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STAFF SUMMARY SHEET

1. (U) **PURPOSE:** To provide the status of DIA's participation in the conduct or support of intramural or extramural human subject research.

2. (U) **BACKGROUND:** The memorandum opposite provides the DIA response to requirements set forth in ESO tasker #710 which requests DIA to indicate whether the Agency conducts or provides funding support for intramural or extramural research which involves human subject participation. Response opposite (enclosure 1) has been prepared for DR signature and forwarding to Director, Environmental and Life Sciences, Office of the Director, Defense Research and Engineering.

3. **DISCUSSION:**

a. (U) A thorough review by all elements of the DIA has determined that only one program (Project STAR GATE) falls within the definition of human subject research. This research is conducted in two areas: in-house activities conducted by DIA civilian personnel and external research activities conducted under DIA contract with the Science Applications International Corporation (SAIC).

b. (S/NF) Both the DIA and DoD General Counsels have determined that the STAR GATE Project constitutes experimentation on human subjects. As required by Procedure 13 of DoD Directive 5240.1-R, approval for project activities has been granted by the Deputy Secretary of Defense. DIA personnel involved with in-house investigations are required to sign a Statement of Consent form approved by the DIA General Counsel. The assignment is voluntary and employees may temporarily choose not to participate in the project at specific times, or permanently discontinue participation at any time. There have been no demonstrated risks of permanent or temporary injury (including physical or psychological) to project personnel beyond risks to which they would ordinarily be exposed in their daily lives.

c. (S/NF) External research conducted by SAIC as required by the current contract is in full compliance with all applicable laws, Federal regulations and DoD instructions. SAIC has provided formal written assurance to DIA that they are in full compliance. In addition, all research plans/activities are constantly monitored by SAIC's Institutional Review Board to ensure that all applicable Federal laws, directives, and regulations are fully and consistently implemented.

4. (U) **RECOMMENDATION:** That DR sign memorandum opposite.

1 Enclosure

1. DIA Tasker ESO #0710

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MEMORANDUM FOR THE DIRECTOR, ENVIRONMENTAL AND LIFE SCIENCES, OFFICE OF THE DIRECTOR, DEFENSE RESEARCH AND ENGINEERING

SUBJECT: Protection of Human Subjects in Research

Reference: OAASD Memorandum, 17 February 1994, subject as above.

1. (S/NF) The Defense Intelligence Agency has determined that only one of its program's, Project STAR GATE, falls within the definition of human subject research. This research is conducted in two areas: in-house investigations conducted by DIA civilian personnel and external research activities conducted under DIA contract with the Science Applications International Corporation (SAIC).

2. (C/NF) Both the DIA and DoD General Counsels have determined that the STAR GATE Project constitutes experimentation on human subjects. As required by Procedure 13 of DoD Directive 5240.1-R, approval for project activities has been granted by the Deputy Secretary of Defense. All personnel involved with in-house investigations are required to sign a Statement of Consent form approved by the DIA General Counsel. Assignment to this Project is voluntary and employees may temporarily choose not to participate in the project at specific times, or permanently discontinue participation at any time. There have been no demonstrated risks of permanent or temporary injury (including physical or psychological) to project personnel beyond risks to which they would ordinarily be exposed in their daily lives.

3. (C/NF) External research conducted by SAIC as required by the current contract is in full compliance with all applicable laws, Federal regulations and DoD instructions. SAIC has provided formal written assurance to the DIA that they are in full compliance. In addition, all research plans/activities are constantly monitored by SAIC's Institutional Review Board to ensure that all applicable Federal laws, directives, and regulations are fully and consistently implemented.

4. (U) The administrative package governing the protection of human subjects in research should be forwarded to my point of contact [redacted] Chief, Technology Assessment and Support Activity (PAG-TA), Washington, D.C. 20340. [redacted] can be contacted at [redacted]

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OFFICE OF THE SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

FEB 17 1994

MEMORANDUM TO DIRECTORS OF THE DEFENSE AGENCIES

SUBJECT: Protection of Human Subjects in Research

On August 11, 1991, the Federal Common Policy for the Protection of Human Subjects in Research was adopted by the Department of Defense (DoD) and published in Title 32, Code of Federal Regulations, Part 219. Subsequently, Policy Guidance for Implementation of the Human Subjects Regulations was issued jointly on June 10, 1993 by the Assistant Secretary of Defense (Health Affairs) and the Office of the Director, Defense Research and Engineering to the Assistant Secretaries of the Military Departments having cognizance for research, development, testing, and acquisition.

It has been brought to our attention that at least one Defense Agency has recently initiated a program in medical technology. To ensure that all Department of Defense Agencies are in compliance with current human use regulations, it is requested that each Director indicate whether his Agency conducts or provides funding support for intramural or extramural research which involves human subject participation. If an Agency does conduct or support human subjects research the required administrative package will be provided to ensure Agency compliance with the above Federal Regulation. For clarity, research is defined as a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Human subjects is defined as a living individual about whom an investigator (professional or student) conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information regarding the individual used for research purposes.

Directors are requested to provide the status of Agency participation in the conduct or support of intramural or extramural human subject research by March 4, 1994 to

Director, Environmental and Life Sciences
Office of the Director, Defense Research and Engineering
Pentagon Room 3D129
Washington, D.C., 20301-3030

Negative responses are required.

My point of contact for this action is Captain John F. Jemionek, MSC, USN, who may be contacted at (703) 697-1494. Your assistance in ensuring total DoD compliance with Federal Regulation in the area of human subject protection in research is appreciated.

Edward D. Martin

Edward D. Martin, M.D.
Acting Assistant Secretary
of Defense (Health Affairs)

Joseph V. Osterman

Joseph V. Osterman
Director, Environmental
and Life Sciences

Rec'd 4 Mo

TASKING CONTROL FORM

UNCLASSIFIED

Validated

Task Control No.: 94-002605	Slant No.: 0	Subject: PROTECTION OF HUMAN SUBJECTS IN RESEARCH		Subject Classification: UNCLASSIFIED
Consumer: ASD/HA	No. Of Scanned Pages: 2			
Office Of Entry: ESS	Primary Action: PC	Tasking Authority: ESS	Validator: VALID1	
DIA Suspense: 03/15/94	Consumer Suspense: 03/16/94	Reference No.: ESO #0710	Document Control No.:	

Guidance: **Guidance Classification:** UNCLASSIFIED

1. TASKER CONTAINS TWO PAGES SCANNED MATERIAL: OSD/ENVIRONMENTAL AND LIFE SCIENCES MEMORANDUM ON PROTECTION OF HUMAN SUBJECTS IN RESEARCH
2. PER SCANNED MEMO, DIA HAS BEEN REQUESTED TO INDICATE WHETHER THE AGENCY CONDUCTS OR PROVIDES FUNDING SUPPORT FOR INTRAMURAL OR EXTRAMURAL RESEARCH WHICH INVOLVES HUMAN SUBJECT PARTICIPATION. IF SO, A STATUS REPORT OF THE AGENCY PARTICIPATION IS REQUIRED. IF NOT, A WRITTEN NEGATIVE REPLY IS NECESSARY.
3. ESS OBTAINED THE REQUESTOR'S APPROVAL ON EXTENDING SUSPENSE FROM 4 MAR 94 TO 15 MAR 94.
3. PC SHOULD TAKE THE LEAD, AND PREPARE A CONSOLIDATED AGENCY RESPONSE FOR DR SIGNATURE.

SG1J 4. ESS POC:

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** EST SHOULD SCAN TWO PAGES. **

Collab:

CC 03/11/94 ----	DA 03/11/94 ----	J2 03/11/94 ----	MC 03/11/94 ----
OC 03/11/94 ----	PS 03/11/94 ----	SC 03/11/94 ----	

Coord:

GC 03/14/94 ----

Info:

ATS CS-X0 DR-XA ES ESO IG MD

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Tasking Authority: Approved For Release 2003/09/10 : CIA-RDP96-00792R000600200001-9

***** PO-2A GUIDANCE *****

ACTION: PAG SUSPENSE: 1200 10 MARCH 1994

COLLAB: PAA/PAE/PAM/PAN/PO/PGI/PGT/P-AS/P-FM SUSPENSE: 0900 08 MARCH 1994
PO-4C 1100 10 MARCH 1994

INFO: PC-HQ/PA/PG/PO-2A (FILE)

GUIDANCE:

- PAG: 1. TAKE THE LEAD FOR PC. COORDINATE/CONSOLIDATE INPUTS FROM PC COLLABS (LISTED ABOVE) AS WELL AS INPUT FROM CC, OC, DA, PS, J2, SC AND MC.
- 2. PREPARE A MEMORANDUM FOR, FOR THE DR SIGNATURE, REPORTING THE STATUS OF AGENCY PARTICIPATION IN RESEARCH INVOLVING HUMAN SUBJECTS. IF RESPONSE IS NEGATIVE, A WRITTEN RESPONSE IS REQUIRED.
- 3. A STAFF SUMMARY SHEET, FOR DIRECTOR NMIPC SIGNATURE, SHOWING THE APPROPRIATE COORDINATION, SHOULD BE INCLUDED AS PART OF THE COMPLETED PACKAGE.
- 4. COORDINATE THE COMPLETED RESPONSE WITH GC PRIOR TO FORWARDING TO PO-4C.
- 5. FORWARD COMPLETED PACKAGE TO PO-4C FOR EDITING NLT 0900 10 MARCH.
- 6. WHEN THE PACKAGE IS RETURNED FROM PO-4C, FORWARD IT TO PC HEADQUARTERS FOR SIGNATURE NLT 1200 10 MARCH.

GC
VV

SG1J 7. UPON COMPLETION, PLEASE PROVIDE CLOSEOUT INFORMATION, VIA HIGGINS, TO PO-2A/[] (W/CY TO [] TO CLEAR SUSPENSE: TASKER NUMBER, DATE/TIME COMPLETED, ACTION TAKEN, ACTION OFFICER, AND CORRESPONDENCE CONTROL NUMBER.

PAG/PAA/PAE/PAM/PAN/PGI/PGT/PO/P-AS/P-FM:

- 1. PREPARE A WRITTEN RESPONSE INDICATING THE STATUS OF ANY KNOWN NMIPC PARTICIPATION IN RESEARCH INVOLVING HUMAN SUBJECTS. IF RESPONSE IS NEGATIVE, A WRITTEN RESPONSE IS REQUIRED.
- 2. FORWARD RESPONSES TO PAG POC, [] NLT 0900 8 MARCH.

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PO-4C: EDIT/FORMAT THE CONSOLIDATED DIA RESPONSE AND RETURN TO PAG NLT 1100 10 MARCH.

SG1J [] (3MAR94)

***** GUIDANCE FOR CC ELEMENTS *****

TCN : 94-002605; SUBJECT: RECORDS SEARCH - PROTECTION OF HUMAN SUBJECTS IN RESEARCH

ACTION : C-AS (C-AS2A2, [] TAKE FOR ACTION AS NOTED ON 311. PC POC TO BE DETERMINED (CONTACT [] NEGATIVE REPORTS ARE

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Approved For Release 2003/09/10 : CIA-RDP96-00792R000600200001-9

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