



Title:	Research Subject to US Department of Energy Regulations		
SOP Number:	2401	Effective Date:	June 2, 2017
Previous Version Dates:			

## 1 Research Subject to U.S. Department of Energy Regulations

When following Department of Energy (DOE) regulations, the IRB reviews and approves the “DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocols that Utilize Personally Identifiable Information (PII)” submitted by the researchers to verify compliance with the DOE requirements for the protection of personally Identifiable Information.

Investigators must promptly (no longer than within 30 days) report the following to the human subject research program manager:

- 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.
- The time frame for “promptly” is defined.
- Any compromise of personally identifiable information must be reported immediately.
- The time frame for “immediately” is defined.