**Section 1005.110 Institutional Review Board Procedures**

a) The IRB review of applications that are deemed not exempt or not eligible for expedited review will occur at convened meetings subject to the Open Meetings Act. IRB meetings will include a majority of IRB members who are present at the meeting in person or by electronic means, including at least one member whose expertise is in non-scientific areas.

b) The IRB has the authority to approve or disapprove, require modification to, or observe research, and to suspend or terminate approval (see Section 1005.130). Reliance on another institution's IRB or an independent IRB for review of research shall be documented by a written agreement that is available for review by federal Office of Human Research Protections upon request.

c) The IRB will provide written notification to researchers of approval or disapproval of, or required modifications to, proposed research.

d) The IRB Chair will review all research applications involving human subjects to determine whether the application involves exempt research.

e) The IRB has the authority to allow repeat release of designated limited data sets that are not from a HIPAA covered program without individualized IRB review.

f) Requests for approval of disclosure of health data and approval of research that involves no more than minimal risk to human subjects and their privacy and confidentiality are eligible for an expedited review procedure. Research projects that are eligible for expedited review include those projects found in the list of research categories published as eligible for expedited review by the Department of Health and Human Services (45 CFR 46) and previously approved projects for which minor changes are proposed during the period for which the IRB has already given approval, when those projects or changes involve minimal risk.

g) If a request is eligible for an expedited review procedure, the review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB.

h) In reviewing the request under an expedited review procedure, the reviewers may approve, but not disapprove, the research application. A research application may be disapproved only after review in accordance with the non-expedited review procedure. Research applications that have been reviewed under, but not approved through, the expedited review procedure will be subject to further IRB review at a convened meeting.

i) Prior to approval, the IRB will determine that all of the following requirements are satisfied:

1) Risks to subjects shall be minimized; researchers shall use procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk;

2) Risks to subjects shall be reasonable in relation to the expected benefits to subjects and the knowledge that may reasonably be expected to result from the research;

3) The selection of subjects shall be equitable;

4) Unless otherwise authorized or permitted by law or regulation, informed consent shall be obtained and appropriately documented from each participating subject or the subject's legally authorized representative. When the IRB determines that the research project must include procedures for obtaining informed consent, the IRB shall ensure that informed consent is to be obtained under circumstances and through procedures that adhere to all applicable laws and regulations, and minimize any coercion or undue influence upon the subject or representative. Unless otherwise authorized or permitted by law or regulation, the following elements of informed consent shall be provided to each human subject:

A) An explanation of the purposes of, and procedures involved in, the research and the expected duration of the subject's participation;

B) A description of any reasonably foreseeable risks or discomforts to the subject;

C) A description of any benefits to the subject or to others that may reasonably be expected from the research;

D) A statement describing how the confidentiality of records identifying the subject will be maintained;

E) Information regarding who should be contacted for answers to questions about the research and research subjects' rights and in the event of a research-related injury to the subject;

F) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of those benefits; and

G) Any additional information that the IRB determines would further protect the rights and welfare of the subject;

5) The research shall make any necessary provisions for data monitoring to ensure the safety of subjects;

6) The privacy of subjects and confidentiality of data shall be assured;

7) When the research involves subjects likely to be vulnerable to coercion or undue influence, additional safeguards shall be included to protect the rights and welfare of these subjects.

j) The IRB may deny requests to conduct the research for reasons including, but not limited to, that the risks posed to human subjects are too great and for noncompliance with applicable laws and regulations. A notice of disapproval shall include the reasons for denial in sufficient detail that allows the researcher to respond. The researcher will be given the opportunity to respond to the denial in person or in writing to the IRB.

k) Any research proposal approved by the IRB shall include a provision that any subject who is participating or has participated in the research project who has a complaint shall be referred to the IRB to determine whether a protocol has been violated.

l) The IRB will review and approve changes to previously approved research projects and requests to continue projects beyond the expiration date of the current IRB approval. Changes shall not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subjects.

m) The IRB will perform continuing, periodic reviews at intervals commensurate with the degree of risk the research poses.

n) The IRB will require a report for each approved research project at its conclusion.

o) For research to be approved at a convened meeting, a majority of members present at the meeting must vote in favor.

p) For reviews under expedited review authority, the majority also prevails, if expedited review is performed by more than one individual.

q) A quorum must be present at IRB meetings to do business.

r) A quorum is a simple majority of full members of the IRB, except that at least one member whose primary concerns are in non-scientific areas must be present.

s) Alternate members of the IRB are counted in the quorum when they are attending all or part of a convened meeting on behalf of full members.

t) Members who are eligible to vote but abstain from voting are counted toward the quorum.

u) Members who must recuse themselves from consideration of a proposal due to conflict of interest shall leave the room during consideration of the proposal and are not counted in the quorum.

v) The researcher has the right to appeal IRB decisions, including disapprovals, terminations of approval, restrictions on study design or study procedures, and approval conditions. Appeals shall be submitted in writing to the IRB within 60 days after the written notice to the researchers of the IRB's decision. Appeals shall provide a rationale for why the researcher believes that the IRB's decision is in error. All written appeals, including those of decisions made through the expedited review process, will be placed on the agenda of the next convened meeting of the IRB.

(Source: Added at 38 Ill. Reg. 19251, effective September 10, 2014)