Subject: Additional Requirements for Research Supported by Other Federal Departments

This policy is limited to the following US Departments adopting the Common Rule:

1. The Department of Defense (DoD): This department includes all military and armed forces branches of the United States and all agencies and functions related to national security.
   a. Experimental subject: For the purposes of this policy and only in the context of DoD research, an experimental subject is a human being where interaction or intervention is for the primary purpose of obtaining data regarding the effect of the intervention or interaction (e.g., a physical procedure, a drug, manipulation of the environment, etc.).
   b. Minimal Risk: For the purposes of this policy and only in the context of DoD research, minimal risk means risk ordinarily encountered in daily life or during performance of routine physical or psychological examination or tests. This must not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).
   c. For the purposes of research involving pregnant women, fetuses, the term "biomedical knowledge" is replaced with "generalizable knowledge."

2. The Department of Education: This department coordinates and oversees activities related to education. This policy also applies to research funded by the National Institute on Disability and Rehabilitation Research (NIDRR).

3. The Department of Energy: This department's primary mission is to advance energy technology and promote related innovation. Research involving human participants also includes studies of intentional modification of the human environment.
   a. Generalizable: For the purposes of this policy and in the context of DoE research, includes the study of tracer chemicals, particles or other materials to characterize airflow. Further, it includes studies in occupied homes or offices that manipulate the environment to achieve research aims, test new articles, and involve collecting information on occupants' view of appliance, materials or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.

4. The Department of Justice: This department's mission is to enforce the law and defend the interest of the US according to the law.

Policy:
It is the policy of the VUMC IRB to assist the Investigator in meeting the additional requirements set forth by each agency for the protection of participants in research as supported by each agency.

I. The Department of Defense (DoD).
   A. For research considered greater than minimal risk the Investigator must assure:
      1. An independent medical monitor (may be more than one) is appointed by name to oversee the progress and conduct of the study. During the study, the monitor has the authority to:
         a) stop the research in progress;
         b) remove individuals from the study;
c) take any steps necessary to protect the safety and well being of participants until the IRB has time to assess the study;

d) report observations to the IRB or Institutional Official; and

e) discuss the protocol with investigators, interview subjects and consult with others outside of the study.

2. Scientific review of initial and major amendment to the research is conducted prior to IRB approval. The IRB may rely on outside experts to provide an evaluation of the scientific merit for DoD-funded research.

3. Certification of local ethical review or equivalent permissions are provided to the IRB when conducting international research.

B. Research on experimental subjects may not utilize a waiver of informed consent process.

C. The applicability of Subpart B (45 CFR 46) is limited to research involving pregnant women as participant in research that is greater than minimal risk and included interventions or invasive procedures to the women or the fetus or involving fetuses or neonates as participants.

D. Fetal research must comply with USC 42, Chapter 6A, Subchapter III, Part H, 289g.

E. Research on children cannot be exempt.

F. Research on prisoners must be reviewed by the full Committee and must include one prisoner representative.

G. If a participant becomes a prisoner the investigator can ask the IRB for the participant to continue participation until the Committee can convene to review and approve the change and until the organizational official and DoD Component office review the IRB’s approval to change the research protocol. Otherwise the IRB shall require all research interventions and interactions with the prisoner cease until the convened IRB can review the protocol change. The convened IRB shall promptly re-review the protocol to ensure the right and wellbeing of the prisoner participant is not in jeopardy. The IRB will review with the prisoner representative present to assure the terms of confinement does not inhibit the ethical conduct of the research and there are no other significant issues preventing the research. This process is not used for recruitment of prisoners into any given study.

H. Epidemiological research may be allowed if the research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factors associated with a disease, is no more than minimal risk, and presents no more than an inconvenience to the participants.

I. Research on prisoners of war is prohibited (e.g., captured or detained). This does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.

J. Exception from informed consent for emergency research is prohibited unless waived by the Secretary of Defense.

K. Additional educational requirements and certification of completion are provided to the appropriate Official within the DoD as required.

L. Any surveys performed on DoD personnel require approval by the DoD after IRB approval is granted.

M. DoD template subject injury language is required. This language is located on the IRB website under template language. The IRB may make additional injury disclosure decisions based on the nature of the injury and the participant population.

N. Research records may be required to be stored by the DoD archives, if applicable.

O. Any findings of serious and/or continuing non-compliance, and any suspension or termination of IRB approval will be reported to the appropriate DoD official within 30 days of the determination as well as any significant changes to the protocol, results of continuing review and changes of the reviewing IRB.

P. Coordinating center responsibilities must include a formal agreement and outline of responsibilities with DoD.
Q. For research involving US military personnel, additional protections include:
   1. Officers are not permitted to influence the decision of subordinates;
   2. Officers and senior non-commissioned officers may not be present at the time of recruitment;
   3. Officers and senior non-commissioned officers have a separate opportunity to participate;
   4. If recruitment involved a percentage of a unit, an independent ombudsman is present; and
   5. The following limitation on dual compensation apply:
      a) Individuals are prohibited from receiving pay for compensation for research during duty hours.
   6. US military personnel may be compensated for research if the participant is involved in the research while not on duty. Federal employees while on duty may be compensated for blood draws up to $50 for each blood draw. Non-federal persons may be compensated for other activities as appropriate according to rates and the nature of the research.

R. The Investigator will be provided with this policy and any additional resources needed to be in compliance with DoD requirements upon IRB review and approval.

II. The Department of Education:
   A. Research funded by the Department of Education will comply with the Protection of Pupil Rights Amendment (PPRA) to include:
      1. No student shall be required, as part of any research project, to submit without prior consent (parental permission and assent) to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:
         a) Political affiliations
         b) Mental and psychological problems potentially embarrassing to the student or his or her family
         c) Sex behaviors and attitudes
         d) Illegal, anti-social, self-incriminating and demeaning behavior
         e) Critical appraisals of other individuals with whom the student has close family relationships
         f) Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers
         g) Religious practices, affiliations, or beliefs of the student or student's parent
         h) Income, other than that required by law to determine eligibility for participation in a program for receiving financial assistance under a program.
   B. Unless consent is waived, prior consent means:
      1. Prior consent of the student, if the student is an adult or emancipated minor
      2. Prior written consent (permission) of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.
   C. Education records may be released without consent under FERPA if all personally identifiable information has been removed including:
      1. Student's name and other direct personal identifiers, such as the student's social security number or student number.
      2. Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and birth mother's maiden name.
3. Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.

4. Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

D. For research funded by the National Institute on Disability and Rehabilitation Research, the IRB includes at least one person primarily concerned with the welfare of any participant that is a child with disability or an individual with mental disability, if applicable.

E. For research not funded by the US Department of Education the IRB verifies by acceptance of the school official’s letter of agreement, that compliance with US Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

1. The right of parents to inspect, upon request, a survey created by a third party before the survey is administered or distributed by a school to students who are minors;
2. Arrangements to protect student privacy in the event of the administration of a survey to students, including the right of parents to inspect, upon request, the survey, if the survey contains one or more of the same eight items of the information noted above.
3. The right of parents to inspect, upon request, any instructional material used as part of the educational curriculum for students who are minors;
4. The administration of physical examinations or screenings that the school may administer to students who are minors.

F. The IRB maintains the right to have access to instructional material used in a research or experimentation program:

1. All instructional material – including teachers’ manuals, films, tapes, or other supplementary instructional material – which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research
2. Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques
3. Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

III. Department of Energy.

A. The IRB Chair decides the level of review and sends a letter to the investigator indicating all criteria has been met according to DoE expectations.

B. Reporting to the Human Subject Research Program Manager is required within 30 days of knowledge of the event for:

1. Any significant adverse event, unanticipated risks, or complaints about the research with a description of any corrective action;
2. Any suspension or termination of IRB approval;
3. Any significant non-compliance with HRPP procedures or requirements;
4. Any compromise of personally identifiable information.

IV. The Department of Justice.

A. The National Institute of Justice requires all projects have a Privacy Certificate approved by the NIJ Human Subjects Protection Officer.

1. The consent document must state that confidentiality may only be broken if the participant reports immediate harm to participants or others. The participant must be informed about any disclosure and the risk of harms from the disclosure.
2. Investigators and study personnel do not have to report child abuse unless the participant signs another consent form allowing child abuse reporting.
B. All research staff are required to sign Employee Confidentiality Statements which are maintained by the Investigator.
C. For NIJ funded research, a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data including informed consent documents, data collection instruments, surveys, or relevant research material.