

WSU/PNNL Research Collaborations - Facility Access, Oversight, Safety and Other Considerations

The information in this document is intended to help facilitate collaboration between WSU and PNNL by outlining the basic considerations and expectations when WSU faculty and/or their staff/students will be conducting research at PNNL facilities and when PNNL employees/students will be conducting research at WSU facilities. The document is not intended to cover every scenario but rather provide the basic considerations, minimum requirements, and appropriate contacts to work through the details. Early communications can help assure all appropriate agreements and approvals are in place and prevent delays in getting started with your research.

Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with the relevant WSU and PNNL compliance offices early in the planning process. Some collaborative projects may be subject to the terms and conditions found in a signed agreement between PNNL and WSU, such as a memorandum of understanding (MOU), a contract or other funding agreement, or a Cooperative Research & Development Agreement (CRADA). This document is intended to support/supplement those agreements and does not supersede any of the requirements described in those documents. Researchers are responsible for reviewing each MOU, contract, CRADA or other agreement that pertains to their research and conducting research in accordance with these documents.

For the avoidance of doubt, nothing in this guidance document shall be interpreted to require PNNL to act contrary to the requirements found in Prime Contract No. DE-AC05-76RL01830 between PNNL and the Department of Energy or any other legal obligation PNNL may have. Similarly, nothing in this guidance shall be interpreted to require WSU to act in contravention of any of its governing statutes, regulations, policies, procedures, or other legal obligations.

General Considerations:

Equipment: The use of shared equipment must be detailed in an agreement (such as a use agreement, loan agreement, CRADA, etc.) that details the ownership arrangements associated with the equipment including liability associated with damage or repair, disposition and where the equipment will be located and accessed. Details should be documented in DOE-approved scope if accessing equipment at PNNL. Any changes (moving the equipment to another facility, modifying who will be operating the equipment, etc.) will require prior approval and likely an amended user agreement.

Materials (Rad, Bio, Chem): Material supplied or owned by one institution and used at the other should be represented by an MTA or other agreement that includes responsibility for tracking, record keeping, liability, disposition, and other requirements associated with using the material. In addition, some materials are subject to export control regulations that may also need to be assessed. (See, e.g., <https://ora.wsu.edu/export-controls/>; <https://www.pnnl.gov/explainer-articles/export-controls>.)

Proprietary or Regulated Data: Data provided by one institution to another, that is not otherwise publicly available without restriction, should be shared under a Data Sharing Agreement (DSA). The DSA may provide for the nature of the data, permissible uses of the data, associated regulatory and security requirements, any applicable restrictions on the sharing of the data with third parties, as well as any pre-publication review requirements should the data be used to support a contemplated publication.

Risk Assessments: Risk assessments may need to be performed by both the facility where the work involving hazardous materials or activities occur, as well as the organization responsible for employing the researchers. (See, e.g., <https://ehs.wsu.edu/workplace-safety/>; https://www.pnnl.gov/support_org/ehss.asp.)

For PNNL work conducted offsite, an Offsite Risk Management Plan (ORMP) generated by the Electronic Prep and Risk for the PNNL project is required. Offsite activities for environmental, safety and health hazards will need to be created in Lab Assist. An Offsite Radiological Work Request and Permit (ORWP) is required for PNNL employees performing research with radiological materials or radiation producing machines at non-PNNL facilities. See HDI exhibit “Experimental or Field Work Off Site or Outside of IOPS or Lab Assist Controls.”

WSU Faculty/Staff/Students must meet the below requirements, as applicable before conducting work at a PNNL facility.

Safety: WSU is ultimately responsible for the safety of its employees regardless of the work location. PI's, staff and students working at another institution must meet safety requirements of the facility they are working at and any requirements from WSU that exceed the local requirements. PI's/Supervisors are responsible for assuring appropriate safety training has occurred in accordance with WSU SPPM 2.18 "General Workplace Safety" (<https://policies.wsu.edu/prf/index/manuals/2-00-contents/2-18-safety-training/>).

PNNL has a separate orientation/on-boarding process required for WSU joint appointees (JAs), students, and other visiting scientists, which outlines their requirements when conducting research at PNNL facilities.

Facility Access: In order to conduct research in PNNL Facilities, WSU personnel must;

- 1) Have an individual agreement (for faculty with a joint appointment), nonemployee access agreement or contract in place as required by PNNL that details the expectations associated with access.
- 2) Complete PNNL training and onboarding (initial and annual).
- 3) Have any relevant PNNL oversight committee approvals for the work (e.g. IRB, IACUC, IBC, RSC).
- 4) Foreign National collaborators require a Security Plan and Risk Assessment initiated by the Foreign Visits and Assignments process. Refer to the HDI exhibit "Request Approval for Foreign National Interaction" for additional guidance. For WSU employees please contact your PNNL host for additional information.

Research Involving Animals:

- WSU PIs conducting research involving animals should be familiar with the WSU IACUC policies governing animal research <https://iacuc.wsu.edu/about/> regardless of where the research will be conducted.
- Dual IACUC review is not required by OLAW or USDA when there are collaborations between institutions; however, there is an expectation that the collaborating institutions have a contract, reliance agreement and/or MOU in place that designates responsibility for animal care and oversight. WSU researchers must review IACUC policy #9 (https://iacuc.wsu.edu/documents/2016/06/policy_9.pdf/) before planning any animal research at non-WSU locations.
- PNNL has an AAALAC accredited Animal Care and Use Program, an active Animal Welfare Assurance and is a registered research facility with USDA. In general, WSU will rely on the PNNL IACUC to review and oversee any animal work occurring by WSU faculty at PNNL facilities. The WSU faculty member must reach out to the WSU Animal Welfare Program (iacuc@wsu.edu) early in the process (well in advance of any animal research being performed) so that a determination about oversight can be made and an appropriate reliance agreement be established.
- The WSU faculty will be required to submit a PNNL IACUC protocol and meet all necessary PNNL IACUC training requirements for work occurring at PNNL facilities.

- WSU employees should be current with their WSU Occupational Health Training -Animals (OHT-A) and may be required to enroll in the OHT-A risk assessment and medical evaluation program.
- DOE notification or approval may be required to conduct animal work at PNNL facilities depending upon the animal model and source of funding.
- Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with both the WSU and PNNL AWP/IACUC Office early in the planning process.

WSU Animal Care and Use Program contacts:

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PNNL Animal Care and Use Program Contacts:

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Research Involving Potentially Biohazardous materials (e.g., infectious agents, toxins, recombinant or synthetic nucleic acid molecules):

- WSU PIs conducting research involving potentially biohazardous materials should be familiar with the WSU biosafety program, including the Institutional Biosafety Committee (IBC) policies, regardless of where the research will be conducted: <https://biosafety.wsu.edu/potentially-biohazardous-materials/>
- Dual IBC review is not required, however PNNL expectations may differ from those of WSU, including services involving occupational health and safety.
- The WSU faculty will be required to submit a PNNL IBC protocol and meet all necessary training requirements for work occurring at PNNL facilities.
- Lab Assist activity(ies) will be required for the work scope to be executed at PNNL. The PNNL host/collaborator can assist with creation and/or identification of such Lab Assist activities.
- Work scope executed at PNNL may require WSU faculty and students to be current with WSU Occupational Health Training and be enrolled in a medical evaluation program. Select documentation of enrollment in the WSU medical surveillance program and approval to work with select controls may be requested by PNNL.
- Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with both the WSU and PNNL Biosafety Officer's early in the planning process.

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Research Involving Human Subjects:

- Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with both the WSU and PNNL Human Research Protection Program/Institutional Review Board Offices early in the planning process. **This early consultation is important if the proposed project may include non-PNNL DOE personnel (e.g., employees, contractors) as participants.**
- Dual IRB review is typically not required when there are collaborations between institutions; however, there is an expectation that the collaborating institutions have a reliance agreement, contract and/or MOU in place that designates responsibilities. It is important to note that contracts, MOUs, data sharing agreements, etc. do not replace the need for a reliance agreement for any federally funded non-exempt human subjects research.
- The WSU faculty member must reach out to the WSU Human Research Protection Program/Institutional Review Board (irb@wsu.edu) and the PNNL Human Research Protection Program (susan.varnum@pnnl.gov) in advance of any research involving human participants being performed so that a determination about oversight can be made and an appropriate reliance agreement can be established. For more information, please visit: <https://irb.wsu.edu/external-collaborations/>
- WSU PIs conducting research involving human participants should be familiar with the [WSU IRB/HRPP policies](#): <https://irb.wsu.edu/about-hrpp-irb/> and [PNNL HRPP Policies](#): <https://humanresearch.pnl.gov/> regardless of where the research will be conducted.
- The IRB of Record and the PI must assure that [DOE specific requirements](#) have been met and are followed during the conduct of research: <https://science.osti.gov/ber/human-subjects/Regulations-and-Requirements/DOE-Specific-Requirements>
- PNNL has a FWA (FWA00025932) and one active registered IRB (IRB00011131). When PNNL serves as the IRB of record, IRB review will be conducted under the terms of the PNNL FWA.
- When PNNL serves as the IRB of record, meeting any WSU specific (policy) requirements will be the responsibility of the PI.
- WSU has an FWA (FWA00002946) and two registered IRBs (IRB 0000449 and IRB 00011272). When WSU is the IRB of record, the review will be conducted under the terms of the WSU FWA.

WSU Human Research Protection Program contacts:

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Research Involving Radioactive Materials or Radiation Producing Machines:

- WSU PIs conducting research involving radioactive materials and/or radiation producing machines should be familiar with the WSU radiation safety program, including the WSU radiation protection manual, regardless of where the research will be conducted:
<https://rso.wsu.edu/rppm/>
- Dual radiation safety committee review and badging is not required.
- Radioactive materials and/or radiation producing machines must be approved by the PNNL Radiation Safety Officer (RSO) prior to use. Materials transferred from WSU's broadscope license for use at PNNL must be initiated by the WSU RSO.
- The WSU faculty will be required to assure PNNL RSO approves all planned research, badging needs, and training requirements for work occurring at PNNL facilities.
- Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with both the WSU and PNNL RSO's early in the planning process.

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PNNL PI's, staff and students must meet the below requirements, as applicable before conducting work at WSU Facilities.

Safety and Security: PNNL is ultimately responsible for the safety of its employees regardless of the work location. PNNL researchers working offsite must meet safety requirements of the facility they are working at and any requirements from PNNL that exceed the local requirements. PI's/Supervisors are responsible for assuring appropriate safety training has occurred for their staff. Within the project charter (in the Electronic Prep & Risk [EPR] system), include a description of the experimental or field work to be conducted off-site or outside of Integrated Operations System (IOPS) or Lab Assist. Refer to the HDI exhibit "Experimental or Field Work Off Site or Outside of IOPS or Lab Assist Controls" and the "Summary of Experimental / Field Work Off Site or Outside of IOPS or Lab Assist Control" document for additional guidance. All documents and materials generated externally while working in a classified subject area need to be reviewed by a derivative classifier. Refer to the HDI exhibit "DC Review of Externally Developed Event Content" for additional guidance.

Facility Access: In order to conduct research in WSU Facilities, PNNL personnel must:

- Complete any required facility orientation & WSU required training
- Work with the Department Chair or Facility Director to determine if a WSU Research Facility Use Agreement will be required.
- Have any relevant WSU oversight committee approvals for the work (e.g. IRB, IACUC, IBC, RSO).

Research Involving Animals:

- PNNL researchers conducting research involving animals at WSU should be familiar with the relevant WSU IACUC policies on animal research and teaching <https://iacuc.wsu.edu/about/> and take required training.
- Research involving animals occurring in WSU facilities requires approval by the WSU IACUC. WSU has an AAALAC accredited Animal Care and Use Program, an active Animal Welfare Assurance and is a registered research facility with USDA.
- Dual IACUC review is not required by OLAW or USDA when there are collaborations between institutions; however, there is an expectation that the collaborating institutions have a contract, reliance agreement and/or MOU in place that designates responsibility for animal care and oversight. The WSU AWP Office will work with PNNL to determine if a reliance agreement is appropriate or if the PNNL IACUC wants to complete a separate review of the protocol.
- PNNL employees should be enrolled in the PNNL Occupational Health program. WSU will accept enrollment in the PNNL program in lieu of enrollment in the WSU Occupational Health program.
- PNNL faculty with a joint appointment wishing to serve as PI on a WSU IACUC protocol need to adhere to https://iacuc.wsu.edu/documents/2016/06/policy_22.pdf/
- Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with both the WSU and PNNL AWP/IACUC Office early in the planning process.

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Research Involving Biohazardous materials (infectious agents, toxins, recombinant DNA/RNA, etc.):

- PNNL PI's conducting research involving potentially biohazardous materials at WSU should be familiar with the WSU biosafety program, including the Institutional Biosafety Committee (IBC) policies (<https://biosafety.wsu.edu/potentially-biohazardous-materials/>).
- WSU IBC oversees research at WSU locations and therefore requires submission of a Biosafety Approval Form (BAF) (<https://biosafety.wsu.edu/forms-templates-inspection-checklists/>).
- All researchers are required to train on a project-specific Biosafety Manual (BSM) that work with potentially biohazardous materials.
- An approved PNNL ORMP generated by Electronic Prep and Risk and approved Lab Assist activities for environmental, safety and health hazards are required prior to execution of experimental work scope(s) at WSU.
- Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with both the WSU and PNNL Biosafety Officer's early in the planning process.

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Research Involving Human Subjects:

- Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with both the WSU and PNNL Human Research Protection Program/Institutional Review Board Offices early in the planning process. **This early consultation is important if the proposed project may include non-PNNL DOE personnel (e.g., employees, contractors) as participants.**

- Dual IRB review is typically not required when there are collaborations between institutions; however, there is an expectation that the collaborating institutions have a reliance agreement, contract and/or MOU in place that designates responsibilities (<https://irb.wsu.edu/external-collaborations/>).
- The PNNL PI must reach out to the WSU Human Research Protection Program/Institutional Review Board (irb@wsu.edu) or the PNNL Human Research Protection Program contact (susan.varnum@pnnl.gov) in advance of any research involving human participants being performed so that a determination about oversight can be made and an appropriate reliance agreement can be established. For more information, please visit: <https://irb.wsu.edu/external-collaborations/>
- PNNL PIs conducting research involving human participants should be familiar with the WSU IRB/HRPP policies (<https://irb.wsu.edu/about-hrpp-irb/>) and PNNL IRB/HRPP policies (<https://humanresearch.pnl.gov/>).
- WSU has an FWA (FWA00002946) and two registered IRBs (IRB 0000449 and IRB 00011272). When WSU IRB is the IRB of record, the review will be conducted under the terms of the WSU FWA. DOE specific requirements will be implemented when required.
- When WSU IRB is the IRB of record, the PNNL PI will be required to submit a WSU IRB protocol and meet all necessary WSU IRB training requirements for work occurring at WSU facilities.

WSU Human Research Protection Program contacts:

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PNNL Human Research Protection Program contact:

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Research Involving Radiation:

- PNNL PIs conducting research involving radioactive materials and/or radiation producing machines at WSU should be familiar with the WSU radiation safety program, including the WSU radiation protection manual (<https://rso.wsu.edu/rppm/>).
- Radioactive materials and/or radiation producing machines must be approved by the WSU Radiation Safety Officer (RSO) prior to use and are subject to oversight by the WSU Radiation Safety Committee. Materials transferred from PNNL must be approved by the WSU RSO and added to WSU's broadscope license.
- An Offsite Radiological Work Request and Permit (ORWP) is required to be in place prior to performing the work at a WSU facility. Contact the Radiation Protection Program for additional details and requirements.

- The PNNL faculty and authorized users will be required to comply with badging and training requirements for work occurring at WSU facilities.
- Since each project can vary based on funding source, who is directing the research, and facilities to be used it is important to communicate with both the WSU and PNNL RSO's early in the planning process.

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Summary of Experimental / Field Work Off Site or Outside of IOPS or Lab Assist Control

INITIATE

- Within the project charter (in the Electronic Prep & Risk [EPR] system), include a description of the experimental or field work to be conducted off-site or outside of Integrated Operations System (IOPS) or Lab Assist.

[See which procedures use this document](#)

PLAN

- Check the "Experimental/Field Work" risk source and the "Work Performed Outside of IOPS" risk trigger to create the Off-Site Risk Catalog within the EPR system. Complete the catalog to develop an Off-Site Risk Register to document the experimental and field work risk sources; assess risk level for each source; and any mitigation/treatment approach or technique.
- Develop an Off-Site Risk Management Plan to manage the portion of the work performed in non-IOPS locations.
- Further risk mitigation or treatment techniques or supplementary documentation may be added to the Off-Site Risk Management Plan, as well as formally recording training documentation for project staff members or non-staff workers. This will be a downloadable document capable of having supplemental information added, signature page for training, etc.
- For Hanford site work, see [Obtain Approval to Use Hanford Site](#).

IMPLEMENT

- Prior to starting work, verify workers have received all work instruction, requirements, and project specific procedures; also verify all required training has been complete.

CONTROL

- Perform project assessments/reviews as specified in the directorate assessment schedule or PMOD project review requirements.
- Annual EPR review.

When planning off-site experimental or field work, consider the following items that have presented challenges in the past:

- accommodations for workers (e.g., transportation, housing, sanitation, food)
- communications plan and infrastructure, local communications, and translation/interpretation services
- emergency contacts and response, including local emergency contacts
- technology protection and export control (TPEC) reviews and access controls (e.g., foreign contacts and sensitive information and equipment). Submit a [TPEC Service Request](#) through the *PNNL Service Catalog* for assistance
- functional support and infrastructure (e.g., transportation and waste handling)
- National Environmental Policy Act (NEPA) or State Environmental Policy Act (SEPA) reviews
- notification for start and completion of work
- work procedure(s) and/or permit(s) (e.g., work, environmental, emission or release, offsite Radiological Work Request and Permit [ORWP])
- site specific required reading, training, conditions (e.g., weather), security clearance, or alarms
- hazards at the site (e.g., weather, dosimeter use, radiological surveys, criminal activity, wild animals)
- transportation of workers, materials, and equipment to the location.

CLOSEOUT

- Workers close out activities as specified by the project manager and the requirements provided by the site owner or operator.

Without IOPS to control the risks, projects will need a higher level of review, approval, and documentation for field and experimental work off site or outside of IOPS spaces.

This does not include the following:

- Paper studies.
- Work performed in laboratory workspaces managed under IOPS control.
- Off-site assignments where only office work is performed.
- Domestic or international business travel (e.g., attending a conference, participating in meetings).
- Contracted work not directly managed by PNNL.

Use the execute project process for general project requirements. Include an operations manager, safety & health representative, and environmental compliance representative throughout the process.

- [Execute Project Lifecycle](#)
 - [Initiate Project](#)
 - [Plan Project](#)
 - [Implement Project](#)
 - [Control Project Performance](#)
 - [Close Project](#)