**Section 1580.40 Institutional Review Board Procedures**

a) The general counsel of the Authority shall review all research applications involving human subjects to determine whether the application involves exempt research. If the general counsel determines that the research is exempt, the general counsel shall provide notice of, and justification for, this determination to the IRB members and the executive director of the Authority. If the general counsel does not receive any notice of disagreement with a determination of exempt status from IRB members within 10 working days after the mailing date of the notice, then the determination that the research is exempt will be considered approved by the IRB. If the general counsel receives notice of disagreement with a determination of exempt status from any IRB member, the research will be considered non-exempt and subject to IRB review and approval under this Part. Research projects determined to be exempt are not subject to further IRB review and approval. A determination by the IRB that a research project is exempt is subject to override by the executive director of the Authority.

b) All research applications involving human subjects that do not involve exempt research shall be reviewed by the IRB, in accordance with this Part. The IRB review of research applications must occur at meetings subject to the Open Meetings Act [5 ILCS 120]. IRB meetings must 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 nonscientific areas. Minutes covering all activities will be taken and made available to the Authority.

c) The IRB shall operate in accordance with all applicable laws and regulations. The IRB has the authority to approve or disapprove, require modification to, or observe research. The IRB must provide written notification to the executive director of the Authority and researchers of approval or disapproval of, or required modifications to, proposed research.

d) The IRB may approve research applications involving human subjects if the IRB has determined that all of the following requirements are satisfied:

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

2) Risks to subjects must 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 must be equitable;

4) Unless otherwise authorized by law or regulation, informed consent must be obtained and appropriately documented for 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 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 by law or regulation, the following elements of informed consent must 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 must make any necessary provisions for data monitoring to ensure the safety of subjects;

6) There are adequate provisions for assuring the privacy of subjects and confidentiality of data;

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

8) The research must comply with applicable laws and regulations.

e) 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 must include the reasons for denial in sufficient detail that allows the researcher to respond. The researcher must be given the opportunity to respond to the denial in person or in writing to the IRB.

f) Research subject to this Part must have the approval of a majority of IRB members present at the meeting before data collection may begin.