



Human Research Ethics Training Tips

NIH mandates single IRB review of multisite clinical trials

<https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>

- Policy applies to multisite NIH grant applications with due dates on or after January 25, 2018 – we have been piloting projects through a new process already
- Purpose is to streamline the IRB review process and eliminate unnecessary duplicative reviews of research by all participating institutions
- Reliance agreements are not new to UNC, typically execute between 200-300/year
- Approach to NIH protocols requiring Full Board review involves an initial review at Board which approves the protocol and model consent form, known sites list PI and liaison only – sites typically not approved at this initial review
- Participating sites are then approved/on-boarded via subsequent modification submissions which may be reviewed expedited – local context worksheet, site specific consents customized, agreement or LOA signed. Approval letters to list approved sites as they are successfully added.

NIH updates policy regarding Certificates of Confidentiality (CoCs)

<https://humansubjects.nih.gov/coc/index>

- CoCs protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific scenarios
- NIH will **automatically** issue CoCs to all research funded by NIH that is collecting or using identifiable information, applications no longer necessary
- **All ongoing or new** NIH research funded as of **December 13, 2016** impacted
- Approximately 800+ projects active at UNC fit the description
- At renewal review, or if the study team proactively submits a modification to address the CoC, the application should be updated at question A.10.3, and if a consent form remains in use, CoC language added.
- Non-NIH funded research may still apply for a CoC, through the normal process
- UNC HRPP actively working to update questions in IRBIS, and possibly update the current CoC language we use at UNC