Reliance on Commercial IRB

UC has contracts with the following commercial IRBs:

- WIRB-Copernicus Group
- Schulman Associates Institutional Review Board
- Quorum Review Institutional Review Board

Inclusion/Exclusion Criteria for Submitting to a Commercial IRB:

Can submit if:

- the project is a study that involves human subjects and is designed to evaluate prospectively the safety and/or effectiveness of new drugs or devices or behavioral intervention
- the protocol for the project was designed and written by the sponsor
- the sponsor holds all INDs/IDEs for the protocol
- the only sponsor of the research is a for-profit entity/company
- UC investigator has not previously submitted the study to a UC IRB (only new projects will be eligible for Schulman review. No transfer of projects already submitted to a UC IRB will be allowed).

Cannot submit if protocol involves:

- xenotransplantation
- embryonic stem cells
- review and approval by the UC IBC (e.g., studies that involve recombinant DNA)
- any research funds from a federal or other not-for-profit funding source
- Phase I study

All external IRB submissions must be submitted through the electronic protocol administration (ePAS).

Required Forms to be Uploaded into ePAS

1. Form I
   - Form I is a decision tree to help identify whether or not a study may be submitted to a commercial IRB

2. Personnel documents and training requirements:

   For everyone listed as research staff members, the following documents/requirements are also needed:
   - CITI Training (must be current)
   - UC COI form (and explanation of any "yes" answers)
   - UC FDA training (only FDA regulated studies; must be current for PIs, Co-PIs, and study coordinators)

3. Other documents:
• CV for PI and Co-PI
• Indemnification or waiver (Note: Study can be submitted to WIRB and Schulman without indemnification, but approval cannot be released until indemnification has been approved; study cannot be submitted to Quorum without indemnification)
• Protocol
• Consent document
• Advertisements, questionnaires, data collection tools, etc. (if applicable)
• HIPAA waiver request or HIPAA authorization form (Note: Quorum will not incorporate HIPAA language into the informed consent document. A standalone HIPAA Authorization form must be used.)
• Cover letter (see Templates and Forms under the Reliance section for WIRB, Schulman, and /or Quorum)

**Commercial IRB Review Process**

1. The UC HRPP office will check the ePAS submission for completeness
   - If the submission is **not complete**, comments will be sent back to the PI
   - If the submission is complete, it will be forwarded to the IRB for review

2. The site is responsible for ensuring the external IRB receives and reviews pertinent documents for initial approval, amendments, continuing reviews and reportable events.

3. Adding research team members:
   - Follow the commercial IRB's procedures for adding personnel
   - Notify UC's IRB by submitting an amendment through ePAS and provide COI documentation

4. The external IRB will review all amendments, continuing review, and reportable events. Changes to key personnel, updates to conflict of interest forms, and continuing review submissions must be submitted to the UC IRB via ePAS.

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