POLICY:

I. Research funded or supported by the Department of Defense (DoD) must be reviewed by the IRB under an additional set of federal regulations [32CFR219]. The DoD follows the DHHS and FDA regulations on human subjects research, but also applies DoD regulations for protection of human subjects at 32 CFR 219 and DoD Instruction 3216.02 “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.”

II. UIC has signed a DoD Addendum (F50423) issued by the Air Force to its Federalwide Assurance (FWA) that signifies UIC applies DoD requirements for the protection of human research subjects when conducting, reviewing, approving, overseeing, supporting or managing DOD-supported research involving human subjects. This assurance addendum is recognized by all branches of the DoD.

III. This policy primarily reflects the general requirements for any DoD-component contained in DoD Instruction 3216.02 (11/08/2011). Additional DoD-component specific requirements may exist. It is the responsibility of the investigator to identify and notify the IRB of any additional requirements.

IV. The investigator is responsible for providing the DoD-component with the required records and following the prescribed record keeping schedule.

V. Research involves the DoD when any of the following apply:
   A. Research is funded by a component of the DoD;
   B. Research involves cooperation, collaboration, or other type of agreement with a component of DoD;
   C. Research uses property, facilities, or assets of a component of DoD, or
   D. Subject population will intentionally include personnel (military or civilian) from a component of DoD.

VI. DoD policies and requirements do not apply when DoD personnel incidentally participate in research that is not supported by DoD, and DoD personnel are not the intended population of the research.

VII. DoD Components
   A. Department of the Navy
B. Office of Naval Research  
C. U.S. Naval Observatory  
D. Naval Academy  
E. Department of the Army  
F. U.S. Army Corps of Engineers  
G. Military Academy (West Point)  
H. Department of the Air Force  
I. Air Force Academy  
J. Marines  
K. Coast Guard  
L. National Guard  
M. Missile Defense Agency  
N. Defense Advances Research Projects Agency (DARPA)  
O. Pentagon Force Protection Agency  
P. Defense Intelligence Agency  
Q. National Geospatial-Intelligence Agency  
R. National Security Agency  
S. Under Secretary of Defense (Personnel and Readiness) 

VIII. Definitions  

A. Detainees: any person captured, detained, held or otherwise controlled under the control of DoD personnel (military and civilian or contractor employee). It does not include persons primarily being held for law enforcement purposes, except where the US is the occupying power. Examples include lawful and unlawful enemy combatants, enemy prisoner of war, civilian internee and retained person.  
1. Enemy Prisoner of war: individuals under the custody or control of the US DoD according to Geneva Convention Relative to the Treatment of Prisoners of War, August 12, 1949 [DoD Directive 2310.01E, September 5, 2008]. 

B. Experimental Subjects: The DoD defines “Research Involving a Human Being as an Experimental Subject” as an activity, for research purposes, where there is an intervention or interaction with a human subject for the primary purpose of obtaining the effect of the intervention or interaction (32 CFR 219.102(f)). This definition does not include activities that are not considered research involving human subjects, activities that meet the exemption criteria at 32 CFR 219.101(b), and research involving the collection or study of existing data, documents, records, or specimens from living individuals (DoDI 3216.02, 11/8/2011).  

C. Research: any activity that is a systematic investigation, including research, development, training and evaluation designed to develop or contribute to generalizable knowledge.  

D. Minimal Risk: When determining the risk level for DoD-supported research, the definition of minimal risk as “...ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” shall 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).

PROCEDURE:

I. DoD-supported research involving human subjects cannot be initiated, including exempt and research not involving human subjects, until:
   A. UIC IRB has approved the research (or made a determination of exemption or research not involving human subjects),
   B. documentation of IRB approval or the determination and, when requested, UIC’s DoD FWA Addendum is forwarded to the human research protections official (HRPO) of the DoD-component, and
   C. notification from the DoD-component HRPO indicating:
      1. concurrence with the institution’s exemption or not human subject research determination, or
      2. acceptance of IRB’s approval and level of risk determination for nonexempt human subject research.
   D. Submission of DoD-component approval to IRB as an amendment. IRB will then notify the researcher that research activities may begin.

II. Additional Subject Protections for DoD-Supported Research
   A. In addition to the vulnerable populations listed in subparts B-D of 45 CFR 46, investigators and IRBs when reviewing DoD supported research shall consider the need for additional safeguards for other vulnerable populations, such as: human subjects and investigators in supervisor-subordinate relationships, human subjects with decisional or mental impairments, human subjects with a physical disability, or any other kind of human subjects in circumstances that may warrant provision of additional protections.
   B. For DoD-supported research, Subparts B-D activities that normally require the review and approval of the Secretary of HHS are routed by the DoD-component to the Assistant Secretary of Defense Research and Development.
   C. To ensure appropriate safeguards are in place for research involving vulnerable subjects, the investigator or IRB may appoint research monitors or advocates to oversee the research or assist subjects.
   D. Pregnant Women: DoD applies subpart B of 45 CFR 46 (refer to UIC HSPF policy Research Involving Pregnant Women, Human Fetuses and Neonates, and Fetal Tissue) with the following modifications:
      1. phrase “biomedical knowledge” is replaced with “generalizable knowledge” through subpart B, and
      2. applicability of subpart B is limited to research involving:
         a) Pregnant women as human subjects involved in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus; or
b) Fetus or neonate as human subjects.

3. Research involving human subjects using fetal tissue shall comply with 42 USC 289g-2.

4. notwithstanding the DoD modifications, the UIC IRBs apply Subpart B to minimal and greater than minimal risk, nonexempt human subject research where pregnant women are the focus of the research, even when the research is DoD supported.

E. Prisoners: DoD applies subpart C of 45 CFR 46 (refer to UIC HSPP policy Research Involving Prisoners) with the following modifications:

1. Research intending to include prisoners as subjects cannot be reviewed by the IRB through an expedited review procedure (in agreement with UIC HSPP policy Research Involving Prisoners).

2. Extends allowable research involving prisoners to include:
   a) Epidemiologic research as described in UIC HSPP policy Research Involving Prisoners, procedure II.E.
   b) Research involving human subjects that would meet the criteria for exemption at 45 CFR 46.101(b), but must be approved by a convened IRB and meet the other requirements of subpart C.

3. If a subject becomes a prisoner after enrolling in a research study which was not approved for prisoner participation, the procedures in UIC HSPP policy Research Involving Prisoners, Procedure V are followed with these additions:
   a) Notification of the incarceration to the DoD-component HRPO by the investigator and Director of OPRS, and
   b) Concurrence of the HRPO with the IRB’s determinations prior to allowing the incarcerated subject to continue in the research.

F. Detainees represent a special population of prisoners and research with detainees is prohibited. Detainees include enemy prisoners of war. While DoD Instruction 3216.02 (11/8/2011) allows exception to this prohibition under certain conditions for investigational drug or device trials, this type of research with prisoners is prohibited by Illinois law and, therefore, is not allowed under UIC HSPP policy.

G. Children: DoD applies subpart D of 45 CFR 46 (refer to UIC HSPP policy Research Involving Children (Including Wards of the State)). The footnote in section 32 CFR 219.101(i) applies to DoD-conducted or -supported research and prohibits applying the exemptions at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

H. Status of Service Members as Adults

1. all active duty Service members and Reserve Component members in a Federal duty status are considered adults for purposes of participation in DoD research.
2. Their participation in DoD-conducted or supported research is therefore not subject to the additional protections in Subpart D.

3. When Service members are under 18 years of age, students at Service Academies, or trainees, the IRB shall carefully consider the recruitment process and necessity to include such members as human subjects.

4. Illinois state law does not contain this exception. Therefore, if the protocol involves recruitment of service members less than 18 years of age, the investigator should consult UIC legal counsel as well as DoD-component before submitting to the IRB.

I. DoD Military personnel:
1. Service members should follow their component and command’s policies regarding participation in human subject research on- or off-duty. The IRB will request documentation of this authorization when reviewing the research.

2. Superiors (military and civilian supervisors, unit officers, and NCOs) are prohibited from influencing the decisions of their subordinates regarding participation as research subjects.

3. Superiors in the chain of command (unit officers, senior NCOs, and equivalent civilians) may not be present at any recruitment or informed consent sessions.

4. When applicable, superiors so exclude shall be afforded the opportunity to participate as human subjects.

5. Ombudsman requirement:
   a) When research is greater than minimal risk and recruitment occurs in a group setting, an ombudsman who is not associated with research must be appointed by the IRB.
   b) Ombudsman will monitor consent process for voluntariness and clarity, and serve as point of contact for subject questions.
   c) Appointment of ombudsman for minimal risk research is at the discretion of the IRB.

J. DoD Civilian personnel
1. Recruitment must follow local policy.

2. Procedures preventing undue influence from superiors must be followed as described in II.I.1.-4. above.

3. When research is greater than minimal risk and recruitment occurs in a group setting, IRB will discuss the need for appointing an ombudsman based on protocol specific considerations.

4. If appointed by the IRB, the ombudsman will function as described in II.1.5.b.

III. Research Monitor
A. Required for DoD-supported greater than minimal risk research.

B. When a research monitor is required, IRB must:
   1. approve the monitor by name and
2. determine, document and provide a written summary of the monitor’s duties, responsibilities and authorities.

C. There may be more than one research monitor if different skills and experience are needed.

D. The monitor may also serve as an ombudsman or a member of the DSMB.

E. Research monitors must:
   1. have appropriate expertise to oversee research;
   2. perform duties assigned by the IRB; and
   3. be independent from the research team.

F. The research monitor has the authority to take appropriate actions to protect human subjects until the IRB can respond to the monitor’s report, including:
   1. stopping research or
   2. removing subjects from the research.

G. Duties are based on specific risks and concerns of research and may include:
   1. oversight functions, such as observing recruitment, enrollment procedures and consent process, oversee study interventions and interactions;
   2. review monitoring plans and unanticipated problems involving risks to subjects or others;
   3. oversee data matching, collection and analysis;
   4. discuss research protocol with researchers, interview subjects, and consult with others outside of study; and
   5. report observations and findings to the IRB or designated official;

H. Requirement for research monitor may be waived by DoD-component heads or delegates.

I. Appointment of research monitor is optional for minimal risk research.

IV. Limitations on waivers of informed consent

A. DoD places limitations on waiver of informed consent for nonexempt human subject research supported by DoD.

B. When the research meets the DoD definition of research involving a human being as an experimental subject (see above), informed consent may not be waived and must be obtained from the experimental subject or the subject’s legal representative.

C. **If consent is to be obtained from the experimental subject's legal representative,** the research must intend to benefit the individual subject.

D. Assistant Secretary of Defense for R&D or delegate may waive this limitation if the research is necessary to advance the development of a medical product for the Military Services, may directly benefit the individual experimental subject, and is conducted in compliance with all other applicable laws and regulations.

E. For minimal risk research, IRB may waive some elements of consent provided consent is completely voluntary and subject understands risks.

F. Participants do not meet the definition of experimental subject when research activities are limited to the exemption criteria at 32 CFR...
219.101(b), and research involving the collection or study of existing data, documents, records, or specimens from living individuals (DoDI 3216.02, 11/8/2011). In these instances, the IRB may waive informed consent in accordance to the criteria at 45 CFR 46.116 (c) and (d).

V. Protecting Subjects from Medical Expenses
A. DoD-conducted greater than minimal risk research must establish procedures to protect subjects from medical expenses that are a direct result of their participation in the research.
B. The above requirement applies only to research activities performed by DoD personnel and does not apply to expenses resulting from injury due to actions performed by the non-DoD institution(s).
C. When DoD personnel are involved in the conduct of human subject research at a collaborating institution and DoD does not have primary involvement, DoD-Components are not required to have procedures to protect human subjects from medical expenses. Determination of primary involvement shall be based on consideration of the type and portion of the DoD involvement in the collaborative research (e.g., research staff, human subjects, facilities, equipment, IRB, and all other assets).
D. When it is difficult to separate DoD involvement from that of the non-DoD institution, the Head of the DoD-Component may waive the requirement for procedures to protect human subjects from medical expenses.
E. The process to be followed must be communicated to the subject or their LAR in the informed consent document.

VI. Compensation of Subjects
A. Type of institution conducting research does not influence compensation.
B. Compensation is influenced by source of funds and whether or not subjects are federal personnel and on-duty.
C. Subjects are federal personnel (active duty and civilian)
   1. On-duty: compensation limited to blood draws
      a) May participate in research during working or duty hours with supervisor approval and no compensation other than $50 per blood draw
      b) Compensation from federal or non-federal source
   2. Off Duty:
      a) No restrictions on compensation, as long as approved by IRB, and source is non-federal
      b) Federal source may be used only to compensate up to $50 per blood draw.
D. Subjects are not federal personnel
   1. No restrictions on compensation as long as approved by IRB
   2. Source may be federal or non-federal.

VII. Classified Research
A. The UIC IRBs generally do not review classified research involving human subjects. Researchers contemplating the application for or the
performance of classified research involving human subjects, should consult with the Office of the Vice Chancellor for Research.

B. DoD research activities generated from a classified program do not need to be viewed as classified as long as:
   1. information required to be in the protocol and needed by the IRB for its review is not classified, and
   2. information needed by potential subjects to provide informed consent is not classified.

VIII. Administration of surveys and interviews
A. Research involving administration of surveys to, or interviews of, DoD personnel may require approval from the DoD-component sponsoring the research.
B. Survey and interview requirements vary depending on the DoD-component, and investigator should contact their DoD HRPO.

IX. International Research
A. Requirements for the conduct of DoD-supported international research vary among the DoD-components, e.g. Department of Navy requires approval of the host country and joint ethics review with the host country when international research involves subjects who are not US citizens or DoD personnel.

X. Investigator Responsibilities When Performing DoD-Supported Research
A. Understand and fulfill the requirements of the supporting DoD component for conducting research involving human subjects.
B. Initial Review Submission: Complete and submit the DoD research supplement (Appendix Q) when submitting a study that is supported by or conducted in collaboration with a DoD component.
C. Submit to the IRB with Appendix Q:
   1. any DoD-component specific requirements regarding human IRB review and reporting, e.g. the Defense Federal Acquisition Regulation Supplement (DFARS) clause.
   2. documentation from the DoD-component of any additional human subject research ethics training requirements and evidence of completion of the training by the investigator and staff.
   3. documentation of scientific review from an established external (e.g., NIH review panel) or internal (e.g., UIC Cancer Center) review process. When an established review process is not available, the Department head may appoint an ad hoc committee.
   4. Independent research monitor’s curriculum vitae and acceptance letter, when applicable.
D. Amendment Submission: Amendments for DoD-supported research should be submitted using the UIC Amendment application form. When the amendment is substantive (i.e., more than minor; UIC HSPP policy Amendments to Previously Approved Research), review and approval by the DoD-component HRPO is required following UIC IRB approval.
E. Do not initiate research (or research changes) until the approvals in Procedure section I. A.-D. are received.

F. If military or civilian DoD personnel will be recruited, submit to the IRB:
   1. documentation that authorization for their recruitment has been obtained from their commander or supervisor;
   2. plan to prevent superiors from influencing the recruitment or consent procedures.

G. Research involving administration of surveys to, or interview of, DoD personnel,
   1. determine requirements of sponsoring DoD-component and
   2. submit survey for review and approval by the DoD-component HRPO following UIC IRB approval.

H. When conducting DoD-supported multi-center research, work with ORS to establish a formal agreement indicating roles and responsibilities of each institution. The agreement must be approved by the DoD component prior to the engagement in the research.
   1. The agreement will include: 1) engaged institutions must have an FWA, 2) the involvement of DoD personnel in the conduct of the research are secondary to non-DoD personnel; and 3) the agreement clearly defines the responsibilities and authorities of each organization in comply with all legal requirements

XI. IRB Responsibilities When Reviewing DoD-Supported Research
A. Consider and document in the minutes the scientific merit of the research when reviewing the initial submission.

B. Ensure the investigator and research staff have met the education and training requirements of the DoD-component.

C. Determine and document in the minutes the risk level (refer to definition of minimal risk above).

D. IRB may use expedited review procedures for minimal risk, nonexempt research limited to the use of materials (e.g., data, documents, records or specimens) that have previously been collected for any purpose, provided the materials were not collected for the currently proposed study.

E. UIC shall promptly notify the appropriate DoD HRPO of the following:
   1. significant changes to the research protocol are approved by the IRB (notification sent through UIC ORS),
   2. results of IRB continuing review (notification sent through UIC ORS),
   3. any changes in the IRB of record (notification sent through UIC ORS),
   4. when notified by any Federal department or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol (notification by HPA), and
   5. all unanticipated problems involving risks to subjects or others, suspensions, terminations, and serious or continuing
noncompliance regarding DoD-supported research involving human subjects (notification by HPA).

6. When the Department of Navy is the sponsor, notification also provided for:
   a) initiation and results of investigations of alleged noncompliance,
   b) audits, investigations, or inspections of DON-supported research protocols,
   c) audits, investigations, or inspections of UIC’s HRPP by outside agencies, and
   d) restrictions, suspensions or terminations of UIC’s assurance.

F. If protocol will recruit DoD military or civilian personnel, ensure:
   1. approval for recruitment obtained from appropriate supervisor, and
   2. procedures are in place to prevent superiors from influencing the recruitment or consent procedures.

G. Greater Than Minimal Risk Research
   1. Appointment of Ombudsman
      a) When research is greater than minimal risk and intends to recruit military personnel in a group setting, IRB must appoint an ombudsman to oversee recruitment and consent process.
      b) Appointment of an ombudsman is at the discretion of the IRB for greater than minimal risk research in non-military DoD personnel and minimal risk research in all subjects.
   2. Appointment of Research Monitor
      a) IRB must appoint a research monitor by name when the research is greater than minimal risk, unless this requirement has been waived by the DoD component head.
      b) IRB must approve and communicate to research monitor, based on protocol specific risk, a written summary of duties, responsibilities and authorities as described in III.E.-G.
      c) Appointment of a monitor is at the discretion of the IRB for minimal risk research
   3. Procedures Protecting Subjects from Medical Expenses
      a) DoD-supported research at UIC is not required to provide procedures, beyond those at 45 CFR 46, for protecting subjects from medical expenses.
      b) An exception to the above statement occurs when DoD personnel have primary involvement in conducting the research.
      c) IRB must review the extent of involvement of DoD personnel in conduct of the research at UIC and determine whether this represents primary involvement. IRB shall use the UIC HSPP policy Engagement of UIC in Human Subjects Research to guide their determination.
d) IRB will ensure in their review that the statement in the consent concerning coverage for research-related injury is accurate and consistent with DoD regulations.

H. Subject Meets Definition of Experimental Subject
   1. Informed Consent cannot be waived.
   2. If consent is to be obtained from the experimental subject’s legal representative, the IRB must determine that the research is intended to be beneficial to the individual experimental subject.
   3. IRB may waive one or more elements of consent for minimal risk research provided consent is completely voluntary and subject understands risks.

I. Subject Compensation
   1. IRB ensures any compensation of subjects is reasonable and agrees with 45 CFR 46 and DoD policies described in section VI.

J. International Research
   1. IRB considers in their review the cultural sensitivities of the setting, laws and regulations of the foreign country and any DoD-component specific requirements.

K. Submit to the HRPO for the DoD-component through the UIC Office of Research Services all required documentation concerning UIC IRB review of the research.

XII. Record Keeping
   A. 32 CFR 219 requires institutions engaged in DoD-supported research involving human subjects to retain records for at least 3 years after the completion of the research. Research involving human subjects may be covered by other Federal regulations (e.g., FDA, HIPAA) and DoD-component regulations that impose longer record keeping requirements.
   B. DoD-components may rely on the non-DoD institutions to keep the required records that were generated by the institution, or the DoD-components may make arrangements to transfer the records.
   C. Records maintained by UIC and UIC investigators that document compliance or noncompliance in conducting DoD-supported human subject research is accessible for inspection and copying by authorized representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD-Component.

REFERENCES:

32 CFR 219.
45 CFR 46 Subparts B-D.
REVISION LOG:

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1, 09/14/16</td>
<td>1.0, 3/17/12</td>
<td>Updating of links; Minor edits</td>
</tr>
</tbody>
</table>