CUNY HRPP Policy: Department of Defense Conducted or Supported Research

1. Applicability

This policy applies to all CUNY research involving human subjects that is supported by or conducted in collaboration with the Department of Defense (DoD). This includes research involving human subjects for which the DoD is:

- Providing at least some of the resources, including but not limited to funding, facilities, equipment or personnel;
- Giving access to or information about DoD personnel for recruitment; or
- Providing identifiable data or specimens from living individuals.

This policy outlines additional requirements for DoD conducted or supported research. All other CUNY policies also apply to DoD conducted or supported research.

2. Prohibitions

2.1. Testing of chemical or biological warfare

Research involving human subjects for testing of chemical or biological warfare agents is generally prohibited, subject to possible exceptions for research for prophylactic, protective, or other peaceful purposes.

2.2. Detainee as a human subject

Research involving a detainee, as defined in DoD Directive 2310.01E, as a human subject is prohibited, except as permitted by the Food and Drug Administration's regulations at Title 21 of the Code of Federal Regulations when for the purpose of diagnosis or treatment of a medical condition in a patient.

3. Scientific Merit

The IRB must consider the scientific merit of all human subjects research conducted in collaboration with DoD or supported by DoD. This is accomplished in the following manner:

The highest-ranking administrator who oversees research at the CUNY College with which the principal investigator has primary affiliation must sign off on the IRB application for the given protocol, indicating that the protocol has sufficient scientific merit to proceed. Please contact your College's HRPP Coordinator to obtain the contact information for the highest-ranking administrator.

4. Risk Evaluation

Minimal risk is defined in the federal regulations as follows: the probability and magnitude of harm or discomfort anticipated in the research are not greater in

and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

When evaluating risks to human subjects involved in DoD conducted or DoD supported research, the phrase, "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests," may not be interpreted to include the inherent risks certain categories of human subjects face in their daily life, such as the risk faced by active duty personnel serving in a war zone.

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).

5. Payment for Participation

5.1. On-duty federal personnel as human subjects

5.1.1. Compensation for blood draws

Federal personnel participating as human subjects in research conducted by CUNY may be compensated up to $50 for each blood draw if the research is in connection with the care of any person entitled to treatment at Government expense, regardless of funding.

5.1.2. General compensation for participation

Federal personnel participating as human subjects in research while on duty may not be otherwise compensated for general research participation, regardless of funding.

5.2. Off-duty federal personnel as human subjects

5.2.1. Compensation for blood draws in federally funded research

Federal personnel participating as human subjects in research conducted by CUNY may be compensated up to $50 for each blood draw if the research is in connection with the care of any person entitled to treatment at Government expense and it is federally funded.

5.2.2. Compensation for blood draws in non-federally funded research

Off-duty federal personnel may be compensated for blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the blood draw.

5.2.3. General compensation for participation

Federal personnel participating as human subjects while off duty may be compensated for research participation in the same way as human subjects who are not federal personnel. Payment to off-duty federal personnel must not be directly from a federal source.

5.3. Non-federal personnel as human subjects in DoD funded research

5.3.1. Compensation for blood draws

Non-federal personnel participating as human subjects in research funded by the DoD may be compensated up to $50 for each blood draw if the research is in connection with the care of any person entitled to treatment at Government expense.

5.3.2. General compensation for participation

Non-federal personnel participating as human subjects in research funded by the DoD may be compensated for research participation in a reasonable amount approved by the IRB according to local prevailing rates and the nature of the research. Payment for general research participation may come directly from federal or non-federal source.

6. Considerations for Recruitment of Service Members

- Superiors of service members shall not be present at any human subject recruitment sessions or during the consent process in which members of units under their command are afforded the opportunity to participate as human subjects. When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

- For greater than minimal risk research involving Service members as human subjects, for which recruitment occurs in a group setting, the IRB must appoint an ombudsman. The ombudsman shall not be associated in any way with the research study. The ombudsman must be present during the recruitment process, in order to monitor that the voluntary involvement or recruitment of the Service members is clearly and adequately stressed, and that the information provided about the research is clear, adequate and accurate.

- For minimal risk research involving Service members as human subjects, for which recruitment occurs in a group setting, the IRB may decide to require an ombudsman, depending on the human subject population, the consent process and the recruitment strategy.

7. Legal Capacity to Consent

All active duty Service members and all Reserve Component members in a federal duty status participating as human subjects in DoD supported research are considered to be consenting adults. When Service members are under 18 years of age, students at Service Academies, or trainees, the IRB must carefully consider the recruitment process and the necessity to include such members as human subjects.

8. Research Monitor

For greater than minimal risk research involving human subjects, the IRB must approve an independent research monitor by name. The duties of the research monitor will be determined by the reviewing IRB on the basis of the specific risks or concerns about the research. These duties may include, but may not be limited to, one or more of the following:

- Observe recruitment, enrollment procedures and consent process
- Oversee study interventions and interactions
- Review monitoring plans and/or reports of unanticipated problems involving risks to subjects or others
- Oversee data collection and analysis

The research monitor must report their observations and findings to the IRB of record for the given protocol. The IRB will determine, on a protocol-by-protocol basis, the frequency with which the research monitor must report to the IRB.

The research monitor has the authority to:

- Stop a research protocol in progress;
- Remove individual human subjects from a research protocol; AND
- Take any appropriate and necessary steps to protect the safety and well-being of human subjects until the IRB can assess the monitor's report.

9. Waiver of Informed Consent

DoD does not allow research involving a human being as an *experimental subject* without prior informed consent from the experimental subject or their legal representative. If the consent is to be obtained from the experimental subject's legal representative, the IRB must determine that the research intends to benefit the individual subject.

NOTE: DoD distinguishes between research involving human subjects and research involving a human being as an experimental subject as follows:

- *Research involving human subjects*: Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research **obtains data through intervention or interaction with the individual or identifiable private information**.

- *Research involving a human being as an experimental subject***:** An activity, for research purposes, where **there is an intervention or interaction** with a living individual **for the primary purpose of obtaining data regarding the effect of the intervention or interaction**.

10. Research involving Prisoners

DoD supported or conducted research that fall within one of the categories of research exempt from IRB review or expedited review and includes prisoners as research subjects must be reviewed and approved by a convened CUNY UI-IRB and meet the requirements outlined in the CUNY Research Involving Prisoners Policy.

In addition to the categories of permissible research involving prisoner subjects outlined in the CUNY Research Involving Prisoners Policy, DoD supported research or research conducted in collaboration with DoD may enroll prisoners in the following category of research:

- Epidemiological research that meets the following criteria:

    - The research describes the prevalence or incidence of a disease by identifying all cases, or studies potential risk factor associations for a disease;
    - The research presents no more than minimal risk;
    - The research presents no more than an inconvenience to the human subject; AND
    - Prisoners are not a particular focus of the research.

11. Reporting

CUNY HRPP will notify the appropriate DoD Human Research Protection Official (HRPO) of the following actions concerning research conducted in collaboration with the DoD or supported by DoD:

- When significant changes to the research protocol are approved by the IRB, including when a subject becomes a prisoner while participating in research;
- The results of the IRB continuing review;
- When the reviewing IRB changes;

- When CUNY is notified by any Federal department or agency or national organization that any part of the CUNY HRPP is under investigation for cause involving a DoD supported research protocol; AND
- Unanticipated problems involving risks to subjects, suspensions, terminations, and serious or continuing noncompliance regarding DoD supported research involving human subjects.

References

1. Code of Federal Regulations, Title 32 – National Defense, Part 219 – Protection of Human Subjects
2. Department of Defense Instruction Number 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Sponsored Research," issued November 8, 2011
3. Department of Defense Directive 2310.01E, "The Department of Defense Detainee Program," issued September 5, 2006
4. United States Code 24 Section 30, "Payments to donors of blood for persons undergoing treatment at Government expense"
5. United States Code 10 Section 980, "Limitation on Use of Humans as Experimental Subjects"