**The Institutional Review Board (IRB) Membership and Guidelines Policy**

**Intent**

ENC follows the guidelines of the *Common Rule* that requires the IRB to have at least five members who are of varying backgrounds and experience, including a diversity of race and gender.

**Policy**

1. The IRB will also be comprised of :
2. One faculty member in the Natural Science division,
3. One faculty member outside the Natural Science division
4. “One member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution” (45 CFR 46.107[d])
5. Two additional at large members

It is recommended that at least two alternate faculty members and an alternate community member will be appointed to assure adequate representation at all scheduled meetings.

1. The IRB shall be chaired by the Provost or designated appointee
2. All members and alternate members must complete the National Institutes of Health on-line course titled, “Protecting Human Research Participants” found at http://phrp.nihtraining.com. Certificates of completion must be placed on file with the Institutional Review Board Chair.
3. Faculty members will be appointed yearly to the IRB by the Provost’s office.
4. The IRB will review proposed research requiring Full Board Review at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it will receive approval of a majority of those members present at the meeting (§ 45 CFR 46.108).
5. A board member who has a conflict of interest with a proposal that is being reviewed must recuse him/herself from the Board’s discussion and the subsequent vote by the Board. The recused board member, however, may answer clarifying questions if requested by the IRB.
6. **Responsibilities of the IRB:** In order to approve research, the IRB must ensure that the following requirements are satisfied:
7. Risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk.
8. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those that may result from the research, as distinguished from those participants would receive even if not participating.
9. Selection of participants is equitable. The IRB should consider the purposes of the research and the setting in which the research will be conducted and be particularly mindful of the special problems of research involving vulnerable populations.
10. Participants should share equally in foreseeable benefits and risks.
11. Informed consent is sought, and will be obtained, from each prospective participant or the participant's legally authorized representative in accordance with, and to the extent required by 45 CFR 46.116.
12. Informed consent is appropriately documented in accordance with, and to the extent required by 45 CFR 46.117.
13. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
14. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
15. Additionally, when some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, or mentally disabled, economically disadvantaged, or educationally disadvantaged persons) additional safeguards are included in the study to protect the rights and welfare of these participants.
16. **The IRB has the authority to require modifications in order to secure approval, or not approve all research activities.** The IRB will also notify the investigators and ENC Provost’s office in writing of its decision to approve or not approve the proposed research, or of modifications required to secure IRB approval. If the proposed research is not approved, the IRB will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to re-apply. When the convened IRB requests substantive clarifications or modifications of protocol or informed consent documents from the principal investigator, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB.

History:

* Reviewed by faculty on 4-18-2012