

Checklist: Additional Requirements for Research Supported by the Department of Energy (version date: June 9, 2021)

Note: The Department of Energy (DOE) IS a [signatory to the Revised Common Rule](#), which took effect January 21, 2019.

Researcher Responsibilities

Researchers are responsible for communicating with their DOE Program Officer to ensure that all DOE requirements are met prior to starting an IRB approved study.

- **Protection of personally identifiable information (PII):** Researchers are required to complete and comply with the requirements outlined in the [DOE Communication Standards and Guidelines](#) for Use by Researchers Conducting Human Subjects Research that Utilizes PII
- Any compromise of personally identifiable information must be reported **immediately** (within 3 working days).

- **Post Approval Reports**

Researchers must **promptly** report the following to the UCLA OHRPP:

- Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.
- Any suspension or termination of IRB approval of research.
- Any significant non-compliance with HRPP procedures or other requirements.

See OHRPP Guidance and Procedure: [Post-Approval Reporting Requirements \(PAR\)](#) for a details and required timelines for “prompt” reporting.

OHRPP Responsibilities

The UCLA IRB/OHRPP is responsible for ensuring that DOE requirements are met prior to approving DOE-supported human subjects research.

- UCLA will periodically conduct self-assessments to ensure compliance with the HRPP procedures and other requirements.
- When conducting classified research, the use of exemption and expedited review methods are prohibited. The fact that research meets a particular exemption category may be noted, but review by a convened IRB is required.
- Any IRB member can appeal a vote to approve research to the Institutional Official, Secretary of Energy, and Director of the Office of Science and Technology, in that order.
- The non-affiliated member must be a non-governmental member with the appropriate security clearances. This individual cannot be a current federal employee or contractor.
- Employees and contractors are considered vulnerable participants. Additional protections that must be considered by the IRB if additional protections are required for research involving employees and contractors

Regulations & References

- DOE Human Subjects Protection Regulations: [10 CFR Part 745](#)
- Protection of Human Research Subjects: [DOE Directive O 443.1B](#)
- DOE Human Subjects Protection Program [website](#)

Change history:

7/5/2018: Removed specific OHRPP staff contact information

2019/5/9: Added reference to Revised Common Rule, updated DOE links

06/09/2021: Added information re: Classified research only full board review is allowed; appealing votes to approve research; non-affiliated member requirements; defined employees and contractors as vulnerable participants; added communication standards and guidelines link for investigators; updated links.