

Standard
Operating
Procedure
Number: 106
Version: 2.0

Title: Signature Authority

Effective Date: 11

e: 11/1/19

1. PURPOSE

The procedure describes signature authority for IRB actions.

2. PROCEDURE

The IRB Manager or designee are authorized to sign any and all documents in connection with the review and approval of research projects involving human subjects, which have been reviewed and approved pursuant to Avera policies and procedures.

3. SPECIFIC PROCEDURES

3.1 Authorization for Signature Authority

Authorization to sign documents not described in this procedure may be made in writing to the IRB Manager.

3.2 Results of Reviews, Actions and Decisions

All IRB letters in regard to research reviews may be signed by the IRB Manager or designee.

All signatures from within the electronic submission program of the IRB require a username and password and will be considered the same as a written signature.

3.3 Routine Internal Correspondence

Any correspondence from the IRB concerning the review of research protocols by the IRB or staff should be signed by the IRB Manager when applicable, or designee if the IRB Manager is not available.

3.4 Correspondence with External Agencies

Any letters, memos, or e-mails sent to federal government agencies, funding agencies (whether private or public) or their agents will be signed by the IRB Manager, or designee if the IRB Manager is not available.

4. RESPONSIBILITY

IRB Manager is responsible for establishing the overall procedure for delegating signature authority.

IRB Manager, IRB Chair(s), IRB members and Research Compliance staff are responsible for adhering to institutional signature authority policies.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.115

6. APPLICABLE DOCUMENTS

None



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| Revision Number | Version Date | Approved By | Date Approved |
|---|-----------------|------------------------------|---------------|
| 2.0 | 10/8/2019 | Avera Institutional Official | 11/1/19 |
| IRB Manager or designee is authorized to sign any and all documents in connection with the review and approval of research projects reviewed by the Avera IRB. IRB letters, memos, or e-mails sent to federal government agencies, funding agencies (whether private or public) or their agents will be signed by the IRB Manager. If the Manager is not available, then a designee may sign in that person's place. | | | |
| 1.0 | August 2016 | Director HSRP / August 2016 | |