

SOP: FO 301 Version No.: 05 Effective Date: 12/2/10	RESEARCH SUBMISSION REQUIREMENTS	Supersedes Document Dated: 7/1/08
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1. POLICY

Steering Committee approved 2/25/11

IRB members 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 whether it adequately meets the IRB's criteria for approval.

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

Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Submission Requirements for Initial Review

Submissions to the IRB are accepted in two formats: paper or the Cyber IRB electronic method. Both formats require that the same documents be included with the submission. The difference between submission formats is in the number of copies that must be included with the submission, and the need for the original signature on an applicable document. Cyber IRB will allow any and all documents to be uploaded with the submission application.

1.1.1. Required: Initial applications must include:

- IRB Submission Application (Form FO 301-A or FO 302-A) in sufficient detail to allow the IRB to ascertain that a study meets the criteria for approval. Applications completed in the paper format, must be signed by the Principal Investigator and the original signature must be on file in the RSPP office.
- If applicable, the complete research protocol from the sponsor indicating version or revision numbers (including sponsor's sample informed consent document).
- If applicable, the Investigator Brochure (investigational drug or biologic), Package Insert (approved drug) or Device Operator Manual or device specifications and the date of such brochure or manual.
- If applicable, any surveys, questionnaires, assessment instruments, and case report forms to be used.

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- If applicable, proposed informed consent/authorization document containing all elements required by federal regulations, as well as those additional elements as appropriate, using the Aurora IRB-approved template as a guide.
- All materials to be received or reviewed by subjects (e.g., diaries, blister packs, instruction sheets, videos).
- Any recruitment materials (e.g., advertisements, letters, phone scripts, “Dear Doctor” letters, etc.) to be used. (See also Policy RR 406).
- If the study is federally funded, and Aurora is the funding recipient (i.e. the “awardee”) of the grant, a copy of the grant (including the budget pages but without the appendices) must be submitted for review. A copy of the grant application or proposal will be retained by the RSPP Office and made available to any IRB member who may wish to review it. The grant application/proposal will be reviewed by the Primary Reviewer.
- Copy of the Principal Investigator’s current CV or other supporting material evidencing clinical privileges necessary to conduct research study.
- Conflict of Interest Statement (GA 104-A) signed by each investigator listed on the submission application. Applications completed in the paper format must include an original signature on each COI form. The original form for each investigator will be kept on file in RSPP office. Applications completed in Cyber IRB do not require an original signature on the COI form. A scanned copy of the signed form may be uploaded with the Cyber IRB submission application. [Note that COI forms are not required for studies that qualify for exemption from IRB review (see policy FO 302)].

Note: All investigators listed on the submission application are required to complete the training requirements found in policy GA 102 (section 1.1) prior to issuance of the final approval letter.

1.1.2 In addition, the following items are required if applicable:

- Delegation of Authority log.
- The DHHS-approved sample consent document (when one exists).

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- The complete DHHS-approved protocol (when one exists).
- Copy of the signed FDA Form 1571, 1572 (IND) or signed Investigator Agreement (IDE).
- If the study involves a Significant Risk Investigation Device Exemption (IDE), a copy of FDA’s IDE letter giving clearance to begin the study.
- If the study involves an investigational drug (i.e. an IND number has been assigned the study drug), and the IND number is not stated in the sponsor’s protocol, a copy of the FDA’s acknowledgment letter noting the IND number issued to the drug, OR a letter from the sponsor stating that the IND number provided on the submission form is the correct IND number for the drug being investigated in the study under review.
- Documentation that the study has been reviewed and approved by other appropriate committees/entities
- IRB form 502A (see Policy SC 502) for Preparatory to Research Activities or to request a waiver of HIPAA authorization. Applications completed in the paper format must include an original signature by the Principal Investigator. The original form will be filed in RSPP office. Applications completed in Cyber IRB do not require an original signature. A scanned copy of the signed form may be uploaded with the Cyber IRB submission application.
- Any investigator who does not meet the definition of “Affiliated with Aurora” set forth in section 1.1.1 of Policy SC 502, must have the support and assistance of a Facilitator (see section 1.5 below) who is “Affiliated with Aurora”, prior to submitting a research request or other related activity to the IRB.

1.2. Requirements for Ongoing Monitoring of IRB Approved Research

1.2.1. During the approval period, the IRB is required to conduct ongoing monitoring of the research study (see Policy RR 403). Investigators must promptly submit documentation to inform the IRB about changes in the status of the study including, but not necessarily limited to:

- Significant protocol violations (as defined in Policy RR 403) must be reported to the IRB on Form RR 403-G.

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- Reports of Unanticipated Problems, as defined in Policy RR 403, must be reported to the IRB on Forms RR 403-A or RR 403-B, as applicable.
- Significant new findings (DSMB reports, annual reports, updates to investigator brochures, etc.) must be reported to the IRB on Form RR 403-F.
- Amendments and/or changes to the research study (including temporary holds on enrollment or enrollment closures), protocol or informed consent document must be reported to the IRB using the IRB Modification form (Form RR 403-C). Investigators must obtain IRB approval before undertaking any change to the approved protocol, except where necessary to eliminate apparent immediate hazards to human subjects.
- Notification that a study has been completed and the IRB file may be permanently closed must be reported to the IRB using the Continuing Review Report/Final Report Form (Form RR 404-A).

1.2.2. Continuing Review Report to Request Renewal of IRB Approval.

The IRB office will notify the investigator that continuing review is due in accordance with Policy RR-404. Investigators must submit:

- A completed Continuing Review Report/Final Report Form (Form RR 404-A).
- All the required materials as indicated on the form.

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

If the IRB or RSPP staff determine that the submitted documents are not adequate, Investigators may be required to submit additional information, or the study may be returned to them for revisions. No incomplete submission will be reviewed by the IRB.

The presence of the Investigator (or his/her representative) may be requested at the IRB meeting in order to answer any questions or explain the details of the study.

1.4. **Access to RSPP Study File Materials**

Access to the study file contents will be limited to the IRB members, RSPP staff, and others as determined appropriate by the RSPP Manager (e.g., study staff, representatives from

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regulatory agencies and accrediting agencies, etc.). Individual requests must be made to the IRB office in advance. The RSPP Manager will determine whether access to the files is allowed.

1.5. Research Facilitator

1.5.1. Facilitator Credentials

Aurora Health Care employees or physicians on the medical staff of any Aurora hospital may serve as an Aurora research facilitator if they meet the following requirements:

- a certificate of completion for the NIH tutorial is on file with the Aurora RSPP office;
- their manager’s approval (if applicable);
- familiarity with Aurora IRB policies and guidelines; and
- be a physician or doctoral level scientist or have a master’s degree.

1.5.2. Facilitator Responsibilities

The research facilitator will:

- direct the investigator (who does not meet the definition of “Affiliated with Aurora”) to appropriate managers or administrators to seek administrative approval and contractual agreements (if applicable) for the study (e.g. clinical units, Clinical Research Department, Radiology Department, etc.);
- direct the investigator to appropriate Aurora IRB policies related to research conduct and to other system-wide policies applicable to research;
- facilitate integration of the research into the clinical operations of the appropriate units or propose additional budgeting to subcontract study management outside of the Aurora clinical staff’s workload (e.g. possibly with the Clinical Research Department, CV Research Department, or Imaging Research Department); and
- review the entire submission packet and sign the final version of the Aurora IRB submission form.

2. SCOPE

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

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3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

45 CFR 46.115

21 CFR 56.108(a)(4)

21 CFR 312, 812

ICH Good Clinical Practice (GCP) Guideline

AAHRPP Elements II.2.D., II.2.E., and II.3.C.1.

4. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.