

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS **EFFECTIVE:** 4/08

POLICY:

The Institutional Review Board (IRB) requires investigators to promptly report any unanticipated problem that involves risks to participants or others. Unanticipated problems involving risks to participants or others include any incident, experience, or outcome that (1) is unexpected in terms of nature, severity, and frequency, (2) is related or possibly related to participation in the research, and (3) suggests that the research places the participant or others at a greater risk of harm, including physical, psychological, economic, or social harm.

Specific Policies

Unanticipated Problems Involving Risks to Participants or Others

Investigators are required to submit to the IRB within 5 business days any of the following:

- Any harm experienced by a participant, which in the opinion of the investigator is both unexpected and related, regardless of whether the harm was an on-site or off-site adverse event.
- Information that indicates a change to the risks or potential benefits of the research. For example:
 - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different from that initially presented to the IRB.
 - A paper is published from another study that shows that the risks or potential benefits of the research may be different from that initially presented to the IRB.
- A breach of confidentiality of the study data than was previously known or recognized.
- A protocol deviation (meaning an accidental or unintentional change to the IRB approval protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
- An unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights and welfare of participants.

Review of an Unanticipated Problem Involving Risks to Participants or Others by the Convened IRB

All committee members of the convened IRB shall review the unanticipated problem submission form. The possible actions that could be taken by the IRB, include but are not limited to:

- Modify the protocol.
- Modify the information disclosed during the consent process.
- Provide additional information to past participants.
- Notify current participants when such information might relate to participants' willingness to continue to take part in the research.
- Require that the current participants re consent to further participation.
- Modify the continuing review schedule.
- Monitor the research.
- Monitor the consent.
- Suspend the research.
- Terminate the research.
- Obtain additional information.

If the IRB determines that the problem is an unanticipated problem involving risks to participants or others, the IRB shall report such problems to the appropriate regulatory agencies and institutional officials.

APPLICABLE TO:

These policies and procedures apply to the Principal Investigators, IRB Members, and IRB Administrator.

RESPONSIBILITY:

Principal Investigators are responsible for reporting all unanticipated problems involving risks to participants or others to the IRB.

IRB Members are responsible for reviewing the unanticipated problem submission form and soliciting relevant expertise, if needed.

IRB Administrator is responsible for reporting the unanticipated problem to OHRP and the DMH Institutional Official.

APPROVED BY:

President and CEO