Commercial IRB FAQs

Q. What is a USF relied upon IRB?

A. A USF relied upon IRB is an IRB that is not appointed and maintained by USF. USF currently has one Social & Behavioral IRB (IRB 02) and three Biomedical IRBs (IRB 01A, IRB 01B, and IRB 01C) that each meet once every month.

USF currently has contracts with five relied upon IRBs that are listed on our FWA. These include:

- All Children’s Hospital (ACH) IRB for studies where all, or the majority, of the research activities occur at ACH by USF faculty, staff or students.
- Florida Department of Health (DOH) IRB for all research projects conducted at or in conjunction with DOH by USF faculty, staff or students.
- Western IRB (WIRB) for industry sponsored multicenter studies and for those studies where there is an Institutional Conflict of Interest (COI).
- Schulman Associates IRB for industry sponsored multicenter studies and for those studies where there is an Institutional Conflict of Interest (COI).
- Quorum IRB for industry sponsored multicenter studies and for those studies where there is an Institutional Conflict of Interest (COI).

Q. What is an Institutional COI?

A. Institutional Conflict of Interest: A situation in which the financial investments, licenses, technology transfer or patents of, or gifts to, the USF System or the personal financial interests or holdings of USF System Senior Administrative Officials might affect, or reasonably appear to affect, institutional processes for the design, conduct, reporting, review or oversight of human subjects research. Potential ICOIs may arise in the following areas; however, these examples are not intended to be exhaustive:

- 4.2.1 when a company that has a financial or business relationship with USF System also donates a gift to USF System;
- 4.2.2 when USF System owns equity in a company and the company has a financial or business relationship with USF System;
- 4.2.3 when USF System licenses an invention to an entity that also has a financial or business relationship with USF System;
- 4.2.4 when a USF System Senior Administrative Official has a business or financial relationship with an external entity, which sponsors USF System Human Subject Research Projects.

A non-USF example of an Institutional COI would be a clinical trial being conducted on Gatorade at the University of Florida.
Q. What studies may be submitted to a USF relied upon Commercial IRB?

A. The following is a list of research studies that are eligible for review by a USF relied upon Commercial IRB:

- Phase 2, 3, and 4 multicenter clinical trials regardless of funding source (i.e., federal, foundation, nonprofit or industry) involving drugs and devices, registry studies or observational trials;
- All clinical research projects in which there is an institutional conflict of interest must be reviewed by WIRB, regardless of funding source.

Q. What studies may not be submitted to a USF relied upon Commercial IRB?

A. The following is a list of research studies which are not eligible for review by a USF relied upon Commercial IRB:

- Phase I clinical trials;
- Principal Investigator-initiated trials where USF faculty/staff hold the Investigational New Drug (IND) or Investigational Device Exemption (IDE) for the test article and USF Principal Investigator-initiated trials which have been determined by the FDA to be IND exempt;
- Studies deemed to have significant local impact, such as waiver of consent in emergency research;
- Research which involves rDNA or other biological agents which must be reviewed and approved by the USF Biosafety Committee; and
- Studies that are sponsored by or conducted at the James A Haley Veterans Hospital
- Studies where all, or the majority, of research activities occur at All Children’s Hospital;
- All research conducted at or in conjunction with the Florida Department of Health (DOH);
- Studies that are exempt from review or that meet the criteria for expedited review.

Q. Can the sponsor/CRO submit to the central IRB on behalf of my PI?

A. Yes as long as the central IRB for the study is one of the USF relied upon Commercial IRBs, but they will need to be provided with a copy of the Commercial IRB Approval to Proceed Letter and if applicable, the COI Management Plan.

Q. What if the central IRB for my study protocol is not a USF relied upon Commercial IRB?

A. Unless there is a contract in place between USF and the central Commercial IRB and the central Commercial IRB has been listed on USF’s Federalwide Assurance (FWA), the central Commercial IRB is not a USF relied upon IRB and cannot be used for review and approval of human subjects’ research projects for USF faculty, staff or students.

Q. How do I start using a USF relied upon Commercial IRB?
A. Attend the training for the Commercial IRB that you plan to use. Register for a Login with the Commercial IRB.

Q. Ok, I’ve registered with one or more of the USF relied upon Commercial IRBs. What do I do next?

A. The process to obtain a Commercial IRB Approval to Proceed letter will remain the same for all three Commercial IRBs. See Commercial IRB Submission Process Flow Diagrams.

- PI/study staff submits the essential documents to OCR intake email OCR@health.usf.edu
  - Draft budget
  - Protocol
  - Draft consent document
  - CTA
  - OCR New Study Questionnaire (NSQ)
- OCR Administrative Specialist uploads documents to OCR SharePoint
- Documents are reviewed by OCR Assistant Director
  - Which IRB will review the study?
  - Verify study team members
    - Site must provide full names of study team members on NSQ. Reference any name changes/aliases if the current HRP/CITI training is registered under a prior name, uses a nickname, or if the first initial and full middle name is used. Misspelled or incomplete names will cause delays.
  - Any Outside Activity related to the study?
    - If yes, Investigator must report in ROAD and disclose the financial COI, if any, in ARC. The COI Management Plan must be in place prior to Commercial IRB submission.
  - Any financial COI related to the study?
    - If yes, Investigator must disclose the COI in ARC and the COI Management Plan must be in place prior to Commercial IRB submission.
    - If there is an Institutional COI, see Commercial IRB Submission Process – Institutional COI Sub-Process flow.
  - Is the study eligible for Commercial IRB submission?
    - If yes, OCR Assistant Director sends an email Request for a Commercial IRB Approval to Proceed letter to USF IRB with a copy of the protocol attached, and a copy of the COI Management Plan attached if applicable. If there are any questions about the protocol meeting requirements, OCR Assistant Director will seek adjudication with the staff at USF DRIC.
- USF IRB confirms HRP/CITI training is current for all study team members
- USF IRB Chair reviews the protocol to ensure that it does not require Biosafety Committee review. If it does require Biosafety Committee review, the study is not eligible for Commercial IRB submission.
- USF IRB generates the Commercial IRB Approval to Proceed letter and routes via email to PI/Department/study team and OCR.
- PI/study team must upload the Commercial IRB Approval to Proceed letter and the COI Management Plan, if applicable, to the Commercial IRB submission. If the sponsor/CRO is submitting on behalf of the PI, they must be provided with the Commercial IRB Approval to Proceed letter and a copy of the COI Management Plan if applicable.
- OCR pulls the IRB Approval letters and approved consent document(s) from the Commercial IRB database at the time of initial approval and at each continuing review and uploads into SharePoint. There is no need to send approval letters unless requested by OCR.

Q. Will the Commercial IRB write my consent document for me?

A. Yes, for a fee. Let your Project Liaison know that the Commercial IRB will write your consent document so that this fee can be included as a pass through cost in the budget. All three Commercial IRBs will confirm that the USF required consent language is present in the approved consent document(s).

Q. Will the Commercial IRB translate my consent document for me?

A. Yes, for a fee. Let your Project Liaison know that you will be requesting translation services for your study documents so that the fees can be included in the study budget.

Q. Who pays the USF relied upon Commercial IRB for their services?

A. The responsible party in the PIs department should review the contract between USF and the sponsor for the clinical trial in question. If the contract states that the sponsor will pay IRB fees directly to the IRB, then no action is needed. If the contract requires USF to invoice the sponsor for reimbursement of IRB fees, attach a copy of the IRB invoice(s) to the study status logs (SSLs) submitted by the study coordinator to the OCR by the 5th day of every month. If the study is in CTMS and thus has no Study Status Log, a copy of the IRB invoice(s) should be submitted to OCRFM@health.usf.edu no later than the 5th day of the month. The department should pay the Commercial IRB fees in a timely fashion and must not wait for the sponsor to reimburse the institution prior to paying Commercial IRB fees incurred.