Administrative Manual
CLINICAL RESEARCH PROGRAMS

Policy Number: **12.06**

Objective: This policy is intended to revise, define and add specific details to Covenant Medical Center's Clinical Research Program Plan and to address compliance issues relating to clinical research trials performed under the supervision of the Covenant Medical Center Institutional Review Board.

Scope: All Covenant facilities and wholly owned entities.

Policy: This Policy shall apply to all FDA or NIH approved clinical research trials, and all other research studies which involve reimbursement for research purposes, and which use Covenant facilities, patients, or the Covenant name.

Procedure:

A. Responsibilities:

1. The Principal Investigator shall bear primary responsibility for the conduct of the project, including fiscal management, compliance with Covenant Medical Center's Corporate Compliance Program, and all applicable federal and state laws and regulations.
2. The Principal Investigator or designee shall provide a designated Covenant Medical Center Research Nurse with the proposed research protocol prior to or concurrent with IRB submission.
3. The Covenant Medical Center Research Nurse will work with the Director of Corporate Compliance and legal counsel to facilitate the approval of contracts and budgets.
4. Covenant's Research Nurse and the Covenant Finance Department will assist the Corporate Compliance Department with completing an analysis of actual research costs. The Research Nurse will also be responsible for the oversight of research charges and reimbursement.
5. Covenant will provide assistance, within budgetary constraints, to the Principal Investigator in meeting the obligations set forth in this policy.

B. Contracts and Indemnification:

1. Prior to the enrollment of any patients in a clinical trial, all contracts and related budgets for clinical research studies shall be submitted to and approved by the Contract Compliance Committee.
2. All contracts for research at Covenant shall list Covenant Medical Center, Inc. as the institution. Contracts must be reviewed for content and approved by Covenant's legal counsel. Unless waived by the Contract Compliance Committee, all contracts shall include:

- Identification of parties: Covenant Medical Center (Institution), the physician (Investigator), and the corporate sponsor (Sponsor)
- Description of project: Clearly identified Research Protocol
- Payment terms: All the Hospital's incremental expenses relating to the study must be covered, including professional fees. In addition, the contract must provide for the payment of expenses related to the diagnosis and treatment of research-related complications.
- Indemnification: The Sponsor shall indemnify Covenant Medical Center and the Principal Investigator from liability in form and substance approved by the Contract Compliance Committee.
- Insurance requirements: The Sponsor shall be required to carry liability insurance covering the research in an amount to be agreed upon not less than $1,000,000 per occurrence. The Sponsor may request liability insurance for Covenant, its employees, and the Principal Investigator in a like amount.
- Compliance with law: The sponsor should agree to comply with all laws and regulations relating to research, including all FDA reporting requirements.
- Patents: Covenant may agree to a requirement that all patents, copyrights and trademarks resulting from the product being tested belong to the Sponsor.
- Confidentiality: Covenant, the Investigator and the Sponsor shall agree to requirement to keep all business and research information strictly confidential.
- Publication rights: Covenant may permit Sponsor edits of publications based upon the research protocol, or other Sponsor imposed limitations on publications.

3. In the absence of a Sponsor prepared draft research contract, Covenant Medical Center will propose a contract addressing the above-mentioned points.
4. No FDA or NIH approved clinical research trials, or other research studies which involve reimbursement for research purposes, or research studies which use Covenant facilities, patients, or the Covenant name will be initiated without IRB approval and contract and budget approval by the Contract Compliance Committee.
5. No monies may be paid by the Sponsor to the Principal Investigator outside of the approved contract; Provided, however, that this provision shall not preclude the Principal Investigator from receiving reasonable compensation from a Sponsor for seminar or symposium presentations relating to the study.
6. Unless waived by the Contract Compliance Committee, Sponsors shall be required to pay an IRB Review, Renewal and/or Amendment Fee to the Hospital in an amount established by the IRB and approved by the Contract Compliance Committee. No part of this fee shall inure to the benefit of the Investigator or any other third person or organization.

C. Administrative / Business Conduct:

1. Covenant supports research as an important element of its Mission, and therefore, encourages Investigators to be involved in research projects. Covenant, within budgetary constraints, will provide research staff to support the activities of the Principal Investigator.

2. All Hospital research related expenses will be reimbursed to appropriate departments and parties no less frequently than quarterly. The Principal Investigator shall be paid a reasonable fee for his/her participation in the study. Fees payable to the Principal Investigator for his or her services relating to the study shall be included in the research budget submitted to the Contract Compliance Committee, or the Principal Investigator shall submit a statement to the Committee certifying that fees payable to him or her are consistent with fair market value for the services which he or she is providing. In the event that fees paid exceed Committee approved fair market value, such excess funds shall be refunded to the Sponsor or may be deposited in a separate fund to be used solely for the education and training of Clinical Research Staff and Physicians; provided that such education shall be directly related to the research duties of the staff member receiving monies from such fund.
3. In general, contracts negotiated with Sponsors must provide for the payment of all incremental direct research related costs incurred by the Hospital. Notwithstanding the foregoing, the Contract Compliance Committee may, in its sole and absolute discretion, approve a study which is projected to result in a financial loss to the Hospital when the importance of the research and its potential benefit to the public is deemed to justify such action.
4. The Research Nurse will track and oversee research charges and reimbursement in collaboration with patient accounting and the appropriate Clinical Director. It is, and shall be the policy of Covenant Medical Center that under no circumstances shall the Hospital bill the patient or any third party payor for items or services for which payment has been received from a study Sponsor.
5. Internal audits shall be carried out randomly or upon the request of the Corporate Compliance Director or any other appropriate person. All transactions relating to an approved research project must be fully documented and properly allocated.

D. Budgetary Issues:

1. The Contract Compliance Committee must approve budgets for all applicable research projects. The IRB Coordinator and/or the Research Nurse will also analyze the budget and communicate with accounting/Finance to identify what may or may not be billed to third party payers for study participant care in order to avoid double billing, and/or billing for experimental treatment, procedures or devices.
2. All payments received or to be received by the Hospital in connection with research must be disclosed to the Contract Compliance Committee, and must be consistent with fair market compensation for the services to be rendered.
3. The budget should include all expenses directly associated with the project, regardless of where they were originally incurred. The Research Nurse and the Contract Compliance Committee shall, to the extent practical shall allocate costs and expenses consistent with the allocation of costs and expenses identified in the Sponsor's sample budget. The Hospital shall verify charges for time spent by the Research Nurse on a quarterly basis, and adjust charges to Investigators for such services if warranted.

4. All payments for salaries and fringe benefits must be in proportion to efforts and commitments. The budget must include the salary expense and/or professional fees for all expected time expenditure on the project by research personnel, principal investigators, co-investigators, and consultants whose time is necessary for the research. In the event that the Study Sponsor is paying the Principal Investigator directly, the Principal Investigator shall submit a certification that fees payable to him or her are consistent with fair market value, and are unrelated to the value referrals or other business generated between the Principal Investigator and the study's sponsors.
5. Usual and ordinary medical/surgical services rendered to a patient enrolled in any research protocol may be billed to third party carriers, if not included in the budget and paid for by the external funding source. Any out-of –pocket cost to be incurred by the patient must be identified and shared with the patient as part of the study enrollment process. Every attempt should be made to include these expenses in the budget and to reimburse the patient when permitted by applicable laws and regulations.
6. Research revenues are to be used to reimburse the hospital for all costs incurred related to the research project.
7. Sponsor organizations and/or the Principal Investigator must be instructed to make checks for the Hospital's research costs payable to Covenant Medical Center, and to send all remittances for same to the attention of the Covenant Research Nurse, or such other Covenant employee as may be identified in the study agreement.

Reviewed by: Board Contract Compliance Committee

Effective date: 11/26/01, 11/1/03, 10/5/05, 10/2008; 10/2011; 7/2014

Review date: 7/2017

Approval:

_____ July, 2014

Edward G. Bruff, Executive Vice President/COO Date

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