

IRB Approval Criteria & Considerations

Regulatory Criteria & Considerations

- (1) Risks to subjects are minimized:
 - (a) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and
 - (b) 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.
- (3) Selection of subjects is equitable, taking into account the purposes of the research and the setting in which the research will be conducted.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, or informed consent is appropriately waived.
- (5) Informed consent will be appropriately documented (signed written consent form or short form), or is appropriately waived.
- (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.
- (8) 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.
 - (a) When study participants include children, pregnant women, fetuses, neonates, prisoners, or wards of the state, then additional regulatory findings must be made.
- (9) Assent by children and permission by parents/guardians is appropriately sought or waived.
- (10) Assent by children and permission by parents/guardians is appropriately documented or waived.
- (11) Appropriate category of research risk for child participants is assigned (45 CFR 46.404-407).
- (12) The research described in the grant application is consistent with the corresponding IRB application.

(13) Valid permission from participants to use, create and share protected health information for research purposes will be obtained using a HIPAA Authorization Form or the IRB has appropriately granted a waiver of such authorization.

(14) If a device study, a determination is made regarding whether it is a Significant Risk or Nonsignificant Risk device study.

(15) If an Investigational New Drug (IND) study, applicable regulations adhered to.

(16) Coordinating Center activities are sufficiently reviewed and approved.

(17) Banking/Repository activities are sufficiently reviewed and approved.

(18) Genome Wide Association Studies (GWAS) certification requirements are met.

(19) Conflicts of interest are sufficiently managed.

Institutional Criteria & Considerations

(1) Human Subjects Protection Training (including pediatric component) for all study team members.

(2) Research Center Membership or follow exceptions outlined in Policy RIA803.

(3) CLIA lab certification for results used for diagnostic/clinical purposes.

(4) Department of Laboratory approval.

(5) Radiation Safety Committee approval.

(6) Letters of Cooperation/Support from the Head of Clinical Area/Institutional representative of where research conducted if external to PI's department/clinic/institution.

(7) Studies potentially needing MTAs, DUAs, or BAAs referred to Research Contracts.

(8) Studies involving non-employees referred to Research HR re the NEAT process.

(9) Administrative review of unfunded studies.

(10) Review by Investigational Drug Service, Institutional Biosafety Committee, etc.

(11) Application of Compensation Plan for research injuries determined.

(12) Payments to participants comply with Policy ORF004.