	Standard Operating Procedure Number: 302	Title: Administrative Review and Distribution of IRB Materials
	Version: 2.0	Effective Date: 8/12/2019

1. PURPOSE

This procedure describes the requirements for document pre-review and distribution prior to IRB review.

2. PROCEDURE

The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure that IRB members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

3. SPECIFIC PROCEDURES

3.1 Exemptions

In addition to the IRB Chair and delegated IRB members, the IRB Manager or staff may review and approve Claims for Exemption submitted by investigators. Such Claims of Exemption will be logged and filed.

3.2 Incomplete Submissions

Incomplete submissions will not be accepted for review until the PI or designee has provided all necessary materials as determined by the IRB Manager or staff. The IRB Manager or staff will notify the submitting PI to obtain any outstanding documentation or additional information before the application is scheduled for review. Incomplete submissions will be logged, but not assigned for review and/or approval.

3.3 Scheduling for Review


Complete submissions that appear to meet qualifications for expedited review will be submitted to the Chair, Vice Chair, or an experienced member of the IRB. If a submission meets expedited review requirements, the review will be performed as described in 401-SOP (Expedited Review). All other submissions will be placed on the agenda of the earliest meeting possible for review by the full IRB.

3.4 Distribution to Members Prior to IRB Meetings

Submission materials described in 300-SOP (Research Submission Requirements) will be distributed to all IRB members generally within seven (7) days prior to the meeting, unless deemed urgent by the Manager or Chair. Each regular member of the IRB, and any alternate members attending the meeting in place of a regular member, will have access to the initial submission materials. Consultants, if utilized for a study review, will only receive copies of material that pertain to their requested input.

3.5 Confidentiality

All material received by the IRB will be considered confidential and will be available only to meeting participants (e.g. regular members, alternate members, and consultants) for the purpose of review. All submission materials will be stored in a project study file with access limited to the IRB members and IRB staff.

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4. RESPONSIBILITY

IRB Manager or staff are responsible for conducting appropriate assessment of submissions.

IRB staff or designee are responsible for ensuring that complete review materials are provided to IRB members and other relevant parties. Chair or Vice Chair is responsible for supporting and assisting the IRB manager in submission activities.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109 and 45 CFR 46.109

6. REFERENCED DOCUMENTS

None

Revision Number	Version Date	Approved By	Date Approved
2.0	7/15/2019	Avera Institutional Official	8/12/2019
<ul style="list-style-type: none"> Minor administrative edits. 			
1.0	August 2016	Director HSRP / August 2016	