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STATEMENT OF WORK

FOR

BIOPHYSICAL RESEARCH AND ANALYSIS

1.0 (S/NF) PURPOSE: The purpose of this effort is to perform biophysical research and analysis on neuromagnetic phenomena.

2.0 (S/NF) BACKGROUND: The FY 1991 Defense Authorization Act identified DIA as executive agent of a new program for examining anomalous phenomena. One of the areas of specific interest was based on results from an earlier DOD sponsored research effort involving brain neuromagnetic responses to various visual or visual-related stimuli. This pilot work was performed by the Biophysical Group at the Los Alamos National Laboratory (LANL), Los Alamos, NM, as part of an Army research effort under the Surgeon General's Research and Development (SGRD) office.

3.0 (S/NF) OBJECTIVE: This statement of work is based on findings from the previous LANL research on this topic. Primary objective of this effort is to identify correlations of brain neuromagnetic responses to a variety of independent conditions or parameters.

4.0 (S/NF) SCOPE: This activity will replicate previous results, will recalibrate the experimental environment, will search for possible artifacts and will initiate new systematic research. This new research will include a variety of population groups and will examine a variety of possible physical variables. All the measurements will be based on passive magnetoencephalograph (MEG) recording instrumentation.

5.0 (U) TECHNICAL/OTHER CONSIDERATIONS:

5.1 (S/NF) This effort is part of a larger external investigation effort in this general phenomenological area that includes a DIA contractor, the Science Applications International Corporation (SAIC). The SAIC program manager for this effort, Dr. Ed May, had been directly involved in the previous LANL activities in this area. Consequently, LANL will be required to work with both the DIA COTR and the SAIC program manager for most of the activities identified in this statement of work (SOW).

5.2 (S/NF) It is anticipated that both government and contractor supplied individuals will be involved in the MEG-measurement activity. All activity involving non-DIA

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Enclosure 1

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and research of John Greenewald, Jr., creator of:

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SECRET

personnel (e.g., contractor supplied) will be coordinated in advance with the DIA COTR. Specific subject/population types to be investigated will be reviewed and approved by the COTR well in advance of their involvement.

5.3 (U) All research protocols, analysis methodologies, specific scheduling, and other procedures will be reviewed/approved by the DIA COTR. A contractor Scientific Oversight Committee (SOC) will review and comment on all experimental protocols, procedures and analysis methods. The SOC will also review and comment on the final report prepared for this effort.

5.4 (U) This effort will be subject to review by the LANL Human Use Review Panel to assure that all experiments with human subjects conform to standard human use guidelines set forth by Health and Human Service and DOD regulations. (Additional human use guidance is provided on attachment 1. to this SOW).

5.5 (U) The contractor will be required to submit brief progress reports and cost data to the DIA COTR on a monthly basis. A final technical report containing all protocols, methodology, analysis techniques, results, and conclusions will be provided to the COTR by 1 July 1992. An advanced draft of this final report will also be required 2 weeks prior to submission of the final report.

5.6 (U) Should unforeseen schedule or other issues arise concerning any of the specific tasks identified in section 6.0, the COTR will be given immediate notice. If necessary, adjustments to priorities and schedules can be approved by the COTR if there is no cost or other impact on the overall project.

6.0 (U) SPECIFIC TASKS:

6.1 (U) Examine the hardware and software used in the earlier remote stimuli study to determine possible instrumental artifacts; calibrate existing electromagnetic/magnetoencephalograph (MEG) environment. This should include, but is not limited to, (a) open sensors; (b) brain equivalent targets; and (c) non-central nervous system targets.

6.2 (S/NF) Perform new remote stimuli experiments with a variety of subject population types and variations to the remote aspect (e.g., vary light stimuli parameters, vary location from MEG room, presence/absence of "senders").

SECRET/NOFORN

SECRET

6.3 (U) For same subject pool as used in item 6.2, perform direct visual stimuli measurements under a variety of MEG sensor locations. Identify correlations to various population groups, where possible.

6.4 (S/NF) Examine results from item 6.3 to determine inter-group discrimination potential of MEG results.

7.0 (U) QUICK REACTION CAPABILITY (QRC): The contractor will maintain quick response capability to problems or unexpected demands (e.g., briefings, unique subject availability,) as may be encountered during this project.

8.0 (U) ALLOCATION OF EFFORT: Level of effort to be applied to each task is shown below:

<u>TASK NO.</u>	<u>ALLOCATION OF EFFORT (%)</u>
6.1	15
6.2	60
6.3	20
6.4	5

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HUMAN USE GUIDELINES

A. DEFINITIONS

1. Human Subject: An individual about whom an investigator conducting research obtains data through interaction with the individual, including both physical procedures and manipulations of the subject or the subject's environment. The term does not include military or civilian personnel who are qualified to test by assignment to duties that call specifically for such qualifications such as test pilots and test engineers.

2. Non-U.S. Citizens: Foreign nationals, excluding, personnel on active duty.

3. Research: The term does not include individual or group training of military personnel such as combat readiness, effectiveness, proficiency, or fitness exercises.

B. GENERAL GUIDANCE

1. The contractor shall conduct research using human subjects at all times so as to be in full compliance with all applicable laws, federal regulations and DOD instructions. Among them are:

a. 45 CFR 46 Health and Human Services (HHS) Regulation, "Protection of Human Subjects";

b. 10 U.S.C. Section 980, "Limitations on Use of Humans as Experimental Subjects";

c. DOD Directive 3216.2 (January 7, 1983) "Protection of Human Subjects in DOD-supported Research";

2. Safeguarding the rights and welfare of subjects at risk in activities supported by this contract is the responsibility of the Contractor. Compliance with this contract will in no way render inapplicable pertinent federal, state, or local laws or regulations. In order to provide for the adequate discharge of this institutional responsibility, no activity involving human subjects under this contract shall be undertaken unless a Contractor Human Use Review Board (CRB) has reviewed and approved such activity.

3. The contractor must provide the Contracting Officer with a written assurance that it is in compliance with all provisions of 45 CFR 46 HHS Regulation, "Protection of Human Subjects," as

amended.

4. The Contractor will assure the Contracting Officer that the identities of all subjects will be protected.

5. Informal consent must be obtained in writing from each human subject before research is undertaken.

6. The contractor shall provide all necessary medical care to research subjects for injury or disease which is the proximate result of participation in the research.

7. Studies conducted outside the United States, its territories or possessions, shall be conducted in compliance with all laws, customs, and practices of the country in which the study is to be conducted.

C. REQUIREMENTS FOR REPORTING AND DOCUMENTATION

1. Copies of all documents presented or required for initial and continuing review of the CRB, e.g., Board minutes pertaining only to the contract, record of subjects consent, transmittal on actions, instructions and conditions resulting from Board deliberations addressed to the activity director, are to be retained by the Contractor for at least three (3) years after completion of the research. All documents shall be accessible for inspection during normal working hours by the DIA COTR or authorized representative.

2. Except as otherwise provided by law, information in the records or possession of the Contractor which refers to or can be identified with a particular subject may not be disclosed except:

a. With the consent of the subject or his legally authorized representative, or

b. As may be necessary for the DIA to carry out its legal responsibilities.

3. Upon expiration or termination of this contract, a list of all unused test material shall be provided to the DIA Contracting Officer.

4. The Contractor shall immediately notify the DIA Contracting Officer, by telephone, of inquiries from sources outside the Department of Defense concerning the use of human subjects under this contract.

SECRET

CONTROL NO. _____

JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

1. (U) Contracting Authority: Virginia Contracting Activity, P. O. Box 46563, Washington, DC 20050-6563.
2. (U) Authority Cited: 10 U.S.C. 2304(c)(1); FAR 6.302-1, "Only one responsible source and no other supplies or services will satisfy Agency requirements."
3. (U) Description of Supplies/Services: The Defense Intelligence Agency (DIA) proposes to procure Biophysical Research and Analysis services for a DIA special evaluation activity. External assistance funds are available for this effort, and are part of a Congressional Directed Program.
4. (U) Description of Action: It is anticipated that a cost-plus-fixed fee contract will be negotiated and awarded to satisfy this requirement. R&D funds for this effort are cited on Purchase Request (PR) No. 330/028Z/91.
5. (U) Reason for Authority Cited:
 - a. (U) This action is based on the need to utilize research achievements from a previous DOD-sponsored R&D effort.
 - b. (S/NF) Between 1985-1989, the Army's Surgeon General Research and Development (SGRD) office sponsored basic research in a phenomenological evaluation area. One of the specific topics initiated by this SGRD effort was examination of brain neuromagnetic activity correlates. This pilot effort was performed by the Biophysics Group at the Los Alamos National Laboratory (LANL), Los Alamos, NM, due to their unique equipment and analysis capability. Investigations from this pilot work yielded positive results. Follow-on to this work is one of the main research activities desired in the Congressional direction as part of DIA's over-all Phenomenological Research Program.
 - c. (S/NF) This specific effort at LANL was originally included in PR 330/0012Z/91, via subcontract from the Science Applications International Corporation (SAIC). However, it has recently been determined that direct MIPR action from DIA to LANL would be more appropriate than an SAIC subcontract at this time for this specific Biophysical Research and Analysis task.

SECRET/NOFORN

1

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Enclosure 2

SECRET

In addition, Dr. Charles Wood, the Biophysical Group's director, had over two years of direct involvement in the previous pilot activity and was responsible for developing all appropriate methodologies and analysis techniques.

d. (S/NF) This neuromagnetic activity research and analysis task requires a sole source procurement in order to efficiently build upon previous pilot study findings and to take advantage of the LANL interdisciplinary staff and their expertise. The Biophysics Group had previously developed all appropriate experimental protocols, analysis techniques, hardware, and task-specific software required for in-depth study of neuromagnetic responses as required under this task,

e. (S/NF) While a few medical facilities exist with similar monitoring systems, none of them have the complex interdisciplinary or analysis capability required for this topic of investigation. In addition, none of them are capable of examining unique parameters or physical variables as required for DIA's over-all evaluation in this area. It would require 3 or more years for another contractor to build up similar expertise. Consequently, sole source procurement from LANL is the proper action for accomplishing this sensitive task in a timely and effective manner.

6. (U) Efforts to Obtain Competition: Due to the uniqueness of this research area, there are no other qualified research facilities and personnel available to satisfy this contract. To bring other potential organizations up to speed would not be possible without unacceptable delays or additional costs.

7. (U) Action to Increase Competition: Every effort will be made to release research results as widely as possible to attract other potential researchers. Not only will this be accomplished through specialized (and properly classified) channels, but also appropriate portion will be released at unclassified levels to attract interest in academic facilities.

8. (U) Market Survey: Based on the significant advantage that the Los Alamos National Laboratory possesses in this area, a market survey would not serve a useful purpose at this time.

9. (U) Interested Sources: No other source has expressed an interest in this requirement.

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2

SECRET

10. (U) Other Factors:

a. (S) Acquisition data availability: Data from previous government-sponsored research is available in DIA. Since this was part of a controlled access project, every effort will be made to downgrade, and where practical, declassify basic aspects of the research. This will, in time, generate a wider interest in this field.

b. (U) Unusual and Compelling Urgency: This task requires timely response from LANL in order to meet the Congressionally-directed requirements. This requirement can only be satisfied via other than full and open competition and by utilizing the existing LANL capabilities.

11. (U) Technical Certification:

I hereby certify that the supporting data under my cognizance which are included in the J&A are accurate and complete to the best of my knowledge and belief.

SG1J

Name: Date: 11 July 91
Title: Signature:

SG1J

12. (U) Requirements Certification:

I hereby certify that the supporting data under my cognizance which are included in the J&A are accurate and complete to the best of my knowledge and belief.

SG1J

Name: Date: 11 July 91
Title: Vice Assistant Deputy Director
for Scientific and Technical Intelligence Signature:

SG1J

13. (U) Fair and Reasonableness Cost/Price Determination: A detailed technical and cost proposal will be required from the contractor, LANL. Prior to award, the Government will conduct an in-depth analysis of all technical and cost aspects of this requirement. Based on the outcome, a fair and reasonable cost will be negotiated. Therefore, I hereby determine that the anticipated cost for this contract action will be fair and reasonable.

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14. (U) Contracting Officer Certification:

In accordance with FAR 6.303-2 (a) (12), I hereby certify that the facts and representation under my cognizance, which are included in this J&A, are accurate and complete to the best of my knowledge and belief.

Date: _____

NAME: _____

Contracting Officer

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4

SECRET

APPROVAL

Based on the foregoing justification, I hereby approve the procurement of BIOPHYSICAL RESEARCH AND ANALYSIS on an other than full and open competition basis pursuant to the authority of 10 U.S.C. 2304(c) , subject to availability of funds, and provided that the services and/or property herein described have otherwise been authorized for acquisition.

Date: _____

Signature: _____

Name: _____

Title: _____

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STATEMENT

**RESEARCH OF PLANNED, ON-GOING,
AND COMPLETED STUDIES**

Research by my staff indicates, to the best of our knowledge, that there is no other known similar or collateral study or analysis, planned, in progress, or completed which fulfills the objectives or specific intent of this proposed contract study: Biophysical Research and Analysis (Purchase Request # 330/028Z/91).

PREPARED BY:

DT-5A

Date: 10 July 91

SG1J

**CERTIFIED AS ACCURATE
AND COMPLETE:**

JOHN T. BERBRICH
Assistant Deputy Director
for Scientific and
Technical Intelligence

Date: 11 July 91

SG1J

Enclosure 3

MIPR CONTROL PROVISIONS AND GUIDANCE

1. Funds cited may be used only for the project delineated in the classified Statement of Work (Enclosure 1).
2. The DIA estimate for this project is \$250,000.00 over a 12 month period.
3. The total MIPR estimate shall not be exceeded by the purchasing office.
4. Changes in purpose, scope or desired results from those delineated in the Statement of Work must have DIA approval. A copy of the final Statement of Work will be provided to DIA/DT-S for review prior to further contractual actions.
5. The MIPR should be addressed to: HQ DOE
Attn: Barbara Moyers, IN-40
Forrestall Bld
Washington, D.C. 20585
6. Two copies of the final contract should be provided to:
Defense Intelligence Agency
ATTN: VP-SF
Washington, D.C. 20340

Enclosure 4

