

**DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**

SUBJECT: INVESTIGATOR'S BROCHURES

STANDARD: PATIENT RIGHTS AND ORGANIZATION ETHICS

EFFECTIVE: 03/07

POLICY: To assure the rights and welfare of humans participating as subjects in research are protected, investigator's brochures will be reviewed and acknowledged by the IRB in accordance with applicable regulations.

PERFORMED BY:

- 1) Full board review or, 2) Expedited review by IRB Chairperson or IRB member(s) appointed by the Chairperson (when applicable-See "Expedited Review" procedure).

IMPLEMENTATION:

Documents for initial review of an Investigator's Brochure include:

- 1) Investigator's Brochure
- 2) Informed Consent in DMH format

Documents for a revised Investigator's Brochure include:

- 1) Investigator's Brochure
- 2) Informed Consent in DMH format
- 3) A Change Document containing the explanation of changes to the Investigator's Brochure will need to be submitted and include: (a) summary of changes, (b) impact on risk/benefit ratio (c) whether an amendment is forthcoming and (d) impact on risk to subjects.

PROCESS:

- 1) The investigator's brochure, when provided by the sponsor or research base, will be provided with all initial review documents to the full board and will be acknowledged.
- 2) For a revised investigator's brochure, the change document and the informed consent will be reviewed via expedited review by the IRB Chairperson(s) or IRB member(s) appointed by the Chairperson for approval.
- 3) If a Change Document is not available, the revised investigator's brochure and informed consent will be reviewed via expedited review by the IRB Chairperson(s) or IRB member(s) appointed by the Chairperson for approval.
- 4) The change document and expedited review of the investigator's brochure will be acknowledged by the full board.

DOCUMENTATION:

- 1) Investigators shall be notified, in writing, within ten days following the meeting date of the IRB decision. A 310 form will be generated for CCOP protocols; a letter will be generated for other trials.
- 2) It is the Investigator's responsibility to notify the study sponsor of action taken by the IRB (when applicable).
- 3) IRB meeting minutes shall be made available for Administrative review upon request.

APPLICABLE TO:

IRB members, Investigators

APPROVED BY:

President and CEO