

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Research Subjects Review Board</b>	<b>Effective Date: 06/02/2020</b>	
	<b>Research Supported by the Department of Defense</b>	<b>Policy 609</b>	<b>Version: 1.3</b>

## POLICY

### 1. Purpose

Outline the additional federal regulatory requirements required under Department of Defense (DoD) Directive Instruction 3216.02 entitled “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.”

### 2. Scope

This policy applies to any employee or agent of the University of Rochester conducting research involving a human being as an experimental subject funded by the DoD, recruiting individuals from the DoD or a DoD component (the Army, Navy, Air Force and Marine Corps), or recruiting DoD personnel through a contract, grant, cooperative agreement, or other arrangement.

### 3. Definitions

- 3.1. *Administrative review* - A review of a research protocol and supporting documents (e.g., safety review, scientific review, IRB minutes) to ensure the institution engaged in the research involving human subjects has met the requirements of all applicable regulations and policies. This review is NOT an IRB review.
- 3.2. *Classified research involving human subjects* - Research involving human subjects where the protocol or other information required by the IRB for review and oversight, or required or provided by the research subjects, includes classified information.
- 3.3. *DoD Personnel* - DoD civilian employees and members of the military services.
- 3.4. *Prisoner of War (POW)* - A detained person as defined in Articles 4 and 5 of the Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949. In particular, one who, while engaged in combat under orders of his government, is captured by the armed forces of the enemy.
- 3.5. *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.
- 3.6. *Research Monitor* - An individual with expertise commensurate with the research protocol and the nature of the risk, whose role is to protect the safety and well-being of human subjects. The Research Monitor may be a member of the RSRB, another individual designated by the Reviewing IRB, or a member of the data and safety monitoring board. The Research Monitor shall be independent of the research team.

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#### 4. References

- 4.1. Department of Defense 32 CFR 219;  
DoD Instruction 3206.12 “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research”
- 4.2. [Policy 505 Scientific Review Standards](#);  
[Policy 603 Research Involving Prisoners](#);  
[Policy 801 Reporting Research Events](#);  
[Policy 802 Non-compliance in Human Subjects Research](#);  
[Guideline for Reporting Research Events](#);  
[Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance and UPIRTSO](#);  
[Guideline for Conducting International Research](#);  
[University of Rochester Policy on Research Misconduct](#)

#### 5. Responsibilities

- 5.1. Investigators and research staff are responsible for compliance with DoD research ethics training requirements.
- 5.2. Investigators are responsible for ensuring compliance with DoD regulatory requirements when conducting research supported by DoD, or when conducting research that recruits DoD personnel, in addition to the University and OHSP policies and guidelines applicable to the conduct of human subject research.
- 5.3. The RSRB is responsible for ensuring compliance with DoD regulatory requirements as indicated in Section 6.1 when the Reviewing IRB for research supported by DoD, or research that recruits DoD personnel. *Note:* The University of Rochester does not currently conduct classified research involving human subjects. Should this type of research be submitted to the RSRB, the RSRB will develop and utilize a checklist to document compliance with additional DoD requirements.
  - When the RSRB is the Relying IRB, the RSRB will defer to the external IRB’s DoD requirements consistent with the negotiated reliance agreement.
- 5.4. The RSRB is responsible for allowing authorized representatives of the DoD access to records that document compliance or noncompliance with this policy at reasonable times and in a reasonable manner.
- 5.5. When the RSRB is the Reviewing IRB, the RSRB is responsible for replacing the phrase “biomedical knowledge” with “generalizable knowledge” when applying sub-part B for DoD-supported research.

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- 5.6. Civilian Investigators seeking to recruit military subjects are responsible for collaboration with a military researcher familiar with service-specific requirements.
- 5.7. Investigators are responsible for notifying the DoD Human Research Protection Officer (HRPO), within 30 days of the following as applies to both convened board or expedited reviews:
  - 5.7.1. The Reviewing IRB has approved the research protocol and before the activities involving human subjects can begin (e.g., human subject recruitment and data collection). The HRPO must perform an administrative review of the research. Review and approval shall be based on confirmation that the research and non-DoD institution are in compliance with applicable regulations and policies, including any applicable laws and requirements and cultural sensitivities of a foreign country when the research is conducted in a foreign country.
  - 5.7.2. Significant changes to the research protocol are approved by the Reviewing IRB.
  - 5.7.3. The Reviewing IRB completes a continuing review.
  - 5.7.4. There is any change in the IRB of record.
  - 5.7.5. Any component of the DoD-supported study is investigated by any federal department, agency or national organization.
- 5.8. The Office of Research Project Administration (ORPA) is responsible for ensuring a formal agreement is established between organizations, specifying the roles and responsibilities of each party when conducting multi-site research.
- 5.9. The Research Monitor, or Monitors if necessary, is responsible for oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and unanticipated problems involving risks to subjects or others; and oversee data matching, data collection, and analysis) and for reporting their observations and findings to the Reviewing IRB, or designee. The Research Monitor has the authority to:
  - Discuss the research protocol with the investigators or research team,
  - Interview human subjects,
  - Consult with others outside of the study about the research,
  - Stop a research study in progress,
  - Remove individuals from a study,
  - Take steps to protect the safety and well-being of subjects until the Reviewing IRB can assess the situation.

## 6. Requirements

- 6.1. When the RSRB is the Reviewing IRB, during the process of initial and continuing review, the RSRB will:

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- 6.1.1. Prohibit research involving prisoners of war.
- 6.1.2. Prohibit research on detainees.
- 6.1.3. Ensure scientific review is conducted according to Policy 505 Scientific Review Standards.
  - 6.1.3.1. During the process of reviewing amendments, the RSRB will perform scientific review on all substantive revisions to approved research. As necessary, the RSRB may refer the scientific review back to the Investigator's department or outside consultation for additional expertise if necessary.
- 6.1.4. During the process of initial review, determine if the research is intended to be beneficial to the subject, and will only allow consent to be obtained from a legally authorized representative when the research will benefit the subject.
- 6.1.5. Consider the evaluation of minimal risk research, when applicable, in that the phrase "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests", shall not be interpreted to include the inherent risks certain categories of subjects face in their everyday life (e.g., risks imposed in research focused on a special population should not be evaluated against inherent risks encountered in their work environment, such as emergency responders, pilot, or soldier in combat zone, or having a medical condition, such as frequent medical tests or constant pain).
- 6.1.6. Require additional protections to minimize undue influence when military personnel are included in the research, such as:
  - 6.1.6.1. Officers are not permitted to influence the decision of their subordinates.
  - 6.1.6.2. Officers and senior non-commissioned officers may not be present at the time of recruitment.
  - 6.1.6.3. Officers and senior non-commissioned officers must have a separate opportunity to participate.
  - 6.1.6.4. When recruitment involves a percentage of a unit, an independent ombudsman is present.
  - 6.1.6.5. For research conducted within the Bureau of Prisons, the additional protections outlined in *Policy 603 Research Involving Prisoners* will be applied.
- 6.1.7. Consider when the appointment of a Research Monitor is necessary. A Research Monitor is required for research that involves greater than minimal risk and, as appropriate, may be required for minimal risk research. The RSRB must approve a written summary of the monitors' duties, authorities, and responsibilities. The RSRB shall communicate with Research Monitors to confirm their duties, authorities, and responsibilities.
- 6.1.8. Determine if the consent form must include a statement that the DoD or a DoD organization is funding the study.
- 6.1.9. Determine if the consent form must include a statement that representatives of the DoD are authorized to review research records.

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- 6.1.10. Determine that the consent form includes the provision for research-related injury, which is consistent with 32 CFR 219.116, “*For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*”
- 6.1.11. Prohibit the exception from consent in emergency medicine research, unless a waiver of advanced informed consent is obtained from the Secretary of Defense.
- 6.1.12. Prohibit waivers of consent for research involving a human being as an experimental subject, unless a waiver is obtained from the Assistant Secretary for Defense for Research and Engineering.
- 6.1.12.1. If the research subject does not meet the definition of “experimental subject,” the RSRB may waive the consent process without approval from the Secretary.
- 6.1.13. Require limitations on dual compensation, including:
- Prohibiting payment for research conducted during duty hours.
  - Only paying for research if the subject is involved in the research when not on duty.
- 6.1.14. Allow payment of federal employees up to \$50 for each blood draw and, for procedures other than blood draws, non-federal persons may receive payment in a reasonable amount commensurate with the prevailing rates and the nature of the research.
- 6.1.15. When reviewing research involving vulnerable populations, apply Department of Health and Human Services OHRP Subparts B, C, and D and the related OHSP policies and guidelines.
- 6.1.16. When reviewing international research, require that the researcher obtain permission to conduct the research by certification or local ethics review, as per the *Guideline for Conducting International Research*. The researcher will also be required to provide the RSRB with an assurance that the proposed project will follow all local laws, regulations, customs, and practices.
- 6.2. Investigators are required to submit any surveys completed by DoD personnel to the DoD for review and approval after the research protocol is reviewed and approved by the Reviewing IRB, and before any recruitment of subjects.
- 6.3. When the RSRB is the Reviewing IRB, the RSRB will review non-compliance consistent with *Policy 802 Non-Compliance*.
- 6.3.1. When the RSRB determines that serious or continuing non-compliance has occurred in a DoD-supported study, the RSRB will report this to the DoD HRPO within 30 days of the RSRB determination according to the *Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance and UPIRTSO*.

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- 6.4. When the RSRB is the Reviewing IRB, the RSRB will review research events consistent with *Policy 801 Reporting Research Events* and the *Guideline for Reporting Research Events*.
  - 6.4.1. When the RSRB determines that an unanticipated problem involving risk to subjects or others has occurred in a DoD-supported study, the RSRB will report this to the DoD HRPO within 30 days of the RSRB determination according to the *Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance and UPIRTSO*.
- 6.5. When the RSRB is the Reviewing IRB, the RSRB will report suspensions and terminations that occur in a DoD-supported study to the DoD HRPO within 30 days of the RSRB determination according to the *Guideline for Reporting Research Events* and the *Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance and UPIRTSO*.
- 6.6. The University of Rochester will review scientific misconduct consistent with *UR Policy on Research Misconduct* and, when scientific misconduct has occurred in a DoD-supported study, will report the incident to the DoD.
- 6.7. When the RSRB is the Reviewing IRB, the RSRB will utilize the *Checklist for RSRB Review of Research Supported by the DoD* (Appendix 1) to document compliance with DoD requirements listed within this policy.

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**Originator/Authors:**

Kelley O'Donoghue, OHSP Director

**Appendices:**

Appendix 1: Sample Checklist for RSRB Review of Research Supported by the DoD

**Revision History:**

01/2015: Section 6.1.5 added to expand on definition of minimal risk per AAHRPP  
06/2018: Sect 3 – removed DoD Addendum definition; Sect 4.1 removed DoD FWA reference; Sect 4.2 add hyperlinks; Sect 5 – removed responsibilities for DoD addendum and DoD training; Sect 5.6, 6.1.8, 6.1.9 added to comply with new DoD requirements; added language throughout for Reviewing and Relying IRB; additional administrative changes  
06/2020: Section 6.1.8 and section 6.1.9 revised wording; updated signatories

**Supersedes Date:**

06/18/2018

**Approved By:**



10/14/2020

Kelley A. O'Donoghue  
Director, OHSP

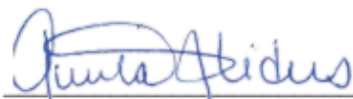
Date



10/13/2020

Nicole Mason  
Executive Director, RSRB

Date



October 13, 2020

Gunta Liders  
Director, ORPA

Date

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## Appendix 1

### Checklist for RSRB Review of Research Supported by the DoD Sample Template

#### OFFICE FOR HUMAN SUBJECT PROTECTION

#### Research Subjects Review Board



### Checklist for RSRB Review of Research Supported by the Department of Defense

Consistent with OHSP Policy 609 Research Supported by the Department of Defense, the following checklist will be used by the RSRB to ensure compliance with DoD regulatory requirements when reviewing research supported by DoD, or research that recruits DoD personnel.

#### Additional Criteria for DoD Research (Check if “Yes” or “N/A”. All must be checked)

<input type="checkbox"/>	<p>The investigator and research staff are aware of the specific DoD requirements and have been educated about these requirements. The following language is included in the initial approval letter:</p> <p>“As the Principal Investigator on a Department of Defense supported research study, you are responsible for ensuring compliance with DoD regulatory requirements, in addition to the University and OHSP policies and guidelines applicable to the conduct of human subject research. You are responsible for notifying the DoD Human Research Protection Official (HRPO) when:</p> <ul style="list-style-type: none"> <li>• The RSRB has approved the research protocol and before the activities involving human subjects can begin (e.g., human subject recruitment and data collection). The HRPO must perform an administrative review of the research; review and approval shall be based on confirmation that the research and non-DoD institution are in compliance with applicable requirements.</li> <li>• Significant changes to the research protocol are approved by the RSRB.</li> <li>• The RSRB completes a continuing review.</li> <li>• There is any change in the IRB of record.</li> <li>• Any component of the DoD-funded study is investigated by any federal department, agency or national organization.</li> </ul>
<input type="checkbox"/>	The review has considered the scientific merit of the research.
<input type="checkbox"/>	The research does <b>NOT</b> involve prisoners of war or detainees as subjects.
<input type="checkbox"/>	Only allow enrollment of individuals with decisional impairment, if the research includes direct benefit.
<input type="checkbox"/>	Additional protections are in place to minimize undue influence when military personnel are included in the research. See Section 6.1.6 of <a href="#">Policy 609 Research Supported by DoD</a> for examples of protections.
<input type="checkbox"/>	When conducting international research, the researcher must obtain permission to conduct the research by certification or local ethics review and provide assurance that the proposed project will follow all local laws, regulations, customs, and practices, as per the <a href="#">Guideline for Conducting International Research</a> .

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<input type="checkbox"/>	<p>For research involving <b>Greater than Minimal Risk</b>, a Research Monitor has been identified and approved by the RSRB. The RSRB has approved a written summary of the monitors' duties, authorities, and responsibilities. The Research Monitor: <b>(Check if "Yes". All must be checked.)</b></p> <p><input type="checkbox"/> Has expertise commensurate with the research protocol and the nature of the risk.</p> <p><input type="checkbox"/> Is independent of the research team</p> <p><input type="checkbox"/> Has the authority to stop a research study in progress, remove individuals from the study, and take steps to protect the safety and well-being of subjects until the RSRB assesses the situation.</p> <p><input type="checkbox"/> Will promptly report observations and findings to the IRB or other designated official.</p> <p><input type="checkbox"/> Has provided a written summary of duties, authorities, and responsibilities, which was approved by the RSRB.</p>
<input type="checkbox"/>	<p>Limit payment for participation:</p> <ul style="list-style-type: none"> <li>• Prohibit payment for research conducted during duty hours.</li> <li>• Only pay for research if the subject is involved in the research when not on duty.</li> <li>• Allow payment of federal employees for up to \$50 for each blood draw and, for procedures other than blood draws, non-federal personnel may receive payment in a reasonable amount commensurate with the prevailing rates and the nature of the research.</li> </ul>
<b>Consent Form Requirements</b>	
<input type="checkbox"/>	The consent includes a statement that the DoD or DoD organization is funding the study.
<input type="checkbox"/>	The consent includes a statement that representatives of the DoD are authorized to review research records.
<input type="checkbox"/>	For research involving <b>Greater than Minimal Risk</b> , the consent form includes the provision for research-related injury, which is consistent with 32 CFR 219.116.
<input type="checkbox"/>	Prohibit the exception from consent in emergency medicine research, unless a waiver is obtained from the Secretary of Defense.
<input type="checkbox"/>	Prohibit waivers of consent for research involving a human being as an experimental subject, unless a waiver is obtained from the Assistant Secretary for Defense for Research and Engineering.