Human Research Subjects Protection Program (HRSPP)

Principle Investigator (PI) Guidance

Argonne NATIONAL LABORATORY

DOE HSPP Contacts

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Argonne HRSPP Team Contacts

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1. Is my project human subjects research?

- To help answer that question, contact the HRSPP Manager at 630-252-1492 or email srupkey@anl.gov, or complete ANL-1211*Human Research Protection Program Assessment.*
- See flip side for examples of projects that may need IRB review.

2. How do I write a project protocol?

- You need to complete and submit your protocol on a template provided by the DOE IRB. Most protocol are submitted on HRP-503.
- Depending on your project, you may also need to develop and submit a participant consent form using another DOE template HRP-502. The consent form must be reviewed by Legal before being submitted to the DOE.
- The HRSPP Manager will assist you in obtaining all the correct templates.

3. How do I submit a protocol to the DOE IRB?

- You will upload your completed protocol in the IRB 10 software.
- The HRSPP Manager will assist you in obtaining access to the DOE's IRB 10 software.

4. How long does it take for the IRB to review?

- The DOE IRB holds most review meetings the second Wed. of each month. For classified, fourth Wed.
- Principle investigators should submit documents three weeks prior to the meeting at which they would like to have their protocols reviewed.
- To present additional information or explain research to IRB members, the PI may present there HSR protocols to the DOE IRB by teleconference.
- You will be notified via email regarding the status of your project within about two week after the IRB meets. It may be longer if the DOE IRB has questions about your protocol.

5. What training do I need?

- If your project is determined to fall under the DOE and Argonne HRSPP then update your JHQ by checking the applicable D11 series of questions.
- TMS will populate with the required courses.
- ESH802 is a one time in-person/virtual course.
- ESH812 or ESH814, ESH816, and ESH818 are accessed through TMS, which provides instructions for taking these courses through a DOE paid provider called Collaborative Institutional Training Initiative (CITI).
- When setting up you CITI account, remember to choose **"OTHER DOE"** as your institution. If you do not, you will end up taking the wrong courses.

6. What is the HRP-422 Training Checklist?

- This DOE form documents that you completed the DOE required CITI training and document reviews.
- By updating your JHQ and completing the related training in your TMS profile you will have completed the DOE CITI requirements. Just check the box on the form.
- You will also attest that you reviewed the following documents:
  - HPR-101-General-DOE *Human Subject Protection Plan*
  - HRP-103-General-DOE *Investigator Manual*
  - 10 CFR Part 745 *Protecting Human Subjects*
  - DOE O 443.1C, *Protection of Human Research Subjects*
  - *Conflict of Interest and Implicit Bias articles.*
- The HRSPP Manager will assist you in obtaining these four documents.
- This DOE form must be completed and upload to the IRB 10 site.

All this information and more is detailed in the LMS-MNL-8, *Research Using Human Subjects or Their Data*

1) **What is this program called?**
   a) DOE calls it the Human Subjects Protection Program (HSPP)
   b) Argonne calls it the Human Research Subjects Protection Program (HRSPP)
   c) Most everyone uses the grammatically awkward term Human Subject Research (HSR) program
   d) All of the above are fine and mean the same thing.

2) **When does the IRB need to review my project?**
   a) All research (including classified research) involving human research subjects must be approved by the U.S. Department of Energy (DOE) through the Argonne Human Research Subjects Protection Program(HRSPP) before it is started or modified, per DOE Order 443,1C, Protection of Human Research Subjects. Check out this flowchart. It is not always obvious, when in doubt ask.

3) **What are some broad example of research that may fall under the HRSPP?**
   a) Administration of surveys, tests and performing interviews
   b) Analysis of photographs or video with humans
   c) Use of any form of information/data from social media
   d) Community engagement and community-based participatory research
   e) Collection and analysis of social, ethnographic, cultural, or political demographics
   f) Modifications to the human environment
   g) Analysis of medical images and health records, whether containing identifiable information or de-identified data.
   h) Collection or analysis of identifiable biospecimens
   i) Collection or analysis of private identifiable information (even de-identified data must be reviewed by the DOEIRB).
   j) Use, storage, or maintenance of secondary research containing identifiable private information or identifiable biospecimens

4) **What documents govern Argonne's HRSPP?**
   a) Primary Document: **LMS-MNL-8 Research Using Human Subjects or Their Data**
   b) LMS-POL-50, Protected Health Information
   c) LMS-PROC-22, Protection of Controlled Unclassified Information
   d) LMS-POL-73, Conflict of Interest in Research – Federal
   e) LMS-POL-26, Employee Conflicts of Interest
   f) LMS-POL-15, Organizational Conflict of Interest
   g) LMS-PROC-278, Outside Consulting or Other Employment

5) **Where does Argonne store it's HRSPP Records?**
   a) In a Box® folder
   b) DOE's IRB10 system
   c) Individual researchers store their project related data per Argonne and their divisional records retention PROCs?

6) **What are the responsibilities of the project manager (PM) and/or PI and researchers?**
   a) Understand when a new or modified project has the potential to be categorized as HSR and implement the requirements of the HRSPP.
   b) Perform HSR only within the scope of work (protocol) approved by the IRB.
   c) Take and confirm applicable HSR project staff take all required HSR training before beginning HSR project work.
   d) Manage research staff to meet all expectations of the IRB-approved protocol.
   e) Alert the PM, PI, division director, and the HRSPP manager immediately when an adverse effect or adverse event, loss of PII or PHI, unanticipated risk to human subjects or others, complaints about the research, noncompliance with approved protocols or procedures, or any suspension or termination of IRB approval of research occurs
   f) Read, understand, acknowledge and abide by the terms of all applicable DUAs, BAAs, and MOUs

7) **Does Argonne have back-up roles for key positions in its HRSPP?**
   a) Primary program manager - Steve Rupkey, Back-up – Dan Schabacker
   b) Primary program manager for classified projects – Dan Schabacker, Back-up – Diane Hart
   c) Primary legal representative – Cheryl Luce Fuga, Back-up – Pranava Upadrashta

8) **How does Argonne flow down HSR requirements to subcontractors per the DOE 443.1C O Protection of Human Research Subjects?**
   a) If we use a subcontractor on a human subjects research project, we would flow down the requirement through legal and purchasing departments.

9) **How does Argonne keep track of training requirements?**
   a) Argonne's TMS system sends automatic reminders of training dates coming due.
   b) CITI will also send you an email notice of refreser training that is coming due.

10) **What types of issues do I report immediately to the HRSPP Manager and Legal regarding human subjects research?**
   a) Significant adverse events
   b) Unanticipated problems
   c) Complaints about the research
   d) Suspension or termination of IRB approval of research
   e) Significant non-compliance
   f) Confirmed or suspected breach of PII and/or PI