

SOP: FO 301 Version No: 1 Effective Date: 1/6/06	RESEARCH SUBMISSION REQUIREMENTS	Supersedes Document: 11/14/05
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1. POLICY

IRB members often rely solely on the documentation submitted by Investigators for initial and continuing review. Therefore this material must provide IRB members with enough information about a study to assess if it adequately meets the IRB's criteria for approval.

A submitted protocol will be scheduled for IRB review when the IRB Administrator has determined that the information and materials submitted present an adequate description of the proposed research.

Principal Investigator, or designee, will be required to attend the IRB meeting to briefly present their new proposal and answer questions.

Specific Policies

1.1 Submission Requirements for Initial Review

1.1.1 Required: Investigators applying for initial approval of a proposed research protocol must submit:

- IRB Application for Initial Review signed by the Investigator (FO 301-A)
- Research protocol, Investigator Brochure, or device specifications (as applicable to study)
- Questionnaires, surveys, and/or assessment instruments
- Proposed informed consent document or statement of research
- Proposed subject instructions
- Any other supporting material, such as examples of recruitment advertising, etc.
- If applicable, a copy of the grant with budget but without appendices (required for federal granting agencies)
- A description of the consenting process
- Verification of appropriate Human Subjects Training for entire research/investigative team
- Curriculum vitae and/or resume for entire research/investigative team
- Investigator Delegation of Responsibility (FO 301-E)

1.1.2 In addition, applicants may be required to submit:

- Financial disclosure statement
- FDA Form 1572 (IND) or signed Investigator agreement (IDE)
- Case report form
- Documentation that the study has been reviewed and approved by other committees charged with oversight of research at the Sparrow Health System, and any department or unit required to cooperate in the study (e.g., Pharmacy, Medical Records, Laboratory).

1.2 Submission Requirements for Continuing Review

1.2.1 Required: During the approval period, Investigators must submit documentation to inform the IRB about changes in the status of the study (FO 301-C) to include, but not necessarily limited to:

- -Deviations from the protocol (protocol violations)
- -Modifications or revisions to the protocol, informed consent form, or any study documents (e.g. reporting forms, Investigator brochure)
- -Reports of internal serious or unexpected adverse events within 48 hours of incident (RR 403-A)
- -Reports of external serious or unexpected adverse events
- -For IND / IDE studies, reports of serious or unexpected adverse events that occur during the approval period as required by FDA regulation
- -Changes to the status of Principal or Sub-investigators

1.2.2 Required: Request to Renew IRB Approval

Thirty (30) days prior to IRB approval expiration date, Investigator requesting renewal of an approved research project must submit:

- A completed and signed Application for Renewed Approval (FO 301-B). All required materials as indicated on the Application for Renewed Approval are to be included at time of submission.

1.3 Action Taken If Documentation is Not Adequate or Additional Information is Required

If the IRB Administrator or IRB determines that the documents submitted are not adequate, Investigators may be required to submit additional information. No incomplete submission will be reviewed by the IRB.

The presence of an Investigator may be required at an IRB meeting to answer questions or explain the details of the study.

2. SCOPE

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

3. RESPONSIBILITY

IRB Administrator is responsible for maintaining current research submission requirements for interested Investigators and for preliminary triage of non-routine submissions.

IRB Administrator is responsible for reviewing submission elements.

IRB Coordinator is responsible for submission receipt and tracking, preparing member review materials, and acknowledgements.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.115

21 CFR 56.108 (a)(4)

21 CFR 312, 812

ICH Good Clinical Practice (GCP) Guideline

5. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.

6. ATTACHMENTS

- FO 301-A IRB Application for Initial Review
- FO 301-B IRB Application for Renewed Approval
- FO 301-C IRB Application for Revision and/or Amendment
- FO 301-D Data Security Guidelines
- FO 301-E Investigator Delegation of Responsibility
- RR 403-A IRB Report of Unexpected Internal Adverse Event

7. PROCESS OVERVIEW

Outline the required documents and supporting information required from Investigators for IRB assessment.

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i>	Ensure that complete submission information is available and provided to all Investigators.	RI 801-A Investigator Responsibilities - IRB Requirements
<i>IRB Coordinator</i>	Document receipt of all submissions. Review submission for completeness. Note any missing information. Route to IRB Administrator.	FO 301-A IRB Submission Checklist (Staff)
<i>IRB Administrator</i>	Evaluate claims for exemption from IRB review per SOP FO 302. Determine action. Evaluate submissions that fit requirements for expedited review per SOP RR 401. Review high-risk studies –route as appropriate. Review studies involving children & route as appropriate.	FO 302-C Claim of Exemption Checklist for Staff RR 401-B Guidance-Expedited Review
<i>IRB Coordinator</i>	Prepare submissions for IRB review. Using IRB Submission Checklist, review for completeness. Review consent form for inclusion of required elements per SOP IC 701-703. Send incomplete submissions back to Investigator with cover letter noting missing material, information. Add new submission for full IRB review to agenda for next meeting.	Acknowledgement/ Request for Additional Information IC 701-A Informed Consent Checklist
<i>IRB Coordinator</i>	Send acknowledgement to Investigator, indicating date of review & notification if his/her presence will be required.	FO 301-D Acknowledgement/ Request for Additional Information