

### Ancillary Review Committees

1. Definition of ancillary review

Ancillary review is conducted in coordination with IRB review to review human subjects research, ensuring research risks are minimized and compliance requirements are met.

2. Types of ancillary review

- a. Radiation Safety
- b. Institutional Biosafety (recombinant DNA/gene transfer studies)
- c. Embryonic Stem Cell Oversight
- d. Scientific Review Committees
- e. Conflict of Interest
- f. IT security
- g. Clinical trials office
- h. Genomic data sharing institutional certification
- i. Environmental Health & Safety
- j. Nursing
- k. Research Pharmacy/Controlled Substances

3. When ancillary review occurs in relation to IRB Review, the following must occur before reviewing IRB approval is issued:

- a. Radiation Safety
- b. Institutional Biosafety (recombinant DNA/gene transfer studies)
- c. Embryonic Stem Cell Oversight
- d. Scientific Review Committees
- e. Conflict of Interest
- f. Other committees, those on which risks to subjects or institutional requirements do not depend, may be reviewed during or after reviewing IRB approval.

4. Maximum duration of ancillary review

- 45 days

5. Ancillary reviews that can be deferred to the reviewing institution.

Some ancillary review can be deferred to the Reviewing IRB, such as the following:

- a. Radiation Safety (if institutions do not have their own RAD license)
- b. Institutional Biosafety (recombinant DNA/gene transfer studies)
- c. Embryonic Stem Cell Oversight (CA, NY and some other states have specific state regulations; cede may not be possible)
- d. Scientific Review Committees
- e. Conflict of Interest
- f. IT security
- g. Environmental Health & Safety

6. Process to facilitate the outcome of ancillary review
  - a. The Reviewing IRB should complete ancillary reviews for the lead institution and any relying institutions that have allowed for such before IRB approval is granted.
  - b. These determinations should be communicated to all Relying Institutions.
  - c. Relying Institutions would have responsibility for the ancillary reviews they have opted to perform as required by local law and institutional policy and have the opportunity to make requests to the reviewing IRB if site-specific information is needed before the Relying Institution is approved by the reviewing IRB.
  - d. These reviews at both the lead and Relying Institution must be completed within the time frame identified.