Covenant Medical Center
Institutional Review Board

Covenant IRB Research Application Process

Overview:

It is the policy of Covenant HealthCare that all research involving human subjects must be reviewed and approved by the Institutional Review Board prior to initiation. The involvement of human subjects in research is not permitted until the IRB has reviewed and approved the research protocol and informed consent. Furthermore, unless the consent process has been specifically waived by the IRB in accordance with 45 CFR 46, no subjects may be included in research unless the investigator has obtained the legal informed consent of the subject or the subject's legally authorized representative. The IRB has the authority to suspend or terminate approval of research that has posed serious threat or harm to subjects, or is not being conducted in accordance with the IRB's requirements.

Submitting a Study for Review:

Correspondence with the IRB is conducted through IRBNet. Instructions for registering and using the site are attached.

Submission materials must be received two weeks preceding the scheduled IRB business meeting to allow adequate time for Board members to review the proposal. Meetings usually occur on the third Wednesday of each month. Approval will be delayed if the applications are incomplete or lack sufficient information for an adequate appraisal. Late submissions will be deferred to the following month.

Submission materials should include:

- Application for Project Review
- The Protocol, giving a complete description of the proposed research in non-technical language
- A copy of the Informed Consent that is appropriate to the proposed research and written in simple, non-technical language that can be easily understood by the prospective subjects. If it is anticipated that study participants will not understand English, consent documents must be translated into the appropriate language(s).
- When appropriate, copies of all questionnaires, interview protocols, assessment materials, experiment session outlines, and descriptions of materials that subjects will encounter
- When advertising is to be used for subject recruitment, the information contained in the advertisement and its mode of communication
- Completion of the Human Participant Protection Education Tutorial
- Submission to CV or resume of principal investigator and sub-investigators

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- **Medical Students and Medical Residents, Nursing students, Undergraduate and Graduate students (non-nursing) –refer to the appropriate Investigator Instruction form for additional requirements**

The Review Process:

Upon receipt, (and prior to review either by the full board or by expedited review), the submission is evaluated to identify and resolve issues that may delay the Board's/or the Chairs' decision. You will be notified of required changes prior to Full Board or Chair review. Incomplete application may delay the review of your project, as corrections will be required prior to sending the project on for final review.

Criteria for IRB approval:

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits to subjects, and to the advancement of knowledge
- Selection of subjects is equitable
- Informed consent will be sought
- Informed consent will be documented
- The research plan adequately provides for the ongoing collection of data to ensure the safety of research participants
- Adequate provisions are made to protect the privacy of subjects, and to maintain the confidentiality of data
- Safeguards are present to ensure the protection of the subjects from undue coercion or influence to participate in the project
- Monetary costs to the subjects are evaluated and found to be reasonable
- Monetary costs to the institution are evaluated and found to be reasonable and agreeable to the parties or departments involved
- The research proposal is approved by the Corporate Compliance Contract Committee (if applicable)

You must be present at the IRB meeting to present your study if your study qualifies for Full Board Review only.

Notification of the IRB's Decision:

The IRB will notify the investigator of the results of the review. If changes are required prior to approval, the IRB will notify the investigator(s), who will make the needed changes and return them to the IRB for final approval prior to initiation of the research. If the IRB decides to disapprove a research activity, written notification will include a statement of the reasons for disapproval. The investigator(s) will be given an opportunity to respond.

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Responsibilities of the Investigator:

The IRB requires that any investigator proposing the undertaking of a research study, possess the professional qualifications necessary to carry out said research in a safe, responsible and qualified manner.

- When requested, the investigator will provide written verification/validation in the form of degrees, licenses, certifications, registrations, or continuing education validations of qualifications to participate in the planned research
- Maintain compliance of all sub-investigators, student investigators, and research associates with the decisions, conditions and requirements set forth by the IRB
- Fully complete an application for review of proposed research
- Submission of appropriate forms (protocol, informed consent, investigator's brochure, etc.)
- Facilitate prior institutional approval for any research-associated costs, resource utilization, space utilization, or use of institutional personnel
- Submit required documents to the Corporate Compliance Contract Committee for review (if applicable)
- Provide regular progress reports upon request or at least once per year (continuing review)
- Promptly report any and all changes in the research process, protocol, or informed consent using the Protocol Revisions Form as will as submission of all pertinent documents. Changes to the protocol cannot be enacted without prior IRB review and approval
- Promptly report any adverse reactions or unanticipated events associated with the research
- Submit a final report following the completion of the study, and a copy of any manuscript submitted for publication

Continuing review of research (FDA regulated studies) and Annual review (non-FDA regulated studies) is an expectation of the principal investigator.

- **Continuing review** will be done at intervals appropriate to the degree of risk, but not less than once per year for FDA sponsored studies. Time interval for continuing review will be made at the time of initial approval and re-evaluated at each expiration date. A courtesy reminder will be sent out at 3, 2 and 1 month prior the study expiration date, if it has not yet been received. **A lapse in approval will result in expiration. You must suspend all study related activities until the approval has been renewed.**

- **Annual updates** are an expectation of Non-FDA regulated studies that receive expedited review and approval. The principal investigator should provide an annual update yearly. A courtesy reminder will be sent out at 3, 2 and 1 month

prior the study expiration date until received. **Lack of submission of an annual update may result in study closure. If the study is closed, you must suspend all study related activities until the approval has been renewed.**

☎ If you have questions relating to the research process, please contact:

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