**Section 1005.100 Institutional Review Board Authority, Role and Composition**

a) The IRB is established by the authority of the Department to protect the health and lives of the people of the State and to fulfill its duty to comply with all applicable requirements of 45 CFR 46 and 21 CFR 50 and 56.

b) An IRB approved by the Director shall review requests for health data disclosure for which IRB review is required by statute or rule, and proposals for research involving human subjects that is conducted by the Department or individuals working on behalf of the Department.

c) The Director may require that proposals submitted to the Department that have been approved by another IRB be subject to review and approval of the Department's IRB.

d) The IRB shall be qualified through the experience, expertise and diversity of its members, including race, gender, cultural backgrounds and sensitivity to community perspectives. The IRB shall review proposed research in light of existing Department commitments, existing laws, regulations and guidelines, and standards of professional conduct and practice. The IRB will include persons with expertise in these areas.

e) The IRB chairperson will solicit recommendations for IRB membership from Department Deputy Directors, IRB members, and, as needed, from other Department staff, and professional and human services agencies and organizations. Individuals who wish to be considered for IRB membership shall indicate their interest by contacting the IRB chairperson. The Director will consider the candidates and make formal appointments to fulfill the specific requirements of the IRB composition as required in this Section and 45 CFR 46.

f) The Director will appoint the IRB members, alternate IRB members, IRB Chair, and IRB Vice-Chairs. The IRB will consist of at least five members with varying backgrounds. Composition of the IRB will reflect the anticipated scope and complexity of review activities, the types of populations involved, and the size and availability of Department resources.

g) IRB Membership

1) The IRB will not consist entirely of men or entirely of women.

2) The IRB will not consist solely of members of one profession.

3) The IRB will include at least one member whose primary concerns are in scientific areas.

4) The IRB will include at least one member who is a non-scientist.

5) The IRB will include at least one member who is not otherwise affiliated with, or part of the immediate family of, a person who is affiliated with the Department. The non-scientist and the member who is not affiliated with the Department may be the same individual.

6) An IRB member shall not participate in the initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB**.** The IRB Chair shall ensure that IRB members with a conflict of interest are not present during IRB votes subject to their conflict of interest.

7) The IRB may invite individuals with special expertise to assist in the review of issues requiring expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

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