IRB Institutional Review Board

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IRB Office Reporting Requirements

The IRB Office promptly reports the following information to the IRB and the Authorized Institutional Official, the Office for Human Research Protections, the Program Manager for Human Subjects Research at the DOE (both the Office of Science and the National Nuclear Security Administration [NNSA]), and the FDA for FDA-regulated studies:

- Injuries to human subjects.
- Unanticipated problems or scientific misconduct involving risks to human research subjects or others.
- Serious or continuing noncompliance by investigators with the requirements of the federal regulations.
- Suspension or termination of IRB approval as a result of adverse events or serious and continuing noncompliance by investigators.
- Changes in IRB membership.

Additionally, the IRB Program Manager is responsible for submitting an annual report to the DOE. This report includes information on all human subjects research-related activities for the prior fiscal year.