcontract will not be approved until we have received approval of the Research on Human Subjects.

If you have any questions or require further information, please contact me or Shannon Bridges, the subcontract administrator, at 576-1426.

Sincerely,

R. L. Waters, Jr., Manager  
Socioeconomic and Administrative  
Support Programs

RLW:SEBridges:ric

Attachments: As stated

c: File - RFP No. SN602-85 - RC

1022034

# JUSTIFICATION FOR SOLE SOURCE OR RESTRICTED COMPETITION PROCUREMENT

Complete and submit this form with the purchase requisition or Form UCN-1127 when total estimated cost is \$5,000 or more. This form is not required when estimate is less than \$5,000; however, you must show "no sub" on the requisition and provide on request sufficient information to enable the buyer to verify that there is no acceptable alternate. Sole source will often delay an award rather than speed an award.

A. Requisition No. or Form UCN-1127 No. SN602 Plant X-10

If work for others and over \$1,000,000, attach ORO Work for Others Review Committee Proposal Information Form OR F4300.

B. Check One:  Sole Source Specific Vendor is Midwest Research Institute  
 No Substitution (Must be manufacturer's product specified from any vendor.)  
 Restricted Competition (Give reasons for restriction and list sources below.)

Estimated Total Cost: \$ 370,000

Brief description of supplies or services: Physiological Studies on responses to electric and magnetic fields in human.

Justification: Reasons given must be factual; personal preference is not sufficient. Attach additional pages if necessary.

A. State why you have selected this source or this manufacturer's product or restricted competition. Identify any unique minimum requirements which only this source can supply and describe why they are important to your work. Describe background investigations, reviews, literature searches, and/or market surveys done by you, your associates, Purchasing, etc. Identify other sources considered and why they were rejected.

Please amplify on any of the following elements which are applicable to your selection of this source: (1) Exclusive capability; (2) Prior experience; (3) Facilities and equipment; (4) Schedule requirements; (5) Excess costs; (6) Other qualifications.

B. If source selected is an educational institution, describe how the institution was selected from among other universities.

C. Outline the procurement history of this requirement, if any. Do you expect follow-on sole source?  YES  NO If yes, describe. Buyer may contact you to discuss options.

Midwest Research Institute has conducted studies of physiological responses to electric and magnetic fields in humans for several years. These studies have been sponsored by the Electric Power Research Institute and the U.S. Department of Energy. The exposure facility for this research produces uniform, low intensity fields over a large area and has been extensively characterized by the ORNL EMF quality assurance team and researchers from the U.S. National Institute of Standards and Technology. This exposure facility at Midwest Research Institute is the only controlled, whole-body human exposure facility in the United States.

Task 1 of the proposed subcontract involves analysis of data collected by Midwest Research Institute under a previous grant from the U.S. Department of Energy. The research team has ready access to all the data and is familiar with the details of this work. They are therefore in the best position to analyze the data quickly and cost-effectively.

Tasks 2 and 3 of this project involve new experiments which require the use of the whole-body EMF exposure system described above. This facility is the only one of its kind in the United States. Construction of such a facility is very expensive and characterization and verification of the fields in the system requires an extended period of measurements and testing. Because the proposed subcontract does not include funds for design, construction, and characterization of a new facility, Midwest Research Institute is the only organization capable of meeting the subcontract requirements.

Approval recommended SE Arjans 4/23/93 Approved EC Baillie 8/12/93

PREPARED BY: NAME	BUILDING	MAILSTOP	PHONE	DATE
Paul Gailley 32885 <i>Paul C. Gailley</i>	3147	6070	4-0419	6/9/93
APPROVED BY: DIVISION HEAD OR HIGHER AUTHORITY	DIVISION	DATE		
<i>G. E. Courville</i> For RB. Shelton	Energy 15			

**ORAU/ORNL COMMITTEE ON HUMAN STUDIES**

**TO:** Dr. Paul Galley  
**FROM:** Dr. William Calson/Chairman, Committee on Human Studies  
**RE:** COMMITTEE ACTION ON YOUR PROPOSAL  
**DATE:** June 29, 1993

Your proposal, "Effects of Electric and Magnetic Fields on Humans" has been reviewed and approved at our last meeting June 25, 1993 without changes.

Progress reports on all active projects are requested during our fall and spring meetings. You will be notified of our next meeting to be held in the fall 1993.

/mvr

1022036



**ASSURANCE OF COMPLIANCE WITH  
HHS REGULATIONS FOR THE PROTECTION  
OF HUMAN RESEARCH SUBJECTS**

**April 18, 1991**

**Midwest Research Institute  
425 Volker Boulevard  
Kansas City, Missouri 64110**

1022037

Institutional Endorsement and HHS Approval

A. Authorized Institutional Official

Signature: *John McKelvey*  
 Name: John McKelvey  
 Title: President & Chief Executive Officer  
 Address: Midwest Research Institute  
425 Volker Boulevard  
Kansas City, Missouri 64110  
 Phone: 816/753-7600, Extension 203

Date: 4/18/91

B. Primary Contact (Indicate if same)

Signature: \_\_\_\_\_  
 Name: Same as above  
 Title: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 Phone: \_\_\_\_\_

Date: \_\_\_\_\_

C. HHS Recommending Official

Signature: *Katherine Duncan*  
 Name: Katherine Duncan, M.D.  
 Title: Adjunct Medical Officer  
 Address: NIH, OPRR - 9000 Rockville Pike  
Bldg. 31, Room 5B59  
Bethesda, MD 20892  
 Phone: (301) 496-7005

Date: 4/29/91

D. Effective Date of Assurance 7/1/91

E. Expiration Date of Assurance 6/30/96

F. HHS Approving Official

Signature: *F. William Dommel, Jr.*  
 Name: F. William Dommel, Jr., J.D.  
 Title: Dir., Div. of Human Subject Protections  
Office for Protection from Research  
Risks, OER

Date: 4/30/91

**MIDWEST RESEARCH INSTITUTE**

**Assurance of Compliance with HHS Regulations for  
Protection of Human Research Subjects**

Midwest Research Institute, hereinafter referred to as "institution," hereby gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended) as specified below.

Institutional Endorsement and HHS Approval	ii
I. Statement of Applicability, Principles, and General Policies	1
II. Implementation	6
III. Addendum - March 28, 1986	24
IV. Addendum - April 18, 1991	26
Exhibit A - The Belmont Report	28
Exhibit B - Title 45, Code of Federal Regulations, Part 46 Protection of Human Subjects	37
- Clarification: Emergency Medical Care OPRR Report Number 91-01	56
Exhibit C - Form 441, Alcohol, Drug Abuse, and Mental Health Administration	60
Exhibit D - Quarterly Surveillance Form	63
Exhibit E - Membership of the Midwest Research Institute Human Subjects Committee	65

The original document defining this institution's Multiple Projects Assurance was approved on July 1, 1982. The document was revised as indicated in Section III and reapproved on July 1, 1986. Current changes in institutional policies and procedures are addressed in Section IV. A revised membership list of the Midwest Research Institute Human Subjects Committee is provided in Exhibit E.

Changes summarized in the addenda of March 28, 1986, and April 18, 1991, are noted in the margins of the text by an asterisk (\*).

**MIDWEST RESEARCH INSTITUTE**

425 Volker Boulevard  
Kansas City, Missouri 64110  
Telephone (816) 753-7600  
Telefax (816) 753-8420

June 21, 1993

Paul Gailey  
Oak Ridge National Laboratory  
P.O. Box 2008, MS 6070  
Oak Ridge, TN 37831

**Subject: MRI Proposal "Effects of Electric and Magnetic Fields on Humans"**

Dear Mr. Gailey:

I have enclosed a copy of Midwest Research Institute's documentation of the Human Subjects Committee review and approval in connection with the proposed study under consideration by Oak Ridge. Please include this in your file for the record.

Sincerely,

MIDWEST RESEARCH INSTITUTE

A handwritten signature in black ink, appearing to read "R. Donaldson", written in a cursive style.

Robert Donaldson, Director,  
Contracts and Facilities Services

RD:mw

Enclosure

1022040

**MIDWEST RESEARCH INSTITUTE  
INTEROFFICE MEMORANDUM**

June 18, 1993

**TO:** Bob Donaldson  
**FROM:** Gene Podrebarac  
Chairman, MRI Human Subjects Committee  
**SUBJECT:** MRI Project No. RA-111  
Neurobehavioral Effects of EMF Exposures

\*\*\*\*\*

- TASK 1:** Effects of EMF Exposure on Cardiovascular Functions
- TASK 2:** Magnetic Field Exposure Effects on EEG Measurer of Human Sensory and Cognitive Functions

The above proposed studies are an extension of studies previously approved by the Committee. The new studies will use previously approved procedures at exposure levels the same as presently used. The Committee was sent the appropriate background information, statement of work, volunteer informed consent form and the Form ADM 441 for review. The Committee members were requested to document (by mail) their approved, disapproval or request for review of the proposed study at a convened meeting of the HSC.

The Committee unanimously approved the activity plan and informed consent form.

Please call me if you have any questions.

MRI HSC Assurance Identification No: M1051  
IRB Identification No. 01

*Eugene G. Podrebarac*

Eugene G. Podrebarac, Ph.D  
Chairman, HSC

*June 18, 1993*

Date

CC: Dr. Charles Graham  
RA-111 File

1022041

OMB No. 0925-0037

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PROTECTION OF HUMAN SUBJECTS  
ASSURANCE/CERTIFICATION/DECLARATION

GRANT     CONTRACT     FELLOW     OTHER  
 New     Competing continuation     Noncompeting continuation     Supplemental

ORIGINAL     FOLLOWUP     EXEMPTION  
(previously undesignated)

APPLICATION IDENTIFICATION NO. (if known)

**POLICY:** A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless an Institutional Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act as implemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46--as revised). The applicant institution must submit certification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) which applies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the proposed activity should submit certification of IRB review and approval with each application. (In exceptional cases, certification may be accepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have an assurance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request from HHS for certification.

1. TITLE OF APPLICATION OR ACTIVITY

Effects of EMF Exposure on Humans

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

Dr. Charles Graham

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (see reverse side)

4. HHS ASSURANCE STATUS

This institution has an approved assurance of compliance on file with HHS which covers this activity.

M1051 Assurance identification number    01 IRB identification number

No assurance of compliance which applies to this activity has been established with HHS, but the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request.

5. CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION

This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This certification fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device. (See reverse side of this form.)

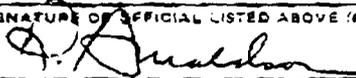
June 18, 1993 Date of IRB review and approval. (If approval is pending, write "pending." Followup certification is required.)  
(month/day/year)

Full Board Review     Expedited Review

This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated and that appropriate further certification (Form HHS 598) will be submitted.

Human subjects are involved, but this activity qualifies for exemption under 46.101(b) in accordance with paragraph \_\_\_\_\_ (insert paragraph number of exemption in 46.101(b), 1 through 3), but the institution did not designate that exemption on the application.

6. Each official signing below certifies that the information provided on this form is correct and that each institution assumes responsibility for assuring required future reviews, approvals, and submissions of certification.

APPLICANT INSTITUTION	COOPERATING INSTITUTION
NAME, ADDRESS, AND TELEPHONE NO. Midwest Research Institute 425 Volker Boulevard Kansas City, MO 64110	NAME, ADDRESS, AND TELEPHONE NO.
NAME AND TITLE OF OFFICIAL (print or type) Robert Donaldson, Director Contracts and Facilities Services	NAME AND TITLE OF OFFICIAL (print or type)
SIGNATURE OF OFFICIAL LISTED ABOVE (and date) 	SIGNATURE OF OFFICIAL LISTED ABOVE (and date)

1022042

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (from front side)

According to 45 CFR 16.121, if an application is made to HHS requiring certification and involving use of an investigational new drug or device, additional information is required. In addition, according to 21 CFR 312.1(a)(2), 30 days must elapse between date of receipt by FDA of Form FD-1571 and use of the drug, unless the 30 day delay period is waived by FDA.

3a. INVESTIGATIONAL NEW DRUG EXEMPTION (if more than one is involved, list others below under NOTES).

SPONSOR NAME

DRUG NAME

DATE OF END OF 30-DAY EXPIRATION OR WAIVER

NUMBER ISSUED

3b. INVESTIGATIONAL DEVICE EXEMPTION

SPONSOR NAME

DEVICE NAME

Unless notified otherwise by FDA, under 21 CFR 812.2(b) (ii) a sponsor is deemed to have an approved IDE if: (1) the IRB has agreed with the sponsor that the device is a nonsignificant risk device, and (2) the IRB has approved the study. (Check applicable box.)

The IRB agrees with the sponsor that this device is a nonsignificant risk device.

OR

The IDE application was submitted to FDA on (date) \_\_\_\_\_ Number issued \_\_\_\_\_.

NOTES

PROJECT NO. 1111-05

## VOLUNTEERS' INFORMED CONSENT

I, \_\_\_\_\_ residing at

\_\_\_\_\_  
hereby acknowledge and certify to the following:

1. I hereby volunteer and consent to be a subject in a research study sponsored by the Department of Energy and directed at Midwest Research Institute (MRI), by Dr. Charles Graham and Mr. Harvey D. Cohen. I understand this study will determine if exposure to magnetic fields at levels (200 mG) found in the home and workplace has any effect on human physiology and performance. I understand there are no known health risks associated with the brief periods of exposure I may experience.

I understand my participation will involve coming to MRI for a brief familiarization session, and then for an all-morning exposure test session. The familiarization session will last about an hour. I will complete various questionnaires, have recording sensors attached to my chest and arm to measure physiological activity (heart rate, blood pressure, respiration, etc.), and I will practice the procedures for taking these measures several times. I understand these procedures and measures are not painful or hazardous to my health.

I will then come to MRI for an exposure test session lasting from 8 am to about 12:30 pm. I am aware that this study includes a comparison group that will not be exposed to the magnetic fields, and that during my test session the fields may or may not be turned on. On arrival at the lab, I will complete the questionnaires and have the recording sensors attached as in the familiarization session. I will then remain seated in the exposure facility for the rest of the morning (reading material will be provided). At intervals, the measures I practiced earlier will be taken.

I agree to not use alcohol for 24 hours prior to the test session. I know this is a basic research study not designed to benefit me personally, and that I will receive a total of \$50.00 for my participation if I complete all study requirements; if not, I will be paid \$5.00 for each hour of scheduled participation.

2. I have been given, in my opinion, an adequate explanation of the nature, duration, and purpose of the experiment, the means by which the experiment will be conducted, and any possible inconvenience, hazards, discomfort, risks, and adverse effects on my health which could result from my participation.

OVER

1022044

3. I understand my questions concerning procedures which affect me will be answered fully and promptly by either Dr. Charles Graham, Principal Investigator, or by Dr. Eugene Podrebarac, Chairman of the MRI Human Subjects Committee, which reviewed and approved this study (816/753-7600).

4. I understand that I have the right to withdraw my consent and to discontinue participation in this experiment at any time without prejudice regardless of the status of the experiment and regardless of the effect of such withdrawal on the objectives and results of the experiment; and I also understand that my participation in the experiment may be terminated at any time by the investigator in charge of the project.

5. I agree that any information obtained from me, by MRI, or its authorized representatives, in connection with this study may be utilized by MRI in publications and reports without identifying me.

6. I hereby certify that the medical-history information that I provide to MRI is complete and correct to the best of my knowledge, and that I have informed MRI staff of all serious or chronic medical problems that I now have or have had.

7. If I am injured as a result of participation in this study, MRI will pay for immediate emergency medical treatment. Beyond its emergency care payment, it is MRI's policy to pay for only those costs for which MRI is legally responsible.

8. My age is \_\_\_\_; The date of my birth is \_\_\_\_\_, 19\_\_.

I am executing this Volunteer's Consent as my free act and deed.

Today's date is \_\_\_\_\_, 19\_\_

Executed in the presence of each other

\_\_\_\_\_  
Signature of Volunteer

\_\_\_\_\_  
Signature of Experimenter

Accepted; ID \_\_\_\_\_  
DOE 111-05  
SCREENING INFORMATION

Interviewer: \_\_\_\_\_ Date: \_\_\_\_\_  
Name: \_\_\_\_\_ Phone: (H) \_\_\_\_\_ (W) \_\_\_\_\_  
Address: \_\_\_\_\_  
\*Age: (18-35) \_\_\_\_\_ Sex: \_\_\_\_\_ Birthdate: \_\_\_\_\_ Height: \_\_\_\_\_  
Weight: \_\_\_\_\_ Educational level/Major \_\_\_\_\_  
Source: \_\_\_\_\_

Have you participated in research studies before? \_\_\_ No \_\_\_ Yes  
(describe) \_\_\_\_\_

Do you work nights? \_\_\_ No \_\_\_ Yes\*  
(describe) \_\_\_\_\_

In the last six months, have you taken any medication regularly?  
\_\_\_ No \_\_\_ Yes\* (describe) \_\_\_\_\_

Do you now take any medication? \_\_\_ No \_\_\_ Yes\*  
(describe) \_\_\_\_\_

Do you smoke cigarettes or use tobacco? \_\_\_ No \_\_\_ Yes  
(describe) \_\_\_\_\_

Are you on any type of special diet? \_\_\_ No \_\_\_ Yes  
(describe) \_\_\_\_\_

Do you have any chronic health problems? \_\_\_ No \_\_\_ Yes\*  
(describe) \_\_\_\_\_

Has a doctor ever told you that you had any problem with your heart  
or blood pressure? \_\_\_ No \_\_\_ Yes\* (describe) \_\_\_\_\_

OVER

Have you ever had surgery?  No  Yes  
(describe) \_\_\_\_\_

Have you ever had any kind of head injury which made you unconscious,  
even for a few seconds?  No  Yes (describe) \_\_\_\_\_

Have you ever had any seizures or attacks?  No  Yes\*  
(describe) \_\_\_\_\_

Do you have any allergies?  No  Yes (describe) \_\_\_\_\_

In the last 3 months, have you been sick at all?  No  Yes  
(describe) \_\_\_\_\_

Not even a cold or the stomach flu or something like that?  No  
 Yes (describe) \_\_\_\_\_ Bed? \_\_\_\_\_ How long? \_\_\_\_\_

Since this study runs only in the morning, is any particular morning better  
than another for you?  
\_\_\_\_\_  
\_\_\_\_\_

Do you have any questions?

OK, good. I'll get back in touch with you as soon as we have reviewed  
this information and worked out a schedule. When is a good  
time to call you back? \_\_\_\_\_  
\_\_\_\_\_

Reviewed by: \_\_\_\_\_ on \_\_\_\_\_ Accept  Reject

\*possible reason for exclusion from participation; IF DOES NOT MEET  
CRITERIA, INFORM VOLUNTEER OF THAT FACT, ASK IF NAME SHOULD BE KEPT  
ON LIST FOR STUDIES WHICH DO NOT REQUIRE THE PARTICULAR RESTRICTION;  
DO NOT CONTINUE WITH SCREENING

## ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

## PROTECTION OF HUMAN SUBJECTS

<b>PROJECT TITLE:</b>	FURTHER STUDIES OF 60-HZ EXPOSURE EFFECTS ON HUMAN FUNCTION	<b>PROJECT NO.</b> RA-111
<b>CHARACTERISTICS OF GROUP(S):</b>	<p>Describe the characteristics of the group(s) to be used: <i>(If additional space is needed for an item, use a separate sheet)</i></p> <p>(a) Sex, race or ethnic group, age, range, etc. Men between the ages of 18 and 35</p> <p>(b) Affiliation of subjects, e.g., institutions, hospitals, general public, etc. Local colleges, universities, research institutes, general public</p> <p>(c) Subjects' general state of health <i>(mental and physical)</i> No physical or mental disease, nonsmoker</p>	
<b>SPECIAL GROUPS:</b>	<p>If human subjects are either children, mentally incompetent, or legally restricted groups, give explanation as to:</p> <p>(a) The necessity for using these particular groups N/A</p> <p>(b) Why adult "normal" groups cannot be used <i>(specifically)</i> N/A</p>	
<b>TYPE OF CONSENT:</b>	<p>What precautionary measures will be taken to insure the protection of human subjects on physical, psychological, social, legal and other issues?</p> <p>(a) Type of consent to be obtained <i>(written or oral)</i> Oral at time of recruitment. Written obtained prior to first session.</p> <p>(b) How and where will permission be recorded By principal investigator or designate at MRI</p> <p>(c) If subjects are minors or mentally incompetent, describe how and by whom permission will be granted N/A</p>	
<b>CONFIDENTIALITY OF DATA:</b>	<p>What precautions will be taken to safeguard identifiable records of individuals? These questions also apply if you are using secondary sources of data</p> <p>(a) Consider the long range use of data <i>(by you and others)</i> Individuals will not be identified in project publications and reports, and consent forms will be destroyed 3 yrs after project completion.</p> <p>(b) Immediate use of data <i>(by you and others)</i> All data will be number coded; access to data with ID information will be limited to project staff.</p> <p>(c) Describe specific procedures to be used to provide confidentiality of data Same as (a) and (b) above.</p>	

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**RISKS TO SUBJECTS:**

Describe in detail any physical, psychological, social, legal, economic or other risks you can foresee, both immediate and long range:

**(a) Immediate risks**

The risks are minimal. The procedures and exposure conditions have been approved for use in previous studies. No known health risks are associated with the brief exposure conditions planned. Heart rate changes seen in previous studies have been within the normal range.

**(b) Long range:**

There are no long-term risks associated with the proposed procedures.

**(c) Rationale for the necessity of such risks**

In our previous research, exposure to 60-Hz magnetic fields was associated with changes in heart rate. In this study we will determine if exposure also induces changes in other important cardiovascular parameters (e.g., ECG, blood pressure) and if some people are more responsive than others.

**(d) Alternatives that were or will be considered**

Studies performed in the work environment.

**(e) Why alternatives may not be feasible**

Inadequate control over exposure and monitoring conditions.

**NON-BENEFICIAL RESEARCH:**

"Non-Beneficial Research" is defined as research involving physiological and psychological investigations of a person, his body or surroundings, which is devoid of therapeutic purpose to that person. If you plan to conduct this type of research and feel that there are no other methods available for obtaining the information needed, please describe:

**(a) What other methods were or will be explored**

See (d) and (e) above.

**(b) The extent of the risks (Describe in detail any physical, psychological, social, legal and other risks you can foresee, both immediate and long range)**

The risks are minimal.

**(c) The importance of the knowledge gained.**

The public is continuously exposed to 60-Hz magnetic fields in the home and workplace. It is important to determine if such exposure has effects on the cardiovascular system, and if individuals differ in their response to exposure.

**(d) Why you feel the value of the information to be gained outweighs the risks.**

The risks are minimal compared to the importance of identifying potential risks in the large population.

**ADDITIONAL COMMENTS:**

Signature

Date

## TEL-SCRIPT FOR DOE SUBJECTS

Thanks for calling. Let me tell you about the study we are doing. This study is funded by the Department of Energy. We want to find out if physiological activity like heart rate, blood pressure and respiration is affected by exposure to magnetic fields similar to those you would find in your home or at work.

To be in the study you need to be able to come to MRI for a morning session lasting from 8 am to about 12:30 pm. We ask that you not use alcohol for 24 hours prior to the session. On arrival at the lab, you will complete some questionnaires and have recording sensors attached to your chest and hand. You will remain seated in the facility all morning, and at different times we will ask you to sit quietly with your eyes closed so that we can record some physiological measures. When we are not taking measurements, you are free to sit quietly and read.

Not all people will be exposed to the fields in this study; for those who are exposed there are no known health risks associated with the brief periods of exposure we will be using. Probably the major benefit, aside from being in an interesting study, is that you will be paid for your participation. You will receive \$ 50.00 for completing the session.

Do you have any questions?  
[answer questions]

Would you like to participate in this study?

IF NO - OK, I can understand that \_\_\_\_ (rephrase reason). We sometimes have studies which do not involve \_\_\_\_; would you like me to keep you on the list so that we can call you if a study like that comes up?

IF YES - good. I need to ask you a few questions to make sure you meet all the criteria for the study. Do you have a few more minutes now? (If not, arrange time for call back).

GO TO SCREENING INFORMATION FORM

1022050

# MIDWEST RESEARCH INSTITUTE

## MEN NEEDED FOR RESEARCH PROJECT

MEN IN GOOD HEALTH BETWEEN THE AGES OF 18 AND 35 ARE NEEDED FOR A HALF-DAY RESEARCH STUDY. THE AIM OF THE STUDY IS TO FIND OUT IF EXPOSURE TO MAGNETIC FIELDS AT LEVELS COMMONLY FOUND IN THE HOME OR WORKPLACE HAS ANY SHORT-TERM INFLUENCE ON HEART RATE OR BLOOD PRESSURE. PARTICIPANTS WILL COME TO MRI FOR ONE MORNING SESSION LASTING FROM 8AM TO AROUND NOON.

**PAYMENT IS \$50.00.**

**FOR INFORMATION CALL:**

**753-7600**

**DON RIFFLE (EXT 341) OR JOE McCLERNON (EXT 674)**

1022051

**FURTHER STUDIES OF 60-HZ EXPOSURE EFFECTS ON HUMAN FUNCTION**

MRI Project No. RA-111

For

Department of Energy

**INTRODUCTION**

Our laboratory studies with human volunteers have repeatedly shown that exposure to 60-Hz electric and magnetic fields has an influence on heart rate. Continuous exposure to the fields slows the heart; intermittent exposure can result in both speeding and slowing. These effects appear to be due more to the magnetic field than to the electric field. People also seem to differ in their response to exposure, and we have found that a person's resting heart rate prior to exposure can be a significant predictor of how they will respond when exposed.

The effects found on heart rate may be a reflection of more important effects occurring elsewhere in the cardiovascular system. We believe it is most important to identify the underlying control mechanisms responsible for the cardiac effects we have seen. The study described here involves making detailed measurements of electrocardiographic activity, blood pressure and respiration during exposure to magnetic fields. The results will help us understand how (or if) exposure influences the electrical potentials generated by the heart or the timing of significant events in the heart cycle, and they will provide preliminary data on the other measures.

The proposed procedures and exposure conditions are similar to those approved for use in our previous studies. The research will be performed in the 60-Hz Human Exposure Test Facility at MRI by staff of the Biobehavioral Sciences Section, headed by Dr. Mary R. Cook. Dr. Charles Graham and Mr. Harvey D. Cohen will serve as co-principal investigators. We request approval of the activity plan and consent form for the study described below.

## STUDY DESCRIPTION

**Human Subjects:** Sixty, healthy young men (aged 18 to 35, no chronic disease or disability, nonsmoker) will be recruited from local colleges, universities, research institutes and the general public for paid participation in the study. Written informed consent will be obtained prior to participation.

**Experimental Design and Procedures:** Subjects will participate initially in a brief 1-hr session to become familiar with the physiological recording procedures, and to provide baseline cardiovascular data. They will complete self-rating scales designed to measure mood and alertness. Vital signs (blood pressure, temperature, pulse) will be recorded. Recording sensors will be attached to the chest and arm to measure the electrocardiogram (ECG), heart rate, blood pressure, respiration, and oxygen saturation. Measures will be taken several times to allow the subject to become familiar with the recording procedures. Subjects with blood pressure or ECG irregularities will not be continued in the study.

Subjects will then be assigned at random to either a sham exposure group (30 men), or a magnetic field exposure group (30 men). Individual differences in heart rate will be equally represented in each group. Each subject will come to MRI for a morning (8 am to 12:30 pm) exposure test session. They will be instructed to eat balanced meals and to not drink alcohol for 24 hours before the session. After collection of self-report and vital sign data, the physiological recording sensors will be attached as in the familiarization session. The subject will then sit reading in the exposure facility for three hours. For subjects in the sham exposed group, the magnetic field will not be turned on during this period. For subjects in the field-exposed group, exposure to the magnetic field will be intermittent. Exposure will comprise alternating 45-minute "field-on" and "field-off" periods. During "field-on" periods, the magnetic field will cycle on and off every 15 seconds. During "field-off" periods, the generating equipment will not be turned on. Magnetic field strength will be 200 mG. The study will be performed double blind, and physiological measures will be obtained at multiple matched points throughout sham and field exposure.

The field exposure conditions in this study are the same as those approved for use in our previous studies. The physiological recording procedures have also been approved for use in previous studies and present no risk to human subjects.

DOE 111-05  
VOLUNTEER EXCLUSION CRITERIA

EXCLUDE VOLUNTEERS:

- \* IF THEY ARE NOT 18 TO 35 YRS OF AGE.
- IF THEY ARE NOT MALE.
- IF THEY WORK NIGHTS (AFTER 10 PM).
- LOOK UP ANY PRESCRIBED MEDICATION IN PDR, CHECK WITH PI.
- \* IF THEY HAVE TAKEN MEDICATION REGULARLY IN THE LAST 6 MONTHS.
- CHECK CHRONIC HEALTH PROBLEMS WITH PI.
- IF THEY HAD BRAIN SEIZURES OR ATTACKS.
- \* IF THEY HAVE HEART OR BLOOD PRESSURE PROBLEMS.

1022054

1111-05

INTERCOM INSTRUCTIONS  
CARDIAC MEASUREMENT TASK

HI (SUBJECT NAME). CAN YOU HEAR ME OK? GOOD.

WE WILL BE TAKING A BASELINE MEASUREMENT IN THE NEXT FEW MINUTES. SO GET YOURSELF INTO A RELAXED AND COMFORTABLE POSITION IN THE CHAIR.

KEEP YOU BACK FLAT AGAINST THE CHAIR AND YOUR FEET STRAIGHT OUT ON THE FOOTSTOOL. DURING THE MEASUREMENT, BE SURE YOUR EYES ARE CLOSED AND YOUR ARMS ARE RESTING COMFORTABLY ON THE ARMS OF THE CHAIR. TRY NOT TO PUT ANY PRESSURE ON THE FINGER SENSORS (MONITOR/CORRECT POSITION IF NEEDED).

WE'LL RECORD FOR ABOUT 3 MIN -- THEN GIVE YOU A SHORT BREAK - AND THEN RECORD FOR ANOTHER 3 MIN. I'LL TELL YOU WHEN WE ARE READY TO START.

DURING 30-SEC BREAK

OK (NAME). THAT ENDS THE FIRST MEASUREMENT. TAKE A LITTLE BREAK. I'LL LET YOU KNOW WHEN WE ARE READY TO START AGAIN.

AFTER 2ND CM3

OK (NAME). EVERYTHING LOOKS FINE. WE GOT A GOOD RECORDING. YOU CAN READ AND RELAX NOW. I'LL GET BACK TO YOU IN ABOUT A HALF AN HOUR.

1022055

**RA-01115-05****ELECTRODE PLACEMENT and CHANNELS**

<u>ELECTRODE NUMBER</u>	<u>LOCATION</u>
4	Index finger
5	Ring finger
6	Upper right chest
8	Upper left chest
9	Left clavicle
10	Right clavicle
11	Left lower chest

---

<u>CHANNEL BECKMAN</u>	<u>FUNCTION</u>	<u>LEAD SELECTOR</u>	<u>PREAMP</u>
1	HR	nc	.05V/mm
2	Finger pulse	nc	.2V/mm
3	ECG II	10-11	.1mV/mm
4	Respiration	nc	.5mv/mm
5	Skin Conductance	5-6	1mv/mm
6	ECG I	10-9	.1mV/mm
7	ECG III	9-11	.1mV/mm
8	Marker	nc	.5V/mm

102205b

**Notice:**

Preliminary approval has been received for this proposed work from the ORNL Human Subjects Committee (see attached letter from the chairman). Paperwork is now submitted to the committee for final approval, and the approval documentation will be forwarded to contracting as soon as it is received.

1022057



**ASSURANCE OF COMPLIANCE WITH  
HHS REGULATIONS FOR THE PROTECTION  
OF HUMAN RESEARCH SUBJECTS**

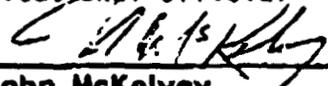
**April 18, 1991**

**Midwest Research Institute  
425 Volker Boulevard  
Kansas City, Missouri 64110**

1022058

Institutional Endorsement and HHS Approval

A. Authorized Institutional Official

Signature:  Date: 4/18/91  
 Name: John McKelvey  
 Title: President & Chief Executive Officer  
 Address: Midwest Research Institute  
325 Volker Boulevard  
Kansas City, Missouri 64110  
 Phone: 816/753-7600, Extension 203

B. Primary Contact (Indicate if same)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
 Name: Same as above  
 Title: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 Phone: \_\_\_\_\_

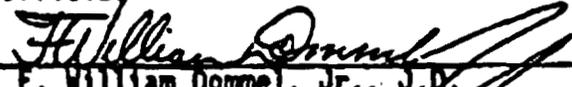
C. HHS Recommending Official

Signature:  Date: 4/29/91  
 Name: Katherine Duncan, M.D.  
 Title: Adjunct Medical Officer  
 Address: NIH, OPRR - 9000 Rockville Pike  
Bldg. 31, Room 5B59  
Bethesda, MD 20892  
 Phone: (301) 496-7005

D. Effective Date of Assurance 7/1/91

E. Expiration Date of Assurance 6/30/96

F. HHS Approving Official

Signature:  Date: 4/30/91  
 Name: F. William Donnel, Jr., J.D.  
 Title: Dir., Div. of Human Subject Protections  
Office for Protection from Research  
Risks, OER

## MIDWEST RESEARCH INSTITUTE

### Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects

Midwest Research Institute, hereinafter referred to as "institution," hereby gives assurance that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended) as specified below.

Institutional Endorsement and HHS Approval	11
I. Statement of Applicability, Principles, and General Policies	1
II. Implementation	6
III. Addendum - March 28, 1986	24
IV. Addendum - April 18, 1991	26
Exhibit A - The Belmont Report	28
Exhibit B - Title 45, Code of Federal Regulations, Part 46 Protection of Human Subjects	37
- Clarification: Emergency Medical Care OPRR Report Number 91-01	56
Exhibit C - Form 441, Alcohol, Drug Abuse, and Mental Health Administration	60
Exhibit D - Quarterly Surveillance Form	63
Exhibit E - Membership of the Midwest Research Institute Human Subjects Committee	65

The original document defining this institution's Multiple Projects Assurance was approved on July 1, 1982. The document was revised as indicated in Section III and reapproved on July 1, 1986. Current changes in institutional policies and procedures are addressed in Section IV. A revised membership list of the Midwest Research Institute Human Subjects Committee is provided in Exhibit E.

Changes summarized in the addenda of March 28, 1986, and April 18, 1991, are noted in the margins of the text by an asterisk (\*).

## INTEROFFICE MEMORANDUM

Date: 19-Aug-1993 04:13pm  
From: M J Harris  
M Harris@8-MJ@4-PROC  
Dept: Town  
Tel No:

TO: Steve Morrell ( MORRELLSW@A1@ADM )  
TO: Karen Edwards ( EDWARDSKC@A1@ADM )  
TO: Shirley Vogel ( VOGELSC@A1@ADM )

Subject: RESEARCH ON HUMAN SUBJECTS

Karen: Shirley Vogel asked me to send this to you. It's a draft procurement procedure dealing with subcontracts involving research on human subjects. This topic is covered by DOE Order 1300.3, which now needs to be activated (if that's the term).

Shirley and Steve: This is the draft that I mentioned this morning. It was put together hastily, but I thought that it was about ready to go. Then our contact at the Lab sent me the DOE Handbook, which in the brief time that I've had to look at it seems to require a whole lot more than the regs or the Order.

You'll see in the very rough "Procedure" section toward the end that there's a lot that needs to be clarified with the Lab people.

PROCUREMENTS INVOLVING RESEARCH ON HUMAN SUBJECTS

4.16-1. PURPOSE

This chapter establishes procedures applicable to procurements involving research on human subjects.

4.16-2. REFERENCES

(a) DOE Regulation 10 CFR 745, "Protection of Human Subjects."

(b) DOE Order 1300.3, "Policy on the Protection of Human Subjects."

(c) DOE Handbook, "Protecting Human Research Subjects at the Department of Energy."

4.16-3. APPLICABILITY

(a) General. This chapter applies to procurements of

research on "human subjects." The term human subject is defined in 10 CFR 745.102 as "a living individual" about whom a researcher obtains either "data through intervention or interaction" or "identifiable private information."

(1) "Intervention" means physical procedures (e.g., medical tests) and also manipulation of the individual or the individual's environment. "Interaction" includes written or oral communications.

(2) "Private information" is information that an individual can reasonably expect (i) is not being observed or recorded or (ii) will not be made public (e.g., a medical record). Private information is "identifiable" when the identity of the subject is or may be readily ascertained by the researcher or associated with the private information.

(b) Exceptions. This chapter does not apply to the following types of research:

(1) Research conducted in educational settings and involving normal educational practices, such as research on the effectiveness of instructional techniques or curricula;

(2) Research involving the use of educational tests, surveys, interviews, or observations of public behavior unless:

(i) The human subjects are public officials or candidates for public office, or

(ii) The information obtained is recorded in such a manner that the human subjects could be identified and disclosure of their responses could place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation;

(3) Research involving the collection or study of existing, publicly available data, documents, or pathological or diagnostic specimens, if the information obtained is recorded by the investigator in such a manner that the human subjects cannot be identified; or

(4) Evaluations of the taste, quality, or consumer acceptance of food, if (i) wholesome foods without additives are consumed, or (ii) food is consumed that contains ingredients, agricultural chemicals, or environmental contaminants at or below levels found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

#### 4.16-4. GENERAL INFORMATION

(a) Two Sequential Steps. The DOE regulations appearing in

10 CFR 745 (which are essentially identical to regulations adopted by all Federal agencies and departments) establish two sequential requirements [for "assurance" and "certification"--discussed in paragraphs (b) through (d) below] that must be met before Federal funds can be expended for research on human subjects.

(b) Assurance. "Assurance" means a written promise by a prospective subcontractor that it will comply with the policy of 10 CFR 745 when conducting research on human subjects. The DOE and other agency regulations provide that, as a minimum, an assurance must include:

(1) A statement of principles for protecting the rights and welfare of human subjects of research;

(2) The designation of an "institutional review board" (IRB) that will have the authority to approve, require modifications to, and disapprove all the institution's research on human subjects;

(3) The resumes of IRB members;

(4) Procedures to be followed by the IRB; and

(5) The institution's procedures for reporting to the IRB and Federal agencies unanticipated risks to subjects, violations of the policy in 10 CFR 745 or other comparable regulations, or suspensions or terminations of IRB approvals.

(c) Approval of Assurances. (1) All assurances must be approved by the Government. Approval can be granted either by the agency sponsoring the research or by the U.S. Department of Health and Human Services. Approval by HHS may be on behalf of all Government agencies.

(2) Research institutions commonly submit their assurances to HHS in advance and independently of any particular procurement. Other agencies are prohibited by regulation from requiring the submission of an assurance by institutions that have a current assurance applicable to the agencies' research approved by HHS for Government-wide use.

(d) Certification. "Certification," the second sequential step, is an official notification by the institution that a specific research project involving human subjects has been reviewed and approved by the institution's IRB in accordance with a previously approved assurance and will be subject to continuing review by the IRB. A certification is therefore generally submitted with a proposal to perform the research.

[Note: See DOE Handbook Section 3. Handbook appears to have additional requirements beyond those mentioned in the regs. Handbook seems also to require that DOE must approve

"experimental protocol," "informed consent" forms, and a "Project Data Summary."]

4.16-5. PROCEDURE (rough outline)

(a) Buyer reviews statement of work to determine whether involves research on human subjects. Where unclear, decide in consultation with [Manager, Policies and Procedures and (?)] Associate Laboratory Director for Life, Environmental, and Social Sciences.

(b) [Question: If ORNL/ORAU committee approval required even though research on human subject will be done by subcontractor, do we need copy of committee approval for subcontract file? Should it be sent to DOE?]

(c) [Question: Should Buyer always send DOE advance notice of unusual procurement? If sent, probably a good idea to include assurance (or evidence of assurance), certification, and possibly "informed consent" forms if these are available--as they might be in sole-source procurement. (Also need to check DOE Handbook on whether additional forms required--e.g., experimental protocol, Project Data Summary.) Otherwise say in advance notice that these will be forwarded later.]

(d) Insert provision such as this in RFP:

The work under the subcontract expected to result from this solicitation involves research on human subjects that is governed by DOE regulations appearing at 10 CFR 745.

In accordance with 10 CFR 745.103(b) and 745.122, [and the DOE Handbook entitled "Protecting Human Research Subjects at the Department of Energy?"] the subcontract can only be awarded to an offeror that has an approved assurance (see 10 CFR 745.103), certification (see 10 CFR 745.103(f)), experimental protocol, and "informed consent" forms.

If offeror has assurance approved by HHS for Government-wide use, then send evidence to that effect and also send certification [and experimental protocol, informed consent forms, and Project Data Summary?].

If offeror does not have approved assurance, then send both assurance [request for approval of assurance?] and certification [and experimental protocol? Informed consent forms? Project Data Summary?].

(e) Include clause such as this in draft subcontract

included in RFP and in final subcontract:

The Seller shall comply with DOE regulations appearing at 10 CFR 745 in the performance of research on human subjects.

Informed consent of subjects shall be obtained as required by 10 CFR 745.116 and documented in accordance with 10 CFR 745.117.

The records maintained by the Seller in accordance with 10 CFR 745.115 shall also be available for inspection and copying by the Company at reasonable times and in a reasonable manner.

Suspensions or terminations of approvals of research issued by the Seller's institutional review board in accordance with 10 CFR 745.113 shall also be reported promptly to the Company.

The Company may terminate this subcontract for default if it finds that the Seller has materially failed to comply with 10 CFR 745.

(e) [Question: Should Buyer check assurance against minimum requirements in 4.16-4(b) above and notify offeror if there are obvious omissions?]

(f) Buyer sends assurance (or evidence of approval of assurance), certification, any other required forms (experimental protocol, informed consent, Project Data Summary?) from apparently successful offeror to DOE [question: ORNL/ORAU committee approval required before send to DOE?] for approval. [Good idea for letter to say that is is being sent in order to obtain DOE approval required by DOE Order 1300.3. Letter should also mention that the procurement was the subject of advance notice sent earlier to DOE.]

(g) Buyer awards subcontract upon receipt of notification from DOE of approval of assurance, certification, etc.

\* \* \* \*

That's it.

Nike Harris

1022065

ER-111:Clark

**APPROVAL OF MIDWEST RESEARCH INSTITUTE CONTRACT, SN602**

Steve Morrell, Procurement and Contracts Division, AD-42, ORO

Energy Programs is recommending approval of the subject contract based on conversations with Imre Gyuk, EE-141. Midwest Research Institute was able to provide proof that their research program is approved by the National Institute of Health (NIH) which, according to Mr. Gyuk, satisfies Department of Energy requirements. As requested by Mr. Gyuk, copies of the approval letter from NIH, along with a copy of the procurement package, have been forwarded to Dr. Susan Rose, ER-72, for her information.

If you have any questions, please call Harold Clark at 576-0823. When replying, please refer to 93-1353.

*Martha J. Kass*

Martha J. Kass, Acting Director  
Energy Programs Division

cc:  
Paul Gailey, ORNL

HClark:6-0823:ap:6-3278:8/31/93:1353.ap

Concurrence

Rtg Symbol

ER-111

Initials/Sig

HC *[Signature]*

Date

9/3/93

Rtg Symbol

ER-111

Initials/Sig

GLR *[Signature]*

Date

9/3/93

Rtg Symbol

ER-111

Initials/Sig

MJK *[Signature]*

Date

9/1/93

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FILE CODE 42200

1022066

United States Government

Department of Energy  
Oak Ridge Field Office

# memorandum

DATE: September 8, 1993

REPLY TO  
ATTN OF: ER-111:Clark

SUBJECT: APPROVAL OF MIDWEST RESEARCH INSTITUTE CONTRACT, SN602

TO: Steve Morrell, Procurement and Contracts Division, AD-42, ORO

Energy Programs is recommending approval of the subject contract based on conversations with Imre Gyuk, EE-141. Midwest Research Institute was able to provide proof that their research program is approved by the National Institute of Health (NIH) which, according to Mr. Gyuk, satisfies Department of Energy requirements. As requested by Mr. Gyuk, copies of the approval letter from NIH, along with a copy of the procurement package, have been forwarded to Dr. Susan Rose, ER-72, for her information.

If you have any questions, please call Harold Clark at 576-0823. When replying, please refer to 93-1353.

  
Martha J. Kass, Acting Director  
Energy Programs Division

cc:  
Paul Gailey, ORNL

1022067