


Standard Operating Procedures for Clinical Research at USF Morsani CRC			
		IRB SUBMISSIONS	
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PURPOSE: This Standard Operating Procedure (SOP) describes the methods for using the USF Institutional Review Board (IRB) or a USF- relied upon IRB for a research protocol involving human subjects.

SCOPE: This SOP applies to all research submitted to the USF IRB or relied upon IRB.

RESPONSIBILITY: The Investigator is responsible for *not* conducting any human subjects research without obtaining prior IRB review and approval.

DEFINITIONS:


Applications for Research Compliance (ARC): Name of website for all electronic applications managed by the Division of Research Integrity and Compliance (DRIC)

Collaborative Institutional Training Initiative (CITI) Program: The Division of Research Integrity & Compliance (DRIC), in conjunction with the CITI Program, has made available online courses in Human Subject Protections, Responsible Conduct of Research, Laboratory Animal Welfare and Good Clinical Practice.

Division of Research Integrity & Compliance Education Program (DRIC): USF IRB that provides educational and outreach opportunities to the USF Research community, including USF & USF Health researchers, Affiliates, and the Tampa Bay area public, in order to advance knowledge on the safe, ethical and responsible conduct of research.

The following types of research studies are will be reviewed by the USF IRB:

- 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

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DEFINITIONS (cont.):

USF relied-upon IRBs:


The USF IRB relies upon the review and approval of certain research products by external IRBs. These include Western Institutional Review Board (WIRB), Quorum Review IRB, Schulman Associates IRB, All Children's Hospital IRB and Florida Department of Health IRB. While USF relied-upon IRBs serve as the IRB of record for certain research, the USF IRB performs an administrative review of the applications to ensure they meet the criteria for external review. The USF IRB is also responsible for the local conduct of the research and would be involved in issues related to subjects participating at the USF site.

The following types of studies are eligible for external IRBs review:


- All industry sponsored Phase 1, 2, 3 & 4 multicenter clinical trials regardless of funding source (i.e., federal, foundation, non-profit 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 one of these external IRBs, regardless of funding source.

PROCEDURE:

1. Investigators who submit studies for USF IRB review and approval are required to do the following:
 - 1.1. All USF and USF Affiliate faculty, staff, and students involved in human subjects research projects must complete a USF IRB approved education program for human subjects protection. Investigators and research staff may complete the CITI program to meet this requirement www.citiprogram.org. Please refer to the http://www.research.usf.edu/dric/hrpp/irb_policies/711-requirements-human-subjects-research-protection-edu.pdf for additional information regarding the USF HRPP education requirements.
 - 1.2. Research staff can upload a copy of their certificates which is valid for two years, in the USF IRB electronic submission system called the eIRB when creating a new study.
 - 1.3. Prior to submitting an application to the IRB, all USF faculty, staff, and students planning to conduct human subjects research (at USF or off-site) must first register on the USF eIRB at <https://eirb.research.usf.edu/Prod>
 - 1.4. All research personnel are required to upload current curriculum vitae (CV) or resume into the eIRB system which is not required for each study, but a current version must be maintained.
 - 1.5. Research staff proposing to recruit human subjects is required to submit an application to the IRB for review and approval **prior to initiating each project.**

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- 1.6. Research staff will login to eIRB using their secure user name and password. Login serves as your electronic signature.
- 1.7. Research staff will create a “New Study” and complete the applicable pages of the application and upload all appropriate supporting documentation (e.g., protocol, informed consent form, etc.). For assistance with eIRB, you may contact the Division of Research Integrity & Compliance (DRIC) ARC Help Desk (eIRB, eCOI, eIACUC): (813) 974-2880, E-Mail: rsch-arc@usf.edu
- 1.8. For questions regarding your individual research projects, you may contact an IRB Research Compliance Administrator (RCA) at the Division of Research Integrity & Compliance at (813) 974-5638.
2. Investigators who submit studies for USF relied-upon IRBs review and approval are required to do the following:
 - 2.1. Investigators and/or designated research personnel seeking external IRB review and approval must go through the USF Office of Clinical Research (OCR) at ocr@health.usf.edu.
 - 2.2. OCR will submit the necessary information to the USF IRB to conduct an administrative review of the research materials.
 - 2.3. The USF IRB will submit a letter to proceed to the Principal Investigator which allows the study to be submitted to the external IRB. Both external IRB and the OCR receive copies of this letter.
 - 2.4. Investigators and designated research personnel will follow external IRBs guidelines for the submission and review.
 - 2.5. All required documents should be submitted at ocr@health.usf.edu and the information can be found at <http://health.usf.edu/medicine/research/ocr/industry-sponsored.htm>

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REFERENCES:	45 CFR 46.115 21 CFR 56.108 (a) 21 CFR 312, 812 USF Human Research Protections Program (HRPP) Guidance for Investigators
RELATED POLICIES:	SOP 201: Regulatory Documentation SOP 202: Privacy and Confidentiality SOP 204: Adverse Event Reporting SOP 205: Institutional Conflicts of Interests
APPENDICES:	
REVISION HISTORY: Keep a running history of all revision dates.	

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	