Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: I.G
Section: IRB Authority and Institutional Commitment
Review Responsibility: HRPP Policy and Procedure Committee
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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. 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.
3. Local Ancillary Reviews: Institution specific reviews that must be completed prior to initiation of a study at that Institution.
4. 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).
5. 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 Master Agreement: 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 VU MC 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 and will be considered on a case by case basis.
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. Single IRB mechanisms.
A. The VUMC IRB is willing to serve as a reviewing IRB (IRB of Record) or as a relying IRB (ceded review to another IRB). However, final determination of reliance is at
the discretion of the HRPP.

B. The VUMC IRB is a participant in the SMART IRB Master Reliance Agreement and the IRB Exchange system for tracking reliance and approved documents.

C. Other mechanisms are available upon request and evaluation by HRPP Administration.

III. The HRPP is responsible for assuring all local context has been gathered from and provided to other institutions in which the VUMC IRB has entered into a valid agreement for single IRB.

IV. When relying on another IRB’s review, the HRPP is still responsible for assuring any ancillary reviews are completed prior to beginning any study for which the single IRB policy applies.

References:
www.sirb.trialinnovationnetwork.org
https://smartirb.org/