Reportable IRB Determinants, Activities, and Definitions

In compliance with applicable accreditation, local, state, and federal reporting requirements, the UK Institutional Review Board (IRB) notifies appropriate officials when research falls under the purview of a federal regulatory agency and one or more of the following occurs:

- IRB determination of**:**
  - **Continuing Noncompliance;**
  - **Serious Noncompliance;**
  - **Unanticipated Problems Involving Risk to Subjects or Others**;
- **Suspension or Termination** of IRB approval in response to above determinations.

Report: The research Compliance Officer (RCO) or designee prepares a report and sends it to the applicable regulatory agency (e.g., Office of Human Research Protection {OHRP} and other Common Rule agencies).

FDA-Regulated research: When research is FDA-regulated, the IRB requires the PI to report to the sponsor who must report to the FDA. If the PI is also the sponsor, then the PI is required to report to the FDA. The IRB can choose to prepare and send the report directly to the FDA, if deemed appropriate.

DEFINITIONS

Noncompliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human subjects research. Noncompliance with IRB and/or federal requirements may involve a range of issues from relatively minor or technical violations which result from inadvertent errors, inattention to detail, or failure to follow operational procedures to more serious violations which pose risk to subjects and/or violations of their rights and welfare.

Continuing noncompliance is defined as persistent failure to adhere to the laws, regulations, or policies governing human research.

Serious noncompliance is defined as a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

1. Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or
2. Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

Unanticipated problem involving risk to subjects or others (UPIRSO) includes any incident, experience, or outcome that meets **all** of the following criteria:

1. ***Unexpected*** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol related documents, such as IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; and
2. ***Related or possibly related*** to participation in the research; and
3. ***Suggests that the research places subjects or others at a greater risk of harm*** (including physical, physiological, economic, or social harm) that was previously known or recognized.

Suspension of IRB approved research is a temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

Termination of IRB approval refers to a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

**For more information, see the Mandated Reporting to External Agencies SOP, Noncompliance SOP Termination or Suspension SOP, and UP and Safety Reporting Policy.*