

**ADMINISTRATIVE REVIEW AND DISTRIBUTION OF MATERIALS**

<b>SOP #:</b>	<b>303</b>	<b>VERSION #:</b>	<b>1</b>	<b>EFFECTIVE DATE:</b>	<b>5/1/09</b>	<b>SUPERSEDES DOCUMENT:</b>	<b>/ /</b>
<b>THIS POLICY PERTAINS TO:</b>			<b>ALL RESEARCH SUBMITTED TO THE IRB</b>				
<b>RESPONSIBILITY FOR EXECUTING POLICY:</b>		<b>ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB STAFF</b>					
<b>LAST REVIEWED ON:</b>		<b>/ /</b>		<b>RESULTS:</b>	<b>REVISED</b>		
<b>APPROVAL AUTHORITY:</b>		<b>Associate Vice President for Research and Economic Development</b>					
<b>APPROVED BY:</b>					<b>DATE:</b>		<b>/ /</b>

**1. POLICY**

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.

**2. SPECIFIC POLICIES**

**2.1 Exemptions**

In addition to the IRB Chairperson and designated IRB members, the IRB Coordinator may review and approve proposals submitted by Investigators for exempt review. Exempt proposals will be logged into the IRB database and filed.

**2.2 Incomplete Submissions**

Incomplete applications will not be accepted for review until the Investigator has provided all necessary materials as determined by the IRB Secretary and or IRB Coordinator. The IRB Secretary or IRB Coordinator will notify the submitting Investigator 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.

**2.3 Scheduling for Review**

Complete applications that appear to meet qualifications for expedited review will be submitted to an experienced member of the IRB. If a submission meets expedited review requirements, the review will be performed as described in SOP RR 402 (Expedited Review). All other applications will be placed on the agenda for the earliest meeting possible for review by the Full IRB.

**2.4 Distribution to Members Prior to IRB Meetings**

Copies of application materials described in SOP FO 301 (Research Submission Requirements) will be distributed to all IRB members, generally at least seven (7) days prior to the meeting. Each regular member of the IRB will receive a copy of the initial application material. All alternate members will receive a copy of the initial application material as well in case they are

called upon to attend the meeting in place of a regular member. Consultants will only receive copies of materials that pertain to their requested input.

The originals of submission materials will be retained by the IRB Secretary in the Research Development and Compliance office and will be available for the IRB meeting.

**3. RESPONSIBILITY**

The IRB Secretary and/or IRB Coordinator are responsible for conducting appropriate assessment of submissions for triage purposes.

The IRB Secretary is responsible for providing an agenda and complete review material packets to IRB members and other relevant parties.

**4. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 56.109  
45 CFR 46.109

**5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

<b>Who</b>	<b>Task</b>
<i>IRB Coordinator, IRB Secretary</i>	Conduct preliminary assessment of submissions for exempt certification to be sure they meet the requirements.
<i>IRB Secretary, IRB Coordinator, IRB Members</i>	Conduct assessment of submission adequacy and contact Investigators for any missing elements.
<i>IRB Secretary</i>	Assemble agenda and reviewers' packets for all regular members and alternate members of the IRB.