Penn IRB SOP Version 15
Summary of Substantive Changes

Un-bolded text is existing language. **Bolded text is new language.**

Applicable Sections	Summary of Changes	Rationale for Changes
GA 102 ACTIVITIES REQUIRING IRB REVIEW	**Added new language:** The University does not apply 45 CRF 46 regulations to non-federally funded research. The IRB will provide for equivalent protections and apply the same policies and procedures to all human participant research.	Clarifies that the Penn IRB may execute more flexibility in reviews when studies are not federally funded.
RR 402 EXPEDITED REVIEW	**Added new language:** When research is FDA regulated (clinical investigations), the IRB requires the submission of product information, such as a package insert, investigator's brochure, or device manual to consider the nature of and any risks posed by the clinical investigation, the degree of uncertainty regarding the risks involved, and whether the study involves novel therapies. The IRB verifies the projected rate of enrollment for clinical investigations led by industry sponsors or other sites from the clinical protocol, DSMB charter, and Data and Safety Monitoring Plan.	Clarifies how the IRB determines the nature of and any risks posed by the clinical investigation, the degree of uncertainty regarding the risks involved, and whether the study involves novel therapies. Clarifies how the IRB verifies the projected rate of enrollment.
RR 403 INITIAL REVIEWS: CRITERIA FOR IRB APPROVAL	**Added new language:** 3.5 Additional Considerations for Initial Review of Community Based Participatory Research Community-based participatory research (CBPR) is a form of community-engaged research, involving a collaborative approach for participation, shared decision-making, and mutual ownership in all aspects of the research process by communities affected. Review of studies that involve community participation may require special considerations and expertise when initially reviewed. While participatory studies	Outlines additional considerations for Community Based Participatory Research. Added to meet AAHRPP Element I.4.C.

	need to meet all requirements for initial approval, the IRB recognizes that community engaged research often requires additional thought to both protect participants and facilitate conduct of the research. The IRB has experience reviewing community-engaged research. The IRB recognizes that there is not a "one size fits all" approach to the review of CBPR and will therefore consider the following tools when appropriate: 3.5.1 Periodic IRB member / staff trainings about review of participatory projects, with emphases on equitability and justice within the review process for community engaged research. Trainings may be conducted by the IRB, investigators, or community members who are or have been engaged in participatory research. 3.5.2 Recruitment of board members with experience conducting participatory projects in both biomedical and social-behavioral settings, including within the clinical investigation milieu. 3.5.3 Distribution of guidance regarding the review and conduct of participatory research. 3.5.4 Recruitment and utilization of board members consultants with lived experiences to advise on the review of the project. Consultants should ideally be members of the community or communities involved in the research. 3.5.5 IRB application requirements related to participatory methods. Minimum requirements include a completed Community Based Research form, a letter of study support from representatives of the community or communities who are actively involved in the research, and a clear and detailed plan for disseminating results to community members throughout and at the conclusion of the study. Other requirements may vary based on specifics of each project and engaged population. They could include assurances of human research ethics training from community	

	members who are actively engaged in the research and confirmation of additional support from relevant associated community organizations.	
RI 801 IRB-REQUIRED INVESTIGATOR ACTIONS	**Added new language:** If the research is a Department of Health and Human Services (DHHS)-approved protocol, the investigator must provide the IRB with (as applicable) a copy of the DHHS-approved sample informed consent document and the DHHS-approved protocol.	Added to meet AAHRPP Element II.2.E. and DHHS requirements
DD 100 DEPARTMENT OF DEFENSE REGULATED RESEARCH	**Added new language:** **Chemical or Biological Agents** Human participant research involving the testing of chemical or biological agents is prohibited, pursuant to Section 1520a of Title 50, United States Code (U.S.C.). Some exceptions for research for prophylactic, protective, or other peaceful purposes apply. Before any excepted testing of chemical or biological agents involving human participants' research can begin, the DoD component seeking to conduct such research must obtain explicit written approval from the DoD Office for Human Research Protections (DOHRP). • The organization permits research involving chemical or biological agents under an exception. The Principal Investigator and research team is responsible for obtaining approval from DoD and must submit documentation of this with their IRB application. **DOD Personnel Recruitment** For greater than minimal risk research involving DoD-personnel, when recruitment and consent occur in a group setting, the IRB must appoint an ombudsperson. The ombudsperson: • Must not have a conflict of interest with the research or be a part of the research team. • Must be present during the HSR recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary, and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials.	Added to align with Revised Common Rule DOD regulations

	• Should be available to address DoD-affiliated personnel's concerns about participation. **Surveys** Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD Information Management Control Officer (IMCO) after the research protocol is reviewed and administratively finalized by the IRB. Documentation of this approval should be provided in the IRB application before enrollment may commence and final approval is issued. When a survey crosses DoD components, additional review is required, and the DOD checklist is required to be completed. The PI is responsible for obtaining all required approvals. **Informed Consent Requirements** If the research involves DoD-affiliated personnel as participants, in addition to the basic and required consent disclosures, the IRB or component HRPO must confirm that the consent documents must include: • If the research involves risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document (ICD) must inform DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating. • If applicable, a statement of potential risks for the revocation of clearance, credentials, or other privileged access or duty. • A statement that the DoD or a DoD organization is funding the study. • A statement that representatives of the DoD are authorized to review research records. For greater than minimal risk research: • Consent documents must include the disclosure that participants may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond participants' participation in the study to such time after the study has ended.	

	• Written materials must document how organizations will care for participants with research-related injuries, including injuries that are the direct result of activities performed by DoD-affiliated personnel in studies that are collaborative with a non-DoD institution. **Genomic Data** Research involving large-scale genomic data from DoD-affiliated personal is subject to additional requirements: • The disclosure of DoD-affiliated personnel's genomic data may pose a risk to national security; accordingly, written materials must describe administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens. • All research involving large-scale genomic data collected from DoD-affiliated personnel must have a certificate of confidentiality from DHHS (Title 42, U.S.C., and Public Law 114-255). • Research involving large-scale genomic data collected from DoD-affiliated personnel is subject to DoD component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards, including the secondary use or sharing of de-identified data or specimens. <u>Research involving pregnant individuals and/or fetuses</u> • Research or experimentation may not be conducted, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation: o May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or o Will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.	

	• The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term. • For human participant research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOHRP must be obtained through the COHPR prior to research starting. <u>Service members and DoD-affiliated personnel</u> Service members and DoD-affiliated personnel are considered to be vulnerable to coercion and undue influence by the DoD due to the nature of the command structure of the organization. Therefore, additional protections for DoD-affiliated personnel are required, as follows (DoDI 3216.02 section 3.9 (f)): • If the research involves DoD-affiliated personnel as participants and if the research includes any risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document must inform DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating. • If the research involves DoD-affiliated personnel, the researcher must receive command or component approval to execute the research. • Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in research. • Military and civilian supervisors, officers, and others in the chain of command must not be present at any participant recruitment sessions or during the consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate recruitment sessions, if applicable. • Service members and all Reserve component and National Guard members in a federal duty status are considered to be adults. If a Service member, Reserve component or National Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the IRB must carefully consider the HSR recruitment process and the necessity of including such member as a human participant.	

Research with Incarcerated Persons

- Research involving incarcerated persons cannot be reviewed by the expedited procedure.
- When the IRB reviews research involving incarcerated persons, at least one incarcerated person representative must be present for quorum.

Emergency Medicine Research

When conducting emergency medicine research, the Principal Investigator is responsible for obtaining approval from the DOHRP on behalf of the Secretary of Defense for a waiver of the advance informed consent provision of 10 USC 980. The Principal Investigator is responsible for following the process required by DOHRP.

Reliance Agreements

The IRB shall adhere to SOP GA 102 when executing reliance agreements between IRBs. These agreements will define the responsibilities of the DoD organization and non-DoD reviewing IRB, including all requirements in Standard I-9 for IRBs serving as reviewing IRBs, and the following additional requirements, including but not limited to:

- The process for serving as a reviewing IRB for DoD institutions collaborating with non-DoD institutions, including who is responsible and the process they go through to obtain DoD approval for a non-DoD institution to be designated to review for DoD research, including ensuring the following conditions are met (DoDI 3216.02 section 3.5):
    - Each institution engaged in non-exempt human participant research must have a current federal assurance of compliance.
    - The non-DoD institution's IRB is registered in accordance with Subpart E of 45 CFR 46.
    - The DoD institution reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol.
    - The DoD institution, non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities

	of each institution in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02, including but not limited to non-DoD institutional responsibilities defined under DoDI 3216.02 section 3.6(b). o If the research constitutes classified human participant research, the COHRP must approve the agreement to rely on the non-DoD institution's IRB.	
DD 100 DEPARTMENT OF DEFENSE REGULATED RESEARCH	**Revised the following language:** **Reporting Requirements** The following shall be promptly (no longer than within 30 days) reported to the Component Office of Human Research Protections (COHRP)~~the DoD human research protection officer~~: • When significant changes to the research protocol are approved by the IRB. • The results of the IRB continuing review. • Change of reviewing IRB. • When the organization is notified by any Federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol. • Reports of audits of DoD-conducted or DoD-supported human participant research by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government. o The PI is responsible for reporting to the IRB and the Component Office of Human Research Protections (COHRP) in alignment with the applicable branch requirements • Allegations of serious or continuing noncompliance related to research involving human participants that are substantiated by investigation, and subsequent actions taken based on the findings.	Revised to align with Revised Common Rule DOD regulations

	○ The IRB will report to the Component Office of Human Research Protections (COHRP) via email. • Substantiated allegations related to classified HSR must be reported immediately. ○ If allegations are received by the study team, the PI is responsible for reporting to the IRB and the Component Office of Human Research Protections (COHRP) in alignment with the applicable branch requirements ○ If allegations are received by the IRB, the IRB will report to the Component Office of Human Research Protections (COHRP) via email. • When the organization is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that any part of an HRPP is under investigation for cause involving a DoD-supported research protocol. • Closure of a DoD-supported study. Any unanticipated problems involving risks to participants or others for any DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer. Any suspension or termination of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer. Reporting of serious noncompliance, continuing noncompliance, and unanticipated problems will be done in accordance with SOPs 408 and 409. **Data and Safety Monitoring** In alignment with RR 403, where appropriate, the IRB will consider provisions for monitoring data to ensure the safety of participants to be appropriate. ~~The IRB considers the appointment of a research monitor:~~	

	~~• Required for research involving greater than minimal risk, although the IRB or organizational official can require this for a portion of the research or studies involving no more than minimal risk if appropriate.~~ ~~• The research monitor is appointed by name and shall be independent of the team conducting the research.~~ ~~• There may be more than one research monitor (e.g. if different skills or experience are needed.)~~ ~~• The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.~~ ~~• The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.~~ ~~• The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:~~ ~~○ Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis).~~ ~~○ Discuss the research protocol with researchers, interview human participants and consult with others outside of the study.~~ ~~○ Report observations and findings to the IRB or a designated official.~~ ~~• The research monitor has the authority to:~~ ~~○ Stop a research study in progress.~~ ~~○ Remove individuals from study.~~ ~~○ Take any steps to protect the safety and well-being of participants until the IRB can assess.~~	
DE 300 DEPARTMENT OF ENERGY	**Added new language:** **Overview** …	Added to align with Revised Common Rule DOE regulations

	DOE requirements apply to all research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research. • When research involves contractors, DOE "Contractor Requirements Document" describing contractor responsibilities for protecting human research participants must be included in contracts. No human participant research conducted with DOE funding at DOE institutions (regardless of funding source), or by DOE or contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research, may be initiated without both a Federalwide Assurance (FWA) or comparable assurance (e.g., Department of Defense assurance) and approval by the cognizant IRB in accordance with 10 CFR Part 745.103. **Department of Energy IRB Review Checklist** … Research that uses social media data must be submitted to the IRB for human participant research review and determination. Research that involves the study of humans in a systematically modified environment must be submitted to the IRB for HSR review and determination. **DOE Personnel Recruitment:** DOE and DOE site contractors are considered vulnerable subjects when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g., by ensuring they do not report to members of the research team), and that data collected about them is kept confidential. The IRB must consider if additional protections are required for research involving employees and contractors.	

	The Penn IRB does not review research involving Human Terrain Mapping (HTM). HTM is defined by DOE as research and data gathering activities primarily conducted for military or intelligence purposes to understand the "human terrain,"—the social, ethnographic, cultural, and political elements of the people among whom the U.S. Armed Forces are operating and/or in countries prone to political instability. Such activities are often referred to as human social culture behavior (HSCB) studies. Investigators who seek to engage in such research must seek special permission from Penn's IO who will engage other appropriate organizational leaders in the decision-making process.). Research involving human participants involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, unless review by another appropriate IRB of record is authorized by the DOE and/or NNSA HSP Program Manager. If authorized by the DOE and/or NNSA HSP Program Manager, research may be reviewed by other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review. **IRB Review Requirements:** … Classified and unclassified human participant research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified. **Reporting Requirements:** …	

	The Human Subjects Protection (HSP) Program Manager (and when an NNSA element is involved, the NNSA HSP Program Manager) must be notified in writing prior to initiation of the HSR portion of a new project, even if it meets the regulatory definition of exempt HSR as outlined in 10 CFR Part 745.104, that involves (DOE 0 443.1C, section 4(d)): • An institution without an established IRB. • A foreign country. • A potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups). • Research subjects in a protected class (prisoners, children, individuals with impaired decision making, or DOE/NNSA federal or DOE/NNSA contractor employees as human subjects, who may be more vulnerable to coercion and undue influence to participate) that is outside of the reviewing IRB's typical range/scope. • The generation or use of classified information. The HSP Program Manager at DOE or NNSA must be notified within 48 hours, with a description of corrective actions taken, of any known or potential incidents of noncompliance.	
DJ 400 DEPARTMENT OF JUSTICE	**Added new language:** **For research conducted with the Bureau of Prisons** … • The researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher. … • The research must have an adequate research design and contribute to the advancement of knowledge about corrections.	Added to align with Common Rule DOJ regulations