Subject: Use of Collaborative Models of IRB Review to Facilitate Review Time and Effort

Definitions:

1. **Federalwide Assurance** (FWA): A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP).
2. **IRBchoice**: An electronic resource that allows sharing of documents and reviews.
3. **IRB of Record**: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an agreement, designating the relationship.
4. **Local Ancillary Reviews**: Institution specific reviews that must be completed prior to initiation of a study at that institution.
5. **Local Context Language**: Language specific to the conduct of human subjects research at each institution (e.g., subject injury language, HIPAA authorizations, genetic testing language).
6. **Local Research Context**: Knowledge of the institution and community environment in which human subjects research will be conducted (e.g., subject injury policy, state specific laws, mandatory reporting of diseases, abuse, etc.).
7. **SMART IRB Exchange**: An electronic resource using the SMART IRB Joinder agreement that allows IRBs to document reliance and share documents.
8. **SMART IRB Joinder**: A national master reliance agreement allowing IRBs to cede review to another based upon the terms of the agreement without negotiating on a study-by-study basis.

Policy:

It is the policy of the VUMC IRB to collaborate with other IRBs in an effort to avoid duplication of effort, when applicable.

I. **Single IRB Reviews**.
   A. The Single IRB review mechanism applies only to NIH funded, multi-center clinical trials that fall under the NIH Policy mandating a single IRB review.
   B. Exceptions for other federally funded research may be requested through the HRPP Administration.
   C. The VUMC HRPP facilitates arrangements of Single IRB review mechanisms as needed, through an approved Reliance Agreement or MOU.
   D. Initial review and subsequent reviews are conducted at the level for which they qualify by the IRB of record for that study and in accordance with the arranged agreement between entities.

II. The VUMC IRB may share documents such as minutes and reviewer’s comments to facilitate another IRB’s review. This shared review mechanism is limited to multi-center clinical
trials which are:
   A. Minimal risk; or
   B. Greater than minimal risk which have identified an external data and safety monitoring board which is responsible for review of all adverse events in conjunction with the local investigator’s assessment of the event as well as local IRB review.
   C. Reviews of industry-supported research will only be shared with Sponsor’s approval.

III. Shared Initial Review by Another Institution.
   A. The VUMC IRB reviews all submitted materials at the level for which it qualifies including but not limited to the protocol, investigator’s brochure, IRB application, consent document(s), initial committee’s review minutes or comments (if applicable) and any other pertinent materials applicable to the assessment of the risk-potential benefit profile of the project.
   B. The VUMC IRB conducts all subsequent reviews according to the HRPP Policies and Procedures listed in section III.
   C. Each IRB remains the IRB of record for its respective site.

IV. Shared Initial Review by the VUMC IRB.
   A. The VUMC IRB reviews all submitted materials at the level for which it qualifies according to HRPP Policy.
   B. Upon completion of its review, the approved documents and meeting minutes or reviewer comments if expedited review are provided to all subsequent reviewing institutions.
   C. The VUMC IRB conducts all subsequent reviews according to the HRPP Policies and Procedures listed in section III.
   D. Each IRB remains the IRB of record for its site.

References:
www.irbchoice.org
https://smartirb.org/