

## HAC Policies and Procedures

### Unanticipated Problems

#### What is an Unanticipated Problem Involving Risks to Subjects or Others?

According to DHHS OHRP guidance, an unanticipated problem is 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 and related documents, such as the HAC approved Description of Research Proposal, the protocol and the informed consent documents; and
  - (b) The characteristics of the subject population being studied.
2. Related or possibly related to a subject's participation in the research.

#### What are Unexpected Problems that Investigators or Research Team Members Have to Promptly Report to the HAC?

Investigators are to promptly report the following problems to the HAC:

- Unanticipated problems that are unexpected and related
  - A. An event that is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document
  - B. An event that is “related or probably related to the research procedures” if in the opinion of the investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not to be caused by the research procedures or if it is more likely than not that the events affects the rights and welfare of current participants.
- Allegations or findings of non-compliance.
- Information that indicates a change to the risks or potential benefits of the research. For example:
  - A. An interim analysis or safety monitoring report that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
  - B. A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the HAC.
- Subjects being incoming incarcerated during their participation in the research which was not approved for a prisoner population
- Breaches of confidentiality such as a stolen laptop with protected health information on it, a digital camera or memory stick stolen with photographs or identifiable data of subjects or violation of policies related to confidentiality
- Increased time off from work resulting in less pay to subjects or parents
- Increased time out of school resulting in lower grades
- Suspected child or domestic abuse
- Errors made by pharmacy technician that gives a research subject several times the amount of the investigational drug which resulted in increased risk of toxicity to the participant, but no actual harm.
- Complaint of a research subject when the complaint indicates unexpected risks or cannot be resolved by the research team.
- Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.

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- Change to protocol taken without prior HAC review to eliminate an apparent immediate hazard to a research subject.
- Event that requires prompt reporting to the sponsor.
- Sponsor imposed suspension of research or enrollment.
- Protocol deviations/protocol violations
- Audit reports from sponsors, accrediting associations, etc.
- Data and safety monitoring board reports

Each of these examples is unexpected in nature, related to participation in the research, and resulted in new circumstances that may increase the risk to subjects or others.

### **Why Should These Issues be reported to the HAC?**

These are problems that HAC should know about so that they may make a decision about whether or not these are unanticipated problems involving risks to participants or others or non-compliance. There is no assumption that these are all unanticipated problems involving risks to participants or others.

### **Is This List the Only Unanticipated Problems that must be reported to the HAC?**

The HAC will accept any report that the investigator thinks the HAC must know about. We will also review this list over time to determine that the research community is aware of its importance and to determine if there are examples that should be added to, or taken from, the list.

### **How Are These Unanticipated Problems Reported to the HAC?**

The principal investigator is responsible for reporting these events to the HAC via the HAC Form 113.

### **What Is The Deadline For Reporting These Events?**

The deadline for reporting these events is available on the HAC website under “Submission and Meeting Deadlines.”

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