

SOP: CO 601 Version No: Effective Date: 01/01/07	INVESTIGATIVE STAFF	Supersedes Document Dated:
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1. POLICY

It is important that staff, subjects, and other interested parties have a means of communicating information about the conduct of a research project directly to the appropriate institutional officials. It is vital that IRB members, department heads, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within the institution. The researcher and his/her research staff interact with subjects; therefore it is vital that open and frequent communication with the investigative team be maintained.

Specific Policies

1.1 Investigator Notifications

- 1.1.1 Initial submission: The Investigator will be notified in writing of the IRB's decision as soon as possible after the meeting. If the approval is pending upon receipt and review of requested materials or responses from the Investigator or Sponsor, the IRB must receive the response within 90 days of the date of notification; however, this period may be extended if the Investigator/Sponsor communicates a need for an extension.
- 1.1.2 Renewals and revisions: Investigators will be notified in writing as soon as possible as to action taken by the IRB for any continuing reviews or revisions.
- 1.1.3 Notification of final approval: Investigators will be notified in writing of the final approval. The IRB-approved consent form (pdf-formatted) will be sent to the investigator via email and dated with the period of approval. The final approval letter will be mailed to the investigator under separate cover. Standard conditions for continued approval include, but are not necessarily limited to:
 - Informed consent is obtained and documented as stated in SOP IC 701-703.
 - The IRB is notified of serious adverse events within appropriate periods as described in SOP RR 403.
 - Changes to the protocol, and deviations from the protocol are reported as described in SOP RR 403.
 - Reports of unanticipated problems or any unforeseen event or events that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research must be promptly reported.
 - Continuing review reports are submitted to the IRB as described in SOP RR 404.
 - Documentation of FDA approval prior to study initiation.
- 1.1.4 Disapproval: Correspondence will provide the reason(s) for disapproval and instructions to the Investigator on what is necessary to resubmit the protocol or to appeal the decision.

1.2 Investigator Appeal of IRB Action

An Investigator may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal must be in writing and submitted to the IRB Administrator. Investigators may also appeal an IRB decision to disapprove a study. Any such appeal may be in writing or in person and must be reviewed by the full IRB at a convened meeting. If the appeal is denied and the study disapproved, the Investigator's institution cannot override the IRB's decision.

1.3 Noncompliance

Investigator noncompliance may often be the result of communication difficulties; therefore the IRB will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the study, especially if the rights and welfare of subjects may be jeopardized.

However, if it appears that an Investigator is intentionally in noncompliance, the IRB, through the IRB Chairperson will notify the Investigator in writing, detailing the alleged noncompliance, specifying corrective action, and stating the consequences. Copies of such correspondence shall also be sent to the Sponsor, the individual's supervisor/department manager, the Institutional Official, and the Medical Staff Executive Committee.

Should noncompliance continue, appropriate action will be determined at a convened meeting. Action by the IRB can include but is not limited to:

- Halting the research until the Investigator is in compliance. If the research is halted, OHRP will be notified if the research is funded by a government agency, and FDA will be notified if the research involves an FDA regulated product or agent.
- Requiring the Investigator to complete a training program.
- Barring the Investigator from conducting further research.
- Any other action deemed appropriate by the IRB.

When unapproved research is discovered, the IRB and the institution will act promptly to halt the research, ensure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the Investigator's fitness to conduct future human subject research.

Serious or continuing noncompliance with federal policies on the protection of human subjects or the policies, procedures or determinations of the IRB must be reported promptly to the Institutional Official and the Medical Staff Executive Committee as well as the appropriate department or agency head for funded proposals, Sponsors if appropriate, and to OHRP and/or FDA as appropriate.

The IRB's responsibility is to protect the rights and welfare of research subjects, which could be placed at risk if there is misconduct on the part of an Investigator or any member of the investigative team. It is, therefore, the duty of the IRB to be receptive to and act on good faith allegations of misconduct. Allegations of misconduct in science should be referred to the Institutional Official for handling under Sparrow Health System policies. The institution shall be responsible for any disciplinary actions against the investigator.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

IRB Administrator is responsible for overseeing all IRB communications.

IRB Administrator is responsible for generating appropriate correspondence in response to IRB meetings and decisions.

IRB Coordinator is responsible for distributing IRB correspondence to appropriate parties.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.113

45 CFR 46.109, 46.113

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

- CO 601-A Notice of IRB Approval (Initial Review, Continuing Review, Amendment)
- CO 601-B Approval Withheld Pending (Conditional Approval)
- CO 601-C Notice of Disapproved Study
- CO 601-D HIPAA Waiver
- CO 601-E Determination of Not Research
- CO 601-F Acknowledgement (Internal/External SAE, HDE Reporting, or other miscellaneous documents from sponsor and/or PI)
- CO 601-G Completion (Closure) Acknowledgement
- CO 601-H Notice of Study Termination by IRB
- CO 601-I SHS/MSU IRB Reliance Acceptance Letter (New study) – BIRB/SIRB/CRIRB
- CO 601-J OCIRB Reliance Acceptance Letter (New study)
- CO 601-K IRB Compliance Assurance
- CO 601-L Exemption Disqualification Notice
- CO 601-M Exempt Determination Letter

7. PROCESS OVERVIEW

The IRB's decision will be reported as soon as possible to the Investigator. Queries must be answered within 90 days of notification. Final approval will occur after all queries are satisfactorily answered. The Investigator will be informed of disapproval in a letter containing the reasons for disapproval. If it appears that an Investigator is intentionally in noncompliance, the IRB, through the IRB Chairperson will notify the Investigator in writing, detailing the alleged noncompliance, specifying corrective action, and stating the consequences. Depending upon the seriousness of the situation, copies of such correspondence may also be sent to the Sponsor, the individual's supervisor/department manager, the Institutional Official, and the Medical Staff Executive Committee.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i>	Ensure that all communications follow established procedures and format.	

<i>IRB Administrator/ IRB Coordinator</i>	Ensure that the determinations and requirements of the IRB are communicated to the Investigator as soon as possible.	
<i>IRB Chairperson (or IRB Administrator as defined in SOP GA 105)</i>	Review and authorize electronic signature for IRB decision communications.	
<i>IRB Administrator</i>	<p>Supervise clerical staff to ensure that all communications with Investigators, regulatory bodies, and others as appropriate are accurate and timely.</p> <p>Ensure that documentation, either electronic or paper, of any communication of determinations, requirements, or actions of the IRB or representatives of the IRB, when acting in a regulated capacity, are maintained, according to procedures in section FO 305: Documentation and Document Management.</p> <p>Ensure that all verbal communications are documented (either electronically or on paper) and retained in the study file according to procedures in section FO 305: Documentation and Document Management.</p> <p>Ensure that the appropriate entities are copied on the documentation and notification of any IRB determinations and actions as described in section CO 602 and as noted on this procedure's attachments.</p>	
<i>IRB Coordinator</i>	<p>Distribute correspondence as directed.</p> <p>Record communications as required.</p>	