RESEARCH SUBMISSION REQUIREMENTS

SOP #:	**301**	**VERSION #:**	**1**	**EFFECTIVE DATE:**	**11/01/14**	**SUPERSEDES DOCUMENT:**	**/ /**
THIS POLICY PERTAINS TO:		**ALL RESEARCH SUBMITTED TO THE IRB**					
RESPONSIBILITY FOR EXECUTING POLICY:		**ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB STAFF**					
LAST REVIEWED ON:		**/ /**	**RESULTS:**	**REVISED**			
APPROVAL AUTHORITY:		**Associate Vice President for Research and Economic Development**					
APPROVED BY:						**DATE:**	**10/23/14**

1. POLICY

IRB members rely principally 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 criteria for approval. A protocol requiring review will be scheduled for IRB review when staff has determined that the information and materials submitted present an adequate description of the proposed research.

2. SPECIFIC POLICIES

2.1 Submission Requirements for Initial Review

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

- Human Subjects Research Form, signed by the Investigators, and their Adviser (if applicable)
- Investigator Letter of Assurance of Compliance
- Student Consent to Release of Educational Record (students only)
- Key Personnel Listing
- Letters of Cooperation
- Questionnaires & assessment instruments
- Proposed informed consent document/Assent (if applicable)
- Proposed subject instructions
- Supporting material, such as examples of recruitment advertising, etc.
- Grant application (if applicable)
- DHHS-approved sample consent document (when one exists)
- The complete DHHS-approved protocol (when one exists)
- Data Safety Monitoring Plan (DSMP) or Data and Safety Monitoring Board (DSMB), if applicable for more than minimal risk research
- Investigator Brochure, or device specifications (if applicable)

In addition, applicants may be required to submit:

- Financial Disclosure Statement
- Documentation of completion of required human subjects education (when requested)
- FDA Form 1572 (drug study) or signed Investigator Agreement (device study)

- HIPAA form (if applicable)
- If additional IRB review being sought at another institution: Name, Address and telephone number of IRB, and copy of the other IRB's approval.
- Documentation of approval by another university committee, e.g. Biosafety Committee and Radiation Committee
- Grant or contract of funding agency minus the budgetary pages

2.1.2 Required: Investigators applying for acknowledgement of Exempt Status for a proposed research protocol must submit:

- Exempt Certification Form with all appropriate signatures
- Key Personnel Listing
- Questionnaires, Survey, Interview Questions (if applicable)
- Informed consent (if appropriate)
- Advertisements (if applicable)
- Documentation of completion of required training (when requested)
- Letters of cooperation
- If additional IRB review being sought at another institution: Name, Address and telephone number of IRB, and copy of the other IRB's approval.

2.2 Submission Requirements for Protocol Change and Continuing Review

2.2.1 Protocol Change

During the approval period, Investigators must submit documentation to inform the IRB about proposed changes to the study including, but not necessarily limited to:

- Completed Protocol Change Form
- Revised Key Personnel Listing (if applicable
- Current approved consent/assent document (if applicable)
- Revised IRB Human Subject Review Form or Exempt Certification Form if change is significant
- Investigator's Protocol or Sponsor's protocol (if applicable)
- Any other relevant documents provided by the Investigator
- Interim results

2.2.2 Continuation/Renewal of IRB Approval

Forty (40) days prior to IRB approval expiration date, Investigators requesting renewal of an approved research project must submit, but not limited to:

- Complete Research Project Review and Progress Report
- Copy of the current consent document(s) with the IRB approval date stamp
- A clean copy of the consent documents(s) without the IRB approval date stamp
- A copy of the current HIPAA Authorization document, if separated from the informed consent (if applicable)
- Interim results summary
- Any other relevant documents provided by the Investigator

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

If the IRB Vice Chairperson or IRB Staff determines that the submitted documents are not adequate, Investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. No incomplete submissions will be reviewed by the IRB.

3. RESPONSIBILITY

The IRB Staff and/or the IRB Vice Chairperson will review all projects to determine if additional information or specific expert consultation is needed. The IRB Staff and/or the IRB Vice Chairperson will defer to another meeting or IRB, or obtain consultation if there is not appropriate scientific or scholarly, or representational expertise.

The IRB and the IRB Staff are responsible for maintaining current research submission requirements for interested Investigators.

The IRB Vice Chairperson or designee will review all Research Project Review and Progress Reports and all Research Project Termination forms.

The IRB Coordinator and IRB Secretary are responsible for preparing member review materials and review of initial submission elements.

The IRB Secretary is responsible for submission receipt, tracking 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. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
IRB Coordinator, IRB Secretary	Ensure that complete submission information is available and provided to all Investigators.
IRB Secretary	Date stamp receipt of all submissions. Review submission for completeness. Note any missing information. Log into IRB Database, print proper Report of Action form, put in file and send for review.
IRB Chairperson, IRB Secretary, IRB Coordinator	<u>Full Board: New Studies/Continuations/Modifications</u> Review submissions, assign to Primary Reviewers and determine if expert consultation is needed. Review Clinical Medical proposals – send to Clinical Medical Subcommittee for review.
IRB Coordinator, IRB Secretary, IRB Members	Evaluate claims for exempt review. Review and document category of exemption Evaluate submissions for expedited review. Route to reviewer

IRB Secretary	Prepare submissions for IRB review. Request from Investigator any missing elements from incomplete submissions. Add new submissions for full IRB review to agenda for next meeting.