

	Standard Operating Procedure Number: 102	Title: SOP Maintenance
	Version: 2.0	Effective Date: 11/1/19

1. PURPOSE

The purpose of this procedure is to state the IRB’s commitment to maintain and follow current Standard Operating Procedures (SOPs) that adhere to regulatory mandates and ethical principles.

2. PROCEDURE

By following regulations and guidance, the IRBs ensure that the rights and welfare of human research subjects will be overseen and protected in a uniform manner, regardless of changes in personnel. Written SOPs are in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects and for the adequate documentation of such oversight. These SOPs provide the framework for the ethical and scientifically sound conduct of human research.

3. SPECIFIC PROCEDURES

3.1 Review, Revision, Approval of Procedures (SOPs)

SOPs will be reviewed by the IRB Manager every three years, and/or as needed. Any changes to the SOPs, or new information identified as being pertinent to the protection of research participants will be available on SharePoint and on the IRB website.

4. RESPONSIBILITY

The Institutional Official is responsible for granting final approval to new and revised IRB policies.

IRB Manager is responsible for establishing and periodically reviewing and modifying (as appropriate) IRB SOPs.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103(b)(4)(5), 45 CFR 46.108
21 CFR 56.108(a) and (b), 21 CFR 56.115(6)

6. APPLICABLE DOCUMENTS

None

Revision Number	Version Date	Approved By	Date Approved
2.0	10/2/2019	Avera Institutional Official	11/1/19
<ul style="list-style-type: none"> Removed that the IRB will disseminate SOPs by email, but instead will post on SharePoint and IRB website. SOPs will be reviewed at least every three years, instead of annually. Updated regulations. Other administrative edits. 			
1.0	August 2016	Director HSRP / August 2016	