



Office of the Human Research Protection Program

## Checklist: Additional Requirements for Research Supported by the Department of Energy (version date: March 14, 2014)

### 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:** Researchers are required to complete and comply with the requirements outlined in the DOE [Checklist](#) 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 IRB must review and approve DOE supported applications to verify compliance with the elements in the DOE IRB [Checklist](#) for Reviewing Human Subjects Research Protocols that Utilize PII
- UCLA will periodically conduct self-assessments to ensure compliance with the HRPP procedures and other requirements.

### 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](#)
- DOE IRB [Checklist](#) for Reviewing Human Subjects Research Protocols that Utilize PII
- DOE [Checklist](#) for Use by Researchers Conducting Human Subjects Research that Utilizes PII

### Questions

If you have questions regarding DOE requirements, please contact the relevant IRB Administrator or Kip Kantelo, OHRPP Director at (310) 825-5855, or [kip.kantelo@research.ucla.edu](mailto:kip.kantelo@research.ucla.edu).