Wittenberg University

Research Ethics and Compliance

Policy on Reporting Unanticipated Problems in Human Subjects in Research

PURPOSE

The purpose of this policy is to facilitate the protection of human subjects in research conducted at Wittenberg University. It is intended to ensure that any unanticipated problems that occur in research to subjects or to research investigators is promptly reported to the Institutional Review Board (IRB). This policy is guided by federal regulations from the Office for Human Research Protection (HRP) within the Department of Health and Human Services (45 CFR Part 46) and by the office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services. Federal regulations require institutions engaged in human subjects research to have written procedures for ensuring prompt reporting to the IRB of "unanticipated problems involving risks to subjects or other" that can occur during a research study regardless of the level of risk or type of research.

DEFINITIONS

In accordance with federal regulations and HRP policies, an Unanticipated Problem is defined as:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the 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 (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Reasonable judgement must be used when determining what constitutes an unanticipated problem. Researchers must consider the psychological, emotional, economic and social harms, not merely physical harms. When in doubt, it is best to err on the side of reporting the event or contact the Institutional Review Board (IRB) for guidance.

Examples of unanticipated problems involving risks to subjects or others include, but are not limited to:

1. A breach of confidentiality
2. A data security breach (i.e., a stolen laptop or misplaced thumb drive) involving identifiable data constitutes an unanticipated problem.
3. A subject complaint when the complaint indicates unexpected risks or cannot be resolved by the investigators,
4. A research team member experiences harm in the conduct of the study
5. A new risk of the study drug, device, or study procedure is identified by an outside source (sponsor, federal regulatory agency, outside site, etc.)

6. A protocol violation is an accidental or unintentional change to or noncompliance with the IRB-approved protocol that increases risk or decreases benefit and/or affects the subject's right's safety, welfare, and/or the integrity of the data.
7. Any adverse event which is defined as any untoward physical or psychological occurrence in an individual participating in research. Adverse events encompass both physical and psychology harms and may happen on occasion in the context of social and behavioral research. An adverse event may constitute an unanticipated problem and must be reported as such to the IRB.

REPORTING PROCEDURES FOR UNANTICIPATED PROBLEMS

Responsibility to Report Unanticipated Problems

Researchers must report unanticipated problems that may involve risk to subjects or other that result from IRB-approved research with human subjects. The problems must be reported when:

- The event occurred on the campus of Wittenberg University where Wittenberg is the IRB of record (the reviewing IRB) OR
- The event occurred off Wittenberg's campus, where Wittenberg is the IRB of record (the reviewing IRB)

Reporting Timeframe and Method

The Principal Investigator (PI) (i.e., Wittenberg faculty member, or staff member) must submit an Unanticipated Problems Report (UPR) to the IRB (irbpetition@wittenberg.edu) within 5 business days of the occurrence or within 5 business days from the date in which the PI learned of the occurrence. The Report form is available online. Only the PI can officially submit the report. Additionally, a timely submission of a follow-up to the IRB is required if the unanticipated problem is unresolved at the time of the initial report.

Reporting and Review Process

This form includes:

1. Project Title
2. Contact information for the PI
3. Contact information for the Co-PIs
4. Event Information such as date of occurrence
5. Event Characteristics
6. A description of the event including how the event affected the rights, safety or welfare of the subject or others, current status of subjects
7. A statement regarding modifications to the research plan or informed consent as a result of this event.
8. A description of the researches' response to the event and how all subjects were informed, if necessary.
9. Signatures of the PI and Co-PI's

The IRB chair compares the content of the UPR with the previously approved project materials such as proposal petitions, informed consent document(s), protocols, investigator brochures, or other supporting documents, to determine whether this event meets the definition of an unanticipated problem involving risk to subjects or others. If the chair agrees the event meets the definition of an unanticipated problem involving risks to subjects or others, the entire IRB will review the report to determine whether the event represents minimal risk of harm or more than minimal risk of harm to subjects in the study. If the event represents minimal risk of harm that is isolated and has been mitigated by the PI, the chair reviews and signs the report.

If the event represents more than minimal risk of harm to subjects in the study, the IRB will decide whether to:

- Suspend or terminate the research
- Have the PI notify current participants when such information might be related to their willingness to continue to take part in the research
- Require modifications to the protocol and/or consent documents
- Impose additional monitoring requirements
- Require additional training of the researcher and research team
- Notify other institutional committees and/or administrative units

All reports of unanticipated problems involving risks to subjects or others are electronically filed with the appropriate research study materials. The IRB has the authority to suspend or terminate approval or research that has been associated with unanticipated problems. When the IRB takes such action it will provide a statement of reason for the action and will promptly report to the appropriate funding agency, if applicable, the Office for Human Research Protections (HRP), and other applicable regulatory authorities. The reports are also reviewed by the IRB at the time of continuing review.

Further guidance is available here:

- HRP: Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Other and Adverse Events
- HRP: Glossary of key terms and examples

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