Department of Defense
DIRECTIVE

NUMBER 3216. 2
March 25, 2002

USD(AT&L)

SUBJECT: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

References: (a) DoD Directive 3216.2, "Protection of Human Subjects in DoD-Supported Research," January 7, 1983 (hereby canceled)
(b) Section 980 of title 10, United States Code
(c) Title 32, Code of Federal Regulations, Part 219, "Protection of Human Subjects," current edition
(d) DoD Directive 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000
(e) through (m), see enclosure 1

1. REISSUANCE AND PURPOSE

This Directive:

1.1. Reissues reference (a) to update policies for protecting the rights and welfare of humans as subjects of study in Department of Defense (DoD)-supported research, development, test and evaluation, and other related activities hereafter referred to as "research."

1.2. Implements 10 U.S.C. 980 (reference (b)).

1.3. Supports implementation of 32 CFR Part 219 (reference (c)), referred to as the "Common Rule."

1.4. Establishes other DoD policies for the ethical conduct of research.

2. APPLICABILITY AND SCOPE

This Directive:

2.1. Applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities and all other organizational entities in the Department of Defense (hereafter referred to collectively as "the DoD Components").

2.2. Applies to research involving human subjects, as defined herein, conducted by a DoD Component (i.e., intramural) and other research that is supported by a DoD Component (i.e., extramural) through a contract, grant, cooperative agreement, or other arrangement.

2.3. Does not apply to the use of investigational new drugs, biological products, or devices for purposes of Force Health Protection. Such use is not research and is governed by DoD Directive 6200.2 (reference (d)).

2.4. Does not apply to accepted medical practice, including the use of investigational products in such practice, undertaken for purposes of treatment, not research. Such medical practice is not research and is not subject to this Directive.

3. DEFINITIONS

Terms used in this Directive are as defined in enclosure 2.

4. POLICY

It is the policy of the Department of Defense that:

4.1. Protection of Human Subjects in Research. The rights and welfare of human subjects in research supported or conducted by the DoD Components shall be protected. This protection encompasses basic respect for persons, beneficence, and justice in the selection of subjects.

4.2. Informed Consent. In general, as required by reference (b), no DoD Component may conduct or use appropriated funds to support research involving a human being as an experimental subject without the prior informed consent of the subject.

4.2.1. In the case of research intended to be beneficial to the subject, if the subject lacks capacity, due to age, condition, or other reason, to make a decision regarding consent to participate in the research, prior consent may be provided by a legal representative of the

subject. In any such case, the determination that research is intended to be beneficial to the subject must be made by an Institutional Review Board (IRB) under reference (c).

4.2.2. Consistent with 10 U.S.C. 980(b) (reference (b)), the requirement for prior informed consent under paragraph 4.2. or subparagraph 4.2.1. may be waived by the Head of a DoD Component with respect to a specific research project to advance the development of a medical product necessary to the Armed Forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws and regulations, including 21 CFR 50.24 (reference (j)).

4.3. Applicability of Federal Policy for Protection of Human Subjects in Research

4.3.1. The Department of Defense has joined with other Federal Agencies to adopt the "Common Rule" Federal policy for protection of human subjects in research. Reference (c) is the Department of Defense's implementation of the Common Rule. All DoD-supported and -conducted research shall comply with reference (c) and this Directive.

4.3.2. The IRBs of the DoD Components established under reference (c) shall consist of members who are either Federal employees, individuals covered under the Inter-governmental Personnel Act (IPA), or consultants consistent with the requirements established by 5 U.S.C. 3109 (reference (e)).

4.3.3. All human subject research supported or conducted by the Department of Defense shall be conducted under an assurance of compliance acceptable to the funding Agency. Research performed at DoD facilities and funded by the Department of Defense shall have a DoD assurance of compliance. The DoD Components conducting or supporting research must ensure that the investigators are familiar with the Nuremberg Code, the Belmont Report, 32 CFR Part 219 (reference (c)), this Directive, and any related requirements.

4.4. Additional Protections for Certain Categories of Research. In addition to the requirements of reference (c), the following requirements apply to research involving certain subjects or purposes.

4.4.1. Research supported or conducted by the Department of Defense that affects vulnerable classes of subjects shall meet the additional protections of 45 CFR Part 46, Subparts B, C, and D (reference (f)) (e.g., fetuses, pregnant women, human in vitro fertilization, prisoners, or children). For purposes of this paragraph, actions authorizing or requiring any action by an official of the Department of Health and Human Services (HHS) with respect to any requirements of reference (f) shall be under the authority of the Director, Defense Research and Engineering.

4.4.2. The involvement of prisoners of war as human subjects of research is prohibited.

4.4.3. For research involving more than minimal risk (as defined in 32 CFR 219.102(i), reference (c)) to subjects, an independent medical monitor shall be appointed by name. Medical monitors shall be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual subject/patient management and safety. Medical monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate.

4.4.3.1. Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of a research project: subject recruitment, subject enrollment, data collection, or data storage and analysis.

4.4.3.2. At the discretion of the IRB, the medical monitor may be assigned to discuss research progress with the principal investigator, interview subjects, consult on individual cases, or evaluate adverse event reports. Medical monitors shall promptly report discrepancies or problems to the IRB. They shall have the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can assess the medical monitor's report.

4.4.4. For research involving more than minimal risk and also involving military personnel, unit officers and noncommissioned officers (NCOs) shall not influence the decisions of their subordinates to participate or not to participate as research subjects. Unit officers and senior NCOs in the chain of command shall not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects. When applicable, officers and NCOs so excluded shall be afforded the opportunity to participate as research subjects in a separate recruitment session. During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research or the unit shall be present to monitor that the voluntary nature of individual participants is adequately stressed and that the information provided about the research is adequate and accurate.

4.4.5. Research involving use of human subjects for testing of chemical or biological agents is generally prohibited by 50 U.S.C. 1520a (reference (g)), subject to possible exceptions for research for prophylactic, protective, or other peaceful purposes. Any such research shall comply with reference (g).

4.5. Education and Training on Protection of Human Subjects in Research. Awareness of human subjects protection requirements shall be established for all DoD personnel involved in the conduct, review, or approval of research covered by this Directive.

4.5.1. Awareness activities shall be commensurate with the duties and responsibilities of the participants in the process of protection of human subjects of research, and compatible with Office of Human Research Protections (OHRP) policies.

4.5.2. Research ethics training shall be incorporated into the continuing education program at all DoD Component activities that conduct research involving human subjects.

4.6. Inclusion of Women and Minorities in Clinical Research Projects. The selection of subjects reflecting gender and minority participation as appropriate shall comply with section 252 of Pub. L. 103-160 (reference (h)). The Head of the DoD Component concerned may exercise the waiver authority under this law.

4.7. Fetal Tissue Research. Fetal tissue research supported or conducted by the Department of Defense shall comply with 42 U.S.C. 289g - 289g-2 (reference (i)).

4.8. Research Misconduct. All DoD Components shall establish procedures to monitor and review the ethical conduct of research. The DoD Components that conduct or support research shall ensure that data and data collection are conducted in an ethical manner. In cases in which data are not collected in an appropriate manner, the DoD Component shall determine if the misconduct was intentional or reckless; was an isolated event or part of a pattern; had significant impact on the research record; or had significant impact on other researchers or institutions. The DoD Component shall initiate and carry through on any actions that are necessary to ensure resolution of misconduct findings. All findings of serious research misconduct under this section shall be reported to the Director, Defense Research and Engineering.

4.9. Relationship to Other Requirements. Some activities subject to this Directive may also be subject to regulations of other Federal Agencies, organizations, and non-U.S. entities. Examples include: Food and Drug Administration policies regarding investigational drugs, vaccines, biological products, or devices; multi-agency research; and international research. Activities subject to this Directive and one or more of these other requirements shall comply with all applicable requirements (e.g., references (c) (32 CFR 219.101(g) and (h)), (j), (k), and (l)).

4.10. Non-compliance. Issues related to non-compliance with this Directive by any DoD Component, subordinate, or supported activity shall be referred initially to the next higher management echelon to take deliberate action to resolve. All findings of serious non-compliance under this section shall be reported to the Director, Defense Research and Engineering.

5. RESPONSIBILITIES

5.1. The Director, Defense Research and Engineering, under the Under Secretary of Defense Acquisition, Technology, and Logistics:

5.1.1. Shall be the single point of contact within the Department of Defense for all matters relating to the Department of Defense's compliance with the "Common Rule" and act as the principal DoD liaison with Agencies outside the Department of Defense on matters pertaining to protection of human subjects in research.

5.1.2. May initiate updates to reference (c) and issue any DoD Instructions or other guidance necessary to implement this Directive. With respect to matters affecting medical research, this shall be done in coordination with the Assistant Secretary of Defense (Health Affairs) (ASD(HA)).

5.1.3. Shall establish a committee to coordinate DoD Component activities in the protection of human subjects. The committee shall be composed of representatives from the DoD Components' human subject protection offices.

5.1.4. Shall exercise the authorities of the Secretary of Defense under reference (c), except for matters not delegable, reserved, or covered by another specific delegation.

5.1.5. Shall establish procedures and standards, consistent with the Federal Policy on Research Misconduct (reference (m)), for the prevention of research misconduct in the Department of Defense.

5.1.6. May grant exceptions to policy under this Directive if justified by special circumstances and consistent with law. Records shall be maintained on exceptions granted under this Directive.

5.2. The Assistant Secretary of Defense for Health Affairs, under the Under Secretary of Defense for Personnel and Readiness shall:

5.2.1. Advise the Director, Defense Research and Engineering on matters related to the involvement of human subjects in research, especially, regarding medical safety, ethics, and standards of professional care and conduct.

5.2.2. Serve as the DoD representative on matters relating to implementation of Food and Drug Administration regulatory requirements (references (j) and (k)).

5.3. The Heads of the DoD Components shall:

5.3.1. Develop, issue, and monitor implementing policies to ensure compliance with this Directive and with any implementing Instructions issued under the authority of this Directive. In research undertakings in which more than one DoD Component is involved, the Heads of the Components shall determine and jointly assign executive responsibility for compliance.

5.3.2. Maintain adequate documentation of DoD-supported or -conducted research involving human subjects and establish procedures for supporting DoD reporting requirements.

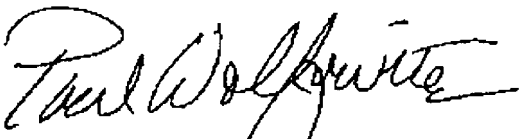
5.3.3. Delegate authorities and responsibilities under this Directive to levels of command or authority appropriate to ensure compliance. This shall include procedures for the investigation and resolution of allegations of non-compliance, and may include procedures for headquarters-level administrative review of research. A DoD Component may delegate

headquarters-level research review responsibility to another DoD Component for purposes of efficiency and consolidation of functional offices.

5.3.4. With respect to research for which primary involvement is from the Department of Defense, establish the required administrative procedures to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in a research project involving more than minimal risk. For this purpose the determination of primary involvement shall be based on consideration of the DoD portion of the total involvement (i.e., funding, personnel, facilities, and all other resources) in the research.

6. EFFECTIVE DATE

This Directive is effective immediately.



Paul Wolfowitz
Deputy Secretary of Defense

Enclosures - 2
E1. References, continued
E2. Definitions

E1. ENCLOSURE 1

REFERENCES, continued

(e) Section 3109 of title 5, United States Code, "Employment of Experts and Consultants, Temporary or Intermittent"
(f) Title 45, Code of Federal Regulations, Part 46, "Protection of Human Subjects," Subparts B, C, and D
(g) Section 1520a of title 50, Unites States Code, "War and National Defense"
(h) Section 2358 note of title 10, United States Code, "National Defense Authorization Act for Fiscal Year 1994," (Public Law 103-160, Sec. 252)
(i) Sections 289g - 289g-2 of title 42, United States Code, "Public Health and Welfare"
(j) Title 21, Code of Federal Regulations, Subchapters A, D, F, and H, "Food and Drug Administration"
(k) Memorandum of Understanding between the Food and Drug Administration and the Department of Defense, "Concerning Investigational Use of Drugs, Antibiotics, Biologicals, and Medical Devices by the Department of Defense," May 1, 1987
(l) DoD Directive 6000.8, "Funding and Administration of Clinical Investigation Program," November 3, 1999
(m) Federal Policy on Research Misconduct, Office of Science and Technology Policy, 65 Federal Register 76260-76264 (December 6, 2000)

E2. ENCLOSURE 2

DEFINITIONS

E2.1.1. Common Rule. The regulation adopted by multiple Federal Agencies for the protection of human subjects in research. The Department of Defense's implementation of the Common Rule is at 32 CFR 219, "Protection of Human Subjects" (reference (c)).

E2.1.2. Research. Any systematic investigation, including research, development, testing, and evaluation (RDT&E), designed to develop or contribute to generalizable knowledge.

E2.1.3. Research Involving a Human Being as an Experimental Subject. An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f), reference (c)). Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose. This does not include:

E2.1.3.1. Activities carried out for purposes of diagnosis, treatment, or prevention of injury and disease in members of the Armed Forces and other mission essential personnel under Force Health Protection programs of the Department of Defense.

E2.1.3.2. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions.

E2.1.3.3. Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance reviews.

E2.1.3.4. Activities exempt under 32 CFR Part 219 (reference (c)).

E2.1.4. Support. Unless otherwise clarified in a specific paragraph of this Directive, this term generally means the provision of funding, personnel, facilities, and all other resources.

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Federal Advisory Committee Charter Modification

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972, (5 U.S.C. Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.65, the Department of Defense gives notice that the name of the Board of Visitors Joint Military Intelligence College is hereby changed to the Board of Visitors National Defense Intelligence College.

The mission of the college's board of visitors remains unchanged; however, the Department of Defense changed the name of the college to the National Defense Intelligence College. As such, the Department of Defense is changing the name of the board of visitors to reflect the college's new name.

The purpose of the Board of Visitors for the National Defense Intelligence College (hereafter referred to as the Board of Visitors) is to provide the Secretary of Defense independent advice on matters relating to the mission of the National Defense Intelligence College. The Director, Defense Intelligence Agency may act upon the Board of Visitor's advice and recommendations.

The Board of Visitors shall be comprised of no more than twelve members, and the Department of Defense, to achieve a balanced membership, will include a cross-section of experts and eminent authorities in the fields of national intelligence, defense and academia.

The Secretary of Defense approves the appointment of the members, and those who are not full-time Federal officers or employees are appointed as Special Government Employees under the authority of 5 U.S.C. 3109. With the exception of travel and per diem for official travel, the members shall serve without compensation. The Director, Defense Intelligence Agency shall select the committee's chairperson from the Board of Visitors at large.

The Board of Visitors shall meet at the call of the committee's Designated Federal Officer, in consultation with the Chairperson and the Director, Defense Intelligence Agency. The Designated Federal Officer shall be a full-time or part-time DoD employee, and shall be appointed in accordance with established DoD policies and procedures. The Designated Federal Officer or duly appointed Alternate Designated Federal Officer shall attend all committee meetings and subcommittee meetings.

The Board of Visitors shall be authorized to establish subcommittees, as necessary and consistent with its mission, and these subcommittees or working groups shall operate under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended), and other appropriate Federal regulations.

Such subcommittees or workgroups shall not work independently of the chartered committee, and shall report all their recommendations and advice to the Board of Visitors for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee nor can they report directly to the Department of Defense or any Federal officers or employees who are not members of the Board of Visitors.

FOR FURTHER INFORMATION: Contact Frank Wilson, DoD Committee Management Officer, 703–601–2554.

May 3, 2007.

L. M. Bynum,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 07–2314 Filed 5–4–07; 4:27 pm]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[DoD–2007–OS–0046]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, DoD.

ACTION: Notice to add a system of records.

SUMMARY: The Office of the Secretary of Defense proposes to add a system of records to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The changes will be effective on June 8, 2007 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to OSD Privacy Act Coordinator, Records Management Section, Washington Headquarters Services, 1155 Defense Pentagon, Washington, DC 20301–1155.

FOR FURTHER INFORMATION CONTACT: Ms. Juanita Irvin at (703) 696–4940.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, were submitted on May 2, 2007, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: May 3, 2007.

L.M. Bynum,

Alternative OSD Federal Register Liaison Officer, Department of Defense.

DoDEA 27

SYSTEM NAME:

Department of Defense Education Activity Research Approval Process.

SYSTEM LOCATION:

Department of Defense Education Activity, 4040 North Fairfax Drive, Arlington, VA 22203–1635.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have requested, or whom Department of Defense Education Activity (DoDEA) has requested, or whom DoDEA has otherwise authorized, to conduct research involving DoDEA staff, DoDEA students, or parents/sponsors of DoDEA students.

CATEGORIES OF RECORDS IN THE SYSTEM:

Research proposals, including the researcher(s)' name, address, email address, telephone number, the university or research affiliation of the researcher, DoDEA Form 2071.3–F1, Research Study Request, and related supporting documents.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 113, Secretary of Defense; 10 U.S.C. 2164, Department of Defense Elementary and Secondary Schools; and 20 U.S.C. 921–932 Overseas Defense Dependent's Education.

PURPOSE(S):

A management tool on research projects concerning Department of Defense Education Activity students, parent(s)/sponsor(s), and faculty or staff.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' set forth at the beginning of the OSD's compilation of systems of records notices also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are file folders and electronic storage media.

RETRIEVABILITY:

Individual's name, case number, subject matter of the research project, and location(s) where the research is being conducted.

SAFEGUARDS:

Access is provided on a 'need-to-know' basis and to authorized authenticated personnel only. Records are maintained in controlled access rooms or areas. Computer terminal access is controlled by terminal identification and the password or similar system. Physical access to terminals is restricted to specifically authorized individuals. Password authorization, assignment and monitoring are the responsibility of the functional managers.

RETENTION AND DISPOSAL:

Destroy 7 years after completion, or when no longer needed for reference. Paper records are destroyed by shredding. Electronic records are destroyed by shredding of computer disks and permanent deletion of files stored on computer hard drives.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Office of Research and Evaluation, Education Directorate, Department of Defense Education Activity, 4040 North Fairfax Drive, Arlington, VA 22203–1635.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of record should address written inquiries to the Privacy Act Officer, Department of Defense Dependents Schools, 4040 North Fairfax Drive, Arlington, VA 22203–1635.

Written requests should contain the individual name and address and must be signed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Privacy Act Officer, Department of Defense Dependents Schools, 4040 North Fairfax Drive, Arlington, VA 22203–1635.

Written requests should contain the individual name and address and must be signed.

CONTESTING RECORD PROCEDURES:

The OSD rules for accessing records, for contesting contents and appealing initial agency determinations are published in OSD Administrative Instruction 81; 32 CFR part 311; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals who have requested permission to conduct research, which have been appointed by Department of Defense Education Activity (DoDEA), or otherwise authorized by DoDEA to conduct research.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7–8863 Filed 5–8–07; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[DoD–2007–OS–0045]

Privacy Act of 1974; Systems of Records

AGENCY: Defense Threat Reduction Agency.

ACTION: Notice to alter a system of records.

SUMMARY: The Defense Threat Reduction Agency proposes to alter a system of records notice to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on June 8, 2007 unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Freedom of Information and Privacy Office, Defense Threat Reduction Agency, 8725 John J. Kingman Road, Fort Belvoir, VA 22060–6201

FOR FURTHER INFORMATION CONTACT: Ms. Brenda Carter at (703) 767–1771.

SUPPLEMENTARY INFORMATION: The Defense Threat Reduction Agency notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on May 2, 2007, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, 'Federal Agency Responsibilities for Maintaining Records About Individuals,' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

HDTRA 014

SYSTEM NAME:

Student Records (August 5, 2005, 70 FR 45371).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with "Department of Defense, Department of Energy, FBI and CIA personnel, local and state government officials, and civilian organizations personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with "Individual's name, Social Security Number (SSN), occupational series, grade, supervisory status, registration, student development curricula, training data (start and completion dates), course descriptions, and related data. Where training is required for professional licenses, certification, or recertification, the file may include proficiency data in one or more skill areas. Electronic records may contain computer logon data and personal emergency contact information."

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with "5 U.S.C. 301, Departmental Regulations; 5 U.S.C. 4103, Establishment of Training Programs; 10 U.S.C. 1701, Management Policies; E.O. 11348, Providing for the further training of Government employees; 5 CFR part 410, Office of Personnel Management-Training; and E.O. 9397 (SSN)."

* * * * *

NOTIFICATION PROCEDURE:

Delete address and replace with "Defense Nuclear Weapons School,

James E. Singer, Esq.,
Bovis, Kyle & Burch, LLC, 53 Perimeter Center East, Third Floor, Atlanta, GA 30346–2298, Counsel for SMC Marketing Corp.

U.S. Consumer Product Safety Commission.

John Gibson Mullan,
Director, Office of Compliance.

Ronald G. Yelenik,
Acting Director, Legal Division, Office of Compliance.

Dated: November 7, 2005.

Howard N. Parnoff,
Trial Attorney, Legal Division, Office of Compliance.

Order

Upon consideration of the Settlement Agreement entered into between SMC Marketing Corp. ("SMC") and the staff of the U.S. Consumer Product Safety Commission (the "Commission"), and the Commission having jurisdiction over the subject matter and over SMC, and it appearing that the Settlement Agreement is in the public interest, it is

I. *Ordered* that the Settlement Agreement be, and hereby is, accepted; and it is

II. *Further Ordered* that SMC shall pay a civil penalty of five hundred thousand dollars ($500,000) in three installments. The first installment of one hundred sixty-six thousand dollars ($166,000) shall be paid within thirty (30) calendar days of service of the Final Order of the Commission accepting the Settlement Agreement. The second installment of one hundred sixty-seven thousand dollars ($167,000) shall be paid within sixty (60) calendar days of service of the Final Order of the Commission accepting the Settlement Agreement. The third installment of one hundred sixty-seven thousand dollars ($167,000) shall be paid within ninety (90) calendar days of service of the Final Order of the Commission accepting the Settlement Agreement. These payments shall be made by check payable to the order of the United States Treasury. Upon the failure of SMC to make a payment or upon the making of a late payment, (i) the entire amount of the civil penalty shall become due and payable, and (ii) interest on the outstanding balance shall accrue and be paid at the federal legal rate of interest under the provisions of 28 U.S.C. 1961(a) and (b).

Provisionally accepted and Provisional Order issued on the 6th day of December, 2005.

By order of the Commission.

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

[FR Doc. 05–23875 Filed 12–8–05; 8:45 am]
BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense (Personnel and Readiness), DoD

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Under Secretary of Defense (Personnel and Readiness) announces the following proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 7, 2006.

ADDRESSES: Written comment and recommendations on the proposed information collection should be sent to the Department of Defense Education Activity (DoDEA), 4040 N. Fairfax Drive, 9th Floor, Arlington, VA 22203, ATTN: Sandra Embler.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address or call at (703) 588–3175.

Title, Form, and OMB Control Number: Department of Defense Education Activity (DoDEA) Non-Sponsored Research Program; DoDEA Form 1: OMB Control Number 0704–TBD.

Needs and Uses: The Department of Defense Education Activity (DoDEA) is a DoD field activity operating under the direction, authority, and control of the Deputy Under Secretary of Defense, Military Community and Family Policy. The DoDEA operates 223 schools in 16 districts located in 13 foreign countries, seven states, Guam, and Puerto Rico. The DoDEA receives requests from researchers to conduct non-DoDEA sponsored research studies in DoDEA schools, districts, and/or areas. To review the proposed research requests, DoDEA developed Form 1, "Research Study Request," in Administrative Instruction 2071.3 (DoDEA AI 2071.3), to collect information about the researcher, the research project, audience, timeline, and the statistical analyses that will be conducted during the proposed research study. This information is needed to ensure that the proposed non-DoDEA sponsored research does not unduly interfere with the classroom instructional process or the regular operations of the school, district, and/or areas.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions; and state, local, or tribal government.

Annual Burden Hours: 75.

Number of Respondents: 75.

Responses Per Respondent: 1.

Average Burden Per Response: 1 hour.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The DoDEA Administrative Instruction 2071.3 (DoDEA AI 2071.3) follows DoD Directive 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," March 25, 2002, that states "The rights and welfare of human subjects in research supported or conducted by the DoD Components shall be protected. This protection encompasses basic respect for persons, beneficence, and justice in the selection of subjects." To ensure that all non-DoDEA sponsored research conducted in the DoDEA school system complies with these guidelines, DoDEA developed Form 1, "Research Study Request," to collect information from researchers that will be used to evaluate the proposed research study. The data collected is analyzed to determine whether the research unduly interferes with the classroom instructional process or the regular operations of the school, and/or areas. Information collected on the DoDEA "Research Study Request" includes the researcher's name, address, telephone number, e-mail address, FAX number (if available), school affiliation (if applicable), the study title, an abstract of the proposed study, an explanation of how the research study (1) is aligned with the DoDEA Community Strategic Plan, and (2) the impact of the study in the researcher's field of study, the major hypothesis(es) or question(s) to be tested, the population and/or sample to be studied, a description and copy of instruments, other data collection activities, the timetable for the study, and the

statistical or other analysis techniques to be used during the study.

Dated: December 5, 2005.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–23816 Filed 12–8–05; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Proposed Collection: Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Under Secretary of Defense (Personnel and Readiness) announces the following proposed extension of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 7, 2006.

ADDRESSES: Written comments and recommendations on the proposed information collection should be sent to the Office of the Under Secretary of Defense for Personnel and Readiness, Office of Legal Policy, ATTN: COL Christopher Garcia, 4000 Defense Pentagon, Washington, DC 20301–4000.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the above address or call at (703) 697–3387.

Title, Associated Form, and OMB Control Number: Claim for Reimbursement and Payment Voucher for Privately-Purchased Protective, Safety, or Health Equipment Used in Combat; DD Form 2902, OMB Number 0704–0436.

Needs and Uses: This information collection requirement is necessary to accept claims and process those claims for reimbursement from separated former members of the Armed Forces and from survivors of deceased members of the Armed Forces. Public Law 108–375, section 351, requires the Department of Defense to reimburse members of the Armed Forces for privately-purchased protective, safety, or health equipment for Operations Noble Eagle, Enduring Freedom, and Iraqi Freedom during the period of September 11, 2001, to July 31, 2004. The DD Form 2902 will be submitted by the former Service member, or survivor of deceased Service member, to an authorizing official identified on the DD Form 2902 for review and approval.

Affected Public: Individuals.

Annual Burden Hours: 1875.

Number of Respondents: 2500.

Responses Per Respondent: 1.

Average Burden Per Response: 45 minutes.

Frequency: Other: One-time.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

This information will be used only to comply with Public Law 108–375, section 351: to pay former Service members and survivors of deceased Service members for reimbursement for privately-purchased protective, health, or safety equipment for Operations Noble Eagle, Enduring Freedom, and Iraqi Freedom. Individual claimants will fill out DD Form 2902, listing the details of what they bought and how much it cost. They will fax or mail the form with supporting documents to an authorizing official for their (or their decedent's) former military Service. The Service authorizing official will use the information on the form to process and pay the claim. The Defense Finance and Accounting Service will use the information on the form to send payment to the claimant.

Dated: December 5, 2005.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–23823 Filed 12–8–05; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

AGENCY: Office of the Secretary, DoD.

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by January 9, 2006.

Title, Form, and OMB Number: Defense Federal Acquisition Regulation Supplement Part 225, Foreign Acquisition, and Related Clauses at 252.225; DD Form 2139; OMB Number 0704–0229.

Type of Request: Extension.

Number of Respondents: 22,445.

Responses per Respondent: 7 (approximate).

Annual Responses: 165,194.

Average Burden Per Response: 0.32 hours.

Annual Burden Hours: 352,440.

Needs and Uses: DoD needs this information to ensure compliance with restrictions on the acquisition of foreign products imposed by statute or policy to protect the industrial base; to ensure compliance with U.S. trade agreements and memoranda of understanding that promote reciprocal trade with U.S. allies; and to prepare reports for submission to the Department of Commerce on the Balance of Payments. In addition, DoD contracting officers will use this information to monitor contractor compliance with National Security Presidential Directive 22 and DoD policy that decrees "zero tolerance" for trafficking in persons.

Affected Public: Business or other for-profit.

Frequency: On Occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Ms. Hillary Jaffe.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings, WHS/ESD/ Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: December 5, 2005.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–23824 Filed 12–8–05; 8:45 am]

BILLING CODE 5001–06–M

RESEARCH STUDY REQUEST

OMB No.
OMB approval expires

PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ORGANIZATION. RETURN COMPLETED FORM TO:
DoD Education Activity, Research and Evaluation Branch, 9th Floor, 4040 N. Fairfax Drive, Arlington, VA 22203

PRIVACY ACT STATEMENT

AUTHORITY: Sections 10 U.S.C. 113, Secretary of Defense; 10 U.S.C. 2164, Department of Defense Elementary and Secondary Schools; and 20 U.S.C. 921-932, Overseas Defense Dependent's Education.
PRINCIPAL PURPOSE(S): To maintain a case file for use by management concerning any research project undertaken concerning DoDEA students, parents/sponsors, faculty or staff; and to permit identification and tracking of authorized research projects and researchers.
ROUTINE USE(S): In addition to disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed under the DoD "Blanket Routine Uses" set forth at the beginning of the OSD's compilation of systems of records notices.
DISCLOSURE: Voluntary; however, failure to disclose the information may prevent individuals from conducting research involving DoDEA.

1. NAME *(Last, First, Middle Initial)*	2. DATE *(YYYYMMDD)*

3. ADDRESS *(Include ZIP Code)*

4. TELEPHONE NUMBERS *(Include Area Code)*

a. HOME	b. WORK

5. FAX NUMBER *(Include Area Code)*	6. E-MAIL ADDRESS

7. ARE YOU CURRENTLY EMPLOYED BY THE DEPARTMENT OF DEFENSE EDUCATION ACTIVITY?

☐ YES IF YES, WHAT IS YOUR CURRENT ASSIGNMENT *(School and District)*
☐ NO

8. TITLE OF RESEARCH

9. PROPOSAL ABSTRACT

D R A F T

10. EXPLAIN HOW YOUR RESEARCH STUDY (1) IS ALIGNED WITH THE DEPARTMENT OF DEFENSE EDUCATION ACTIVITY (DoDEA) COMMUNITY STRATEGIC PLAN, AND (2) WILL BENEFIT DoDEA.

11. WHAT IS (ARE) THE RESEARCH QUESTIONS OR MAJOR HYPOTHESIS TO BE TESTED?

12. DESCRIBE THE POPULATION AND/OR SAMPLE TO BE STUDIED.

(1) SAMPLE	(2) NUMBER	(3) DESCRIPTION *(Grades, Schools, Demographics)*
a. STUDENTS		
b. ADMINISTRATION		
c. STAFF/OTHERS		
d. SPONSORS/ GUARDIANS		

13. DESCRIBE YOUR PLANS FOR CONDUCTING THE STUDY INCLUDING ADMINISTRATION OF INSTRUMENTS, OTHER DATA COLLECTION ACTIVITIES, AND THE TIMETABLE YOU WILL FOLLOW. *(Include a copy of all questionnaires, surveys, exams, interview protocols, etc. you plan to use.)*

(1) PARTICIPANTS	(2) INSTRUMENT/ TYPE OF DATA COLLECTED	(3) AMOUNT OF TIME REQUIRED	(4) TIMELINE
a. STUDENTS			
b. ADMINISTRATION			
c. STAFF/OTHERS			
d. SPONSORS/ GUARDIANS			

14. DESCRIBE WHAT, IF ANY, SPECIFIC RESOURCES YOU WILL NEED FROM DoDEA *(e.g. materials, room, mailbox, etc.).*

15. IF REQUESTING DATA FROM DoDEA, DESCRIBE IN DETAIL THE DATA YOU ARE REQUESTING *(e.g. demographics, sample size, specific measures, etc.).*

16. FOR EACH RESEARCH QUESTION LISTED, DESCRIBE IN DETAIL THE SPECIFIC ANALYTIC PROCEDURES THAT WILL BE USED.

D R A F T

17. IN WHAT FORM(S) AND TO WHOM WILL YOU REPORT YOUR FINDINGS?

18. DATE COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI) TRAINING WAS COMPLETED
(YYYYMMDD)

19. ATTACHMENTS *(X all the items below which you are attaching to this application.)*

- ☐ A COPY OF THE INSTITUTIONAL REVIEW BOARD (IRB) FOR HUMAN SUBJECTS *(Required).*
- ☐ CONSENT FORMS *(Required if study includes data collected from human subjects).*
- ☐ INSTRUMENTS TO BE USED *(Surveys, interview questions, observation forms, etc.) (Required if used in study).*
- ☐ OTHER *(Specify):*

RESEARCH AGREEMENT

Guidelines:

1. Research shall be conducted in accordance with the Department of Defense Education Activity (DoDEA) Administrative Instruction (2071.3).

2. Research involving pupils, sponsors and/or personnel of the Department of Defense Education Activity (DoDEA) must protect the dignity, well-being, and confidentiality of the individual(s), including the rights guaranteed legally and constitutionally and by DoDEA policies.

3. Permission to conduct research is not an endorsement by DoDEA and does not compel any personnel of the DoDEA to participate in research studies.

4. The researcher shall inform all participants (i.e. students, sponsors/guardians, DoDEA personnel) that participation in the proposed research is voluntary.

5. The researcher shall obtain informed consent from participants of legal age; and will obtain informed assent from participants and consent from a sponsor/guardian when participants are not of legal age, unless a waiver is obtained.

6. Personal, social, and psychological research of any nature must NOT be in conflict with the rights of individuals or groups.

7. The researcher shall obtain permission for all information collections as required under Public Law 104-13, "Paperwork Reduction Act of 1995" and DoD Directive 8910.1, "Management and Control of Information Requirements," June 11, 1993.

8. All information obtained will be held in accordance with the Privacy Act (5 USC 552a).

9. The research shall not unduly interfere with the classroom instructional process or the regular operations of the school or district.

10. The researcher shall cooperate with the staff member(s) designated by the district or school to coordinate the research. It is the researcher's responsibility to become familiar with DoDEA operating policies.

11. Researchers are not to refer to the specific military installation, the names or locations of the schools, or the name of the school system (DoDEA, Domestic Dependent Elementary and Secondary Schools (DDESS), or Department of Defense Dependents Schools (DoDDS)) in any reports generated from this research. It may only be stated that the study was conducted in a school that serves children of military sponsors. In addition, there must not be any association with the DoDEA on surveys, letters, documents, etc. (e.g. Government letterhead, name of installation, etc.).

12. The researcher shall submit an electronic copy of the final research report to the Chief, Research and Evaluation, DoDEA.

13. The Principal, Superintendent, Area Deputy Director, Chief, Research and Evaluation Branch, or the Director, DoDEA may terminate a research study that receives permission at any time.

13. Permission to conduct research is not an endorsement and does not compel any personnel of the DoDEA to participate in research studies.

I acknowledge receipt of the Guidelines for Research in DoDEA and agree to abide by the guidelines as stated.

1. SIGNATURE OF RESEARCHER	2. DATE *(YYYYMMDD)*

RESEARCH ENDORSEMENT

1. RESEARCHER (*Last name, First name, Middle name)*

2. RESEARCH TITLE

D R A F T

THE FOLLOWING SECTION TO BE COMPLETED BY INDIVIDUALS CONDUCTING RESEARCH UNDER THE DIRECTION OF A FACULTY OR STAFF SPONSOR. ALL OTHER INDIVIDUALS SHOULD ATTACH A CURRENT CURRICULUM VITA OR BIOSKETCH.

3. FACULTY OR STAFF SPONSOR

a. NAME *(Last, First, Middle Initial)*

b. ADDRESS *(Include ZIP Code)*

c. TELEPHONE NUMBER *(Include Area Code)*	d. EMAIL ADDRESS

e. UNIVERSITY/DEPARTMENT/ORGANIZATION

f. SIGNATURE

PRINCIPAL AND SUPERINTENDENT CONSENT

1. PRINCIPAL

a. I have reviewed the Research Study Request for _____

b. entitled _____

c. I *(X one)* ☐ agree ☐ disagree that my school will participate in this research study.

I also understand that given my consent, this research will be conducted in accordance with Department of Defense Education Activity (DoDEA) policy.

_____ _____

d. Date *(YYYYMMDD)* e. School Name

_____

f. Principal's Name *(Last, First, Middle Initial)*

_____

g. Principal's Signature

Please forward this request to your Superintendent after completion of this form.

2. SUPERINTENDENT

a. I *(X one)* ☐ agree ☐ disagree that my school will participate in this research study.

I also understand that given my consent, this research will be conducted in accordance with Department of Defense Education Activity (DoDEA) policy.

_____ _____

b. Date *(YYYYMMDD)* c. Superintendent's Name *(Last, First, Middle Initial)*

_____

d. Superintendent's Signature

3. TO BE COMPLETED BY THE PRINCIPAL AND SUPERINTENDENT

If you disagreed above, please state your reasons below.

Superintendent: Return to the DODEA: Chief, Research and Evaluation Branch

Fax: (703) 588-3175

GLOSSARY

Action Research. A systematic inquiry by practitioners to improve teaching and learning. Action research projects are designed solely for the purposes of informing one's self, with no intention or action to share the results of the project with others.

Federal Assurance. A formal, written agreement of commitment to relevant human subject protection policies and review by the Institutional Review Board (IRB).

Collaborative Institutional Training Initiative (CITI) Training. An online course (www.citiprogram.org) which provides a comprehensive selection of educational modules that can be used to provide ethics training to all members of the research community and satisfy institutional instructional mandates in The Protection of Human Research Subjects.

Consent. The agreement of a person (or his or her legally authorized representative) to serve as a research subject, with full knowledge of all anticipated risks and benefits of the research.

Informed Assent. A child's affirmative agreement to participate in research. It is similar to the consent, but in age appropriate language. Mere failure to object should not, absent affirmative agreement, be construed as assent.

IRB. An Institutional Review Board established in accord with and for the purposes expressed in references (b) and (c).

Legal Age of Consent. The legal age at which an individual can provide consent to participate in research. The legal age of consent varies across states, in DoDEA the legal age includes students who have reached the age of 18 by the beginning of the current school year.

Research Studies. Research studies, including data collection activities, referred to in this Administrative Instruction are those studies that involve students, sponsors, or staff in activities such as:

Studies conducted to develop and/or validate educational theories, techniques, instruments, methods, or materials.

Studies describing, examining, and assessing or evaluating policies, practices, programs, methods, organizational structure, human interaction, teaching, learning materials, facilities, or other aspects of the DODEA school system.

Studies conducted to obtain information, opinions, or attitudes through measurement means; such as surveys, questionnaires, interviews, observations, tests, or inventories.

Any research involving human subjects as defined in references (b), (c), and (d) including studies exempt from reference (c) under section 219.101(b).