HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

Other Reportable Information or Occurrences (ORIO) Reports

- ORIOs are used to report a number of different types of events associated with the conduct of a human research projects that are not reported as Adverse Events.
- Some ORIOs describe events that represent **noncompliance** with human subjects regulations, laws, institutional policies or IRB requirements or may describe unanticipated problems (UaP). Events that represent potential **serious or continuing noncompliance or a UaP** require **prompt reporting (**within 7 calendar days) to the IRB.
    - **Serious noncompliance** materially increases risks or causes substantive harm to research participants or materially compromises the rights or welfare of participants.
    - **Continuing noncompliance** recurs after an investigator has been notified of a similar or related noncompliance concern pertaining to one or more protocols.
    - **Unanticipated problems** are any incident, experience, or outcome that meets **all** of the following criteria:
        - It is “unexpected” in terms of its nature, severity, or frequency given 1) the research procedures described in the protocol-related documents, such as IRB-approved research protocol and informed consent documentation; and 2) the characteristics of the subject population being studied;
        - It is “related” or "possibly related “to the participation in the research; meaning there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
        - It suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- Examples of events requiring prompt reporting include (within 7 calendar days):
    - Human research conducted **without IRB approval** or determination of exemption
    - Research conducted **without informed consent**, unless the IRB approved a waiver
    - **Major protocol deviations** that impact subjects safety or the integrity of the data
    - **Multiple protocol deviations** of the same type that suggest a problem with the design or conduct of the study (10+ deviations of a similar type, such as use of an incorrect consent document)
    - **Incidents involving subject data** or biospecimens that may impact subject confidentiality or the integrity of the research
    - **Complaints** about the study that cannot be resolved by the study team
- Investigators are encouraged to report other ORIOs as they are occur.

Nature of Event	eResearch Report Description
Accident/Incident	**Use to report accidents/incidents involving:** • Data • Specimens • Facilities For example, events involving server intrusions, stolen laptops, loss of specimens, etc. ***To report accidents or incidents involving harm to subjects, submit an Adverse Event report.***

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Complaint	**Use to report complaints from:**
	• Subjects
	• Others
	  ○ Potential subjects who were recruited but did not enroll
	  ○ Family members or others complaining on behalf of a subject
	  ○ Researchers, students, or staff
	  ○ Reports from the U-M Compliance Hotline

Protocol Deviation/Violation	**Use to report:** • Deliberate Procedural Deviations (including "protocol exceptions") • Accidental Procedural Deviations • Appointment/Visit Deviations • Intervention Errors or Deviations • Consent Process Deviations or Problems
Report of Study Lapse	**Use to report:** Status of research during a lapse in IRB approval when Continuing Review is required. This includes any: • Recruitment • Subject enrollment • Interaction/interventions with subjects • Analysis of identifiable data
Subject Incarceration	**For studies not previously approved to enroll prisoners, use to report when:** • A prisoner is enrolled unintentionally • Intent to continue participation of a previously enrolled subject who becomes incarcerated (prisoner, involuntarily committed psychiatric patient, etc.) **Note:** For most research reviewed by IRB-HSBS, an amendment is required ***prior to*** enrolling a prisoner in research or continuing to interact with someone who has become incarcerated.
Notification of Audit/Inspection/Inquiry	**Use to:** Advise the IRB, ***prior to*** an audit/inspection/inquiry, of any documentation that may be needed by the auditor/inspector (e.g. copies of IRB outcomes regarding protocol issues)
Pertinent Publication/Public announcement	**Use to report:** • Information affecting the risk/benefit ratio of the study • Information affecting subjects willingness to participate in the research
Report to/from Oversight Entity	**Use to report:** • Review reports from the U-M Office of Research Compliance Review (ORCR) • Progress report to the IRB • Annual report to or from DSMB • Other reports to the IRB that do not fit into one of the other categories
Subject Withdrawal	**Use this:** • When withdrawal(s) prompt an amendment to change the research (complete the ORIO and obtain IRB acknowledgement prior to beginning the amendment submission) • To track withdrawals as they occur (optional)