

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: SERIOUS ADVERSE EVENTS

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 1/98; 2/02; 7/06;
3/08

POLICY:

The HHS regulations at 45 CFR 46 do not define or use the term *adverse event*, nor is there a common definition of this term across government and non-government entities. The term *adverse event*, in general, is used very broadly and includes any event meeting the following definition:

An adverse event is any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

In the context of multicenter clinical trials, adverse events can be characterized as either on-site adverse events or off-site adverse events. On-site adverse events are those adverse events experienced by participants enrolled by the investigator(s) here at Decatur Memorial Hospital, whereas off-site adverse events are those adverse events experienced by participants enrolled by investigators at other institutions engaged in the clinical trial. In the context of a single-center clinical trial, all adverse events would be considered on-site adverse events.

Specific Policies

On-Site Serious Adverse Events

Within 15 business days of the principal investigator's knowledge of the event, the PI must submit an Adverse Event Submission Form. The Adverse Event Submission Form will be reviewed by the convened IRB at the next scheduled meeting.

Off-Site Serious Adverse Events

If the event is off-site, the convened IRB will review these events in summary form at the time of continuing review. Safety reports are not to be submitted to the IRB.

APPLICABLE TO:

These policies and procedures apply to the Principal Investigators, IRB Administrator, Document Specialist, and Study Coordinators.

RESPONSIBILITY:

Principal Investigators are responsible for reporting all serious adverse events. IRB Administrator is responsible for posting on-site adverse events to the agenda, and for ensuring the summary of safety reports and serious adverse events are included with the continuing review.

Document Specialists and Study Coordinators are responsible for creating and maintaining the summary of all safety reports and serious adverse events.

APPROVED BY:

President and CEO