CHAPTER 2 – Criteria for IRB Approval

Approvals of Research
The duties and responsibilities of the members of the IRB are best described by reproducing the statement published in 45 CFR 46.111.

For research subject to the 1991 Common Rule and FDA research:

46.111 Criteria for IRB approval of research.

a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:
   i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by §46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

6. When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects

7. When appropriate*, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*When research is more than minimal risk and involves an intervention
b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

For non-FDA research subject to the revised Common Rule when it goes into effect: “The IRB will review and has authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. When the revised Common Rule goes into effect, this will include exempt research activities under §__.104 for which limited IRB review is a condition of exemption (under §__.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by §46.116.

5. Informed consent will be appropriately documented, or appropriately waived in accordance with §__.117.

6. When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
When research is more than minimal risk and involves an intervention

At the time of this policy revision, ETSU is not allowing exemption under exempt categories 7 and 8. However, the information regarding limited review is included below.

8. For purposes of conducting the limited IRB review required by §__.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and will make the following determinations:

   (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §__.116(a)(1)-(4), (a)(6), and (d);

   (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §__.117; and

   (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

b) when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.”

IRB Committee Determinations

After review, the possible actions which may be taken by the IRB are:

⇒ Approval of the proposal
⇒ Approval with stipulations
⇒ Defer pending receipt of additional information
⇒ Disapproval

A. Approved: An approval is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 (see prior page) and no changes are recommended to the proposal.

B. Approval with stipulations: An approved pending status is given if the research meets the 45 CFR 46.111 criteria for research approval and any modifications required by the IRB require simply concurrence by the Investigator. When the modifications requiring simple concurrence are received from the investigator, the Chair or his/her designee may then review and confirm the modifications through an expedited procedure. The proposal may be referred back to the full committee if deemed necessary by the Chair or his/her designee. The research may not be initiated until a final approval letter is received.

C. Defer pending receipt of additional information: When the convened board requests substantive modifications or clarifications directly relevant to the determinations required at 45 CFR 46.111, IRB approval of the proposed research is deferred, pending subsequent
review by the convened board of responsive material. The investigator will receive a written request for specific or additional information required.

D. Disapproval: Disapproval is given if the proposal does not meet the criteria for approval as defined in 45 CFR 46.111 (refer to prior page). If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Confidentiality
The IRB membership must be diligent to maintain confidentiality. The Board must be free to deliberate in private without fear of coercion. With the exception of the IRB Chair or Vice-Chair, at no time may an investigator discuss deliberation content or outcomes with IRB members post-review. The IRB policy is to notify the investigator in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. The OPHRS staff will be responsible for dispatching written notifications (post-deliberation) to the appropriate investigator.

With the implementation of the Primary Reviewer System, designated IRB members tasked with conducting primary reviews are authorized by the convened Board to contact the Principal Investigator to discuss issues related to clarity, risk, benefits, etc.