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Covenant Health

Conflicts of Interest

PURPOSE

It is the policy of Covenant Health to comply with federal regulations regarding financial disclosure of potential conflict of interest in research, as made part of the Code of Federal Regulations. This policy is intended to ensure that the design, conduct and reporting of research will not be biased by any conflicting financial interest of those investigators responsible for the research. This policy is supplemental to Covenant Health SQIPR policy # LDR.1C.003, Conflict of Interest.

This Policy consists of two parts:
Part 1 – Public Health Service (PHS) funded research and
Part 2 – Food and Drug Administration (FDA) regulated research

PART 1 – PHS Funded Research
Group Oncology, Grants and Subcontracts

A. APPLICABILITY

Part 1 of this policy applies to all investigators who are involved in PHS funded research conducted at Covenant Health facilities

B. DEFINITIONS

Compelling Circumstances are those facts that convince the Covenant Health COI Committee that a financially interested individual should be permitted to conduct human subject's research. When considering a request by a financially-interested individual to conduct human subjects research, the circumstances that the COI Committee should evaluate include the nature of the research, the magnitude of the interest and the degree to which it is related to the research, the extent to which the interest could be directly and substantially affected by the research, the degree to which the interest could affect the research, and the

degree of risk to the human subjects involved that is inherent in the research protocol. A material conflict of interest requires a written mitigation plan to be monitored by the COI Committee.

Conducting Research means, with respect to a research protocol, designing research, directing research or serving as the principal investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication.

Designated Institutional Official means individuals responsible for reviewing all Significant Financial Interest disclosures; determining whether a Financial Conflict of Interest (FCOI) potentially exists, and sending potential FCOIs to the Conflict of Interest Committee for review and/or management. The Designated Institutional Official will chair the Conflict of Interest Committee and submit FCOI and other reports to applicable awarding components/funders.

Disclosure means a release of relevant information about significant financial interests in human subjects research to parties outside Covenant Health's COI review and management processes (e.g., to research subjects or journal editors).

Externally-funded research means all externally funded research, including grants, contracts, and cooperative agreements. External sponsors include, but are not limited to PHS-Awarding Components (e.g. NIH), other federal funding agencies (e.g. DoD, NSF), foundations, private companies and individuals.

Family Member means the spouse or dependent children of an Investigator.

Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting the results of Research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Financially Interested Individual means a covered individual who holds a significant financial interest that would reasonably appear to be affected by the individual's human subject's research.

Human Subjects Research includes all research meeting the definition of "research" performed with "human subjects" as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation. In the event that the Common Rule definitions of "human subjects" or "research" are modified through rulemaking, any such revisions shall apply for the purposes of this guidance.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Covenant Health, which may include, but is not limited to research, consultation, speaking engagements, teaching, professional practice, contract negotiation, clinical activities, purchasing and institutional committee memberships.

Investigator means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants, and all senior/key personnel on a project, regardless of funding.

PD/PI means a Project Director or Principal Investigator of a research project. In funded research, the PD/PI is included in the definitions of senior/key personnel and Investigator.

PHS-funded Research means all research which is sponsored by the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including but not limited to the National Institutes of Health (NIH), the Center for Disease Control (DCD), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ).

Rebuttable Presumption Against Financial Interests in Human Subjects Research
means Covenant Health will presume, in order to assure that all potentially problematic circumstances are reviewed, that a financially interested individual may not conduct the human subjects research in question. This rule is not intended to be absolute: a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the COI Committee, constitute compelling circumstances. The individual would then be allowed to conduct the research under conditions specified by the COI Committee and approved by the Covenant Health IRB.

Reporting means the provision of information about significant financial interests in human subjects research by a covered individual to responsible institutional officials and to the Covenant Health COI committee, or the transmission of such information within institutional channels (e.g., from the COI Committee to the Covenant Health IRB).

Responsible Institutional Officials means the Institutional Official, who is responsible for the oversight of research programs within Covenant Health.

Responsible IRB is the Covenant Health institutional review boards with jurisdiction over the research as specified in the federal wide assurance (FWA) that Covenant Health has provided to the U.S. Department of Health and Human

Services.

Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in a grant application, progress report, or any other report submitted to a funding agency.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's *institutional responsibilities:*

- With regard to any publicly traded entity, a significant financial interest exists if the value of the remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship): equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5000, or when the Investigator (or the Investigator's spouse, or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interest.
- Investigators must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the institutional responsibilities; except for travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education (as defined at 20 USC 1001(a)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Significant Financial Interest does *not* include:

- salary, royalties, or other remuneration paid by Covenant Health to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to Covenant Health and agreements to share in royalties related to such rights;
- income from investment vehicles, such as mutual funds and retirement

accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or location government agency, an Institution of higher education; or
- income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined as 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

B. RESPONSIBILITIES OF COVENANT HEALTH

Policy. Covenant Health will maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with 42 CFR 50 Subpart F and 45 CFR 94,. The Policy (Part 1) applies to research that is funded by PHS, The Policy will be made publicly available via the Institute's public-facing website.

Training. Covenant Health is responsible for informing each Investigator of this Policy; relevant regulations, and the Investigator's responsibility to disclose significant financial interest. Investigators are required to complete Investigator COI training before engaging in research, and at least once every four years. In addition, Investigators will be trained/re-trained immediately when:

- Covenant Health revises this Policy in any manner that affects the requirements of investigators;
- An Investigator is new to Covenant Health; or
- Covenant Health finds that an Investigator is not in compliance with the Institute's financial conflict of interest policy or management plan(s).

Reporting.
PHS-funded Research. Covenant Health is obligated under 42 CFR 50 Subpart F and 45 CFR 94 to report to the PHS Awarding Component all related significant financial interests that are deemed financial conflicts of interest (FCOI), as defined in this Policy, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. Covenant Health must review, manage, mitigate, report, and when appropriate, conduct retrospective reviews of potentially conflicted projects as described in this Policy.

INVESTIGATOR DISCLOSURE REQUIREMENTS

Initial Disclosures. Each Investigator (as defined in this Policy – individuals responsible for the design, conduct, or reporting of research or proposed research in a funding application) is required to disclose the Investigator's Significant Financial Interests – and those of the Investigator's spouse, and dependent children – prior to submitting an application for PHS-funded research.

Disclosing Significant Financial Interests allow Covenant Health to determine whether a “Financial Conflict of Interest” exists, whether it is related to the research, and whether management or mitigation strategies must be implemented to ensure objectivity in research.

Investigators who are new to Covenant Health must disclose Significant Financial Interests before transferring any research to Covenant Health and before engaging in any research activities at Covenant Health.

Disclosures must be made, in writing, to the Research Administration office in accordance with their published Investigator COI Disclosure form(s).

Subsequent Disclosures. Each Investigator who participates in research must submit an updated disclosure of significant financial interests at least once per year during the period of the award or project, to determine whether the interest, if any, is a “Financial Conflict of Interest” that is potentially related to the research.

The disclosure must include any information that was not initially disclosed to the Institute, and shall also include updated information on any previously-disclosed significant financial interests (e.g. updated value of a previously disclosed equity interest).

Additionally, Investigators must submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (through purchase, marriage, inheritance, etc.) a new significant financial interest.

Management of Subrecipients. When Covenant Health carries out research through a subrecipient (e.g. subcontractors), Covenant Health must take reasonable steps to ensure that the subrecipient Investigator(s) will comply with either the subrecipient’s or Covenant Health’s Investigator Conflict of Interest Policy.

Special Provisions for PHS-funded Subrecipients: When Covenant Health carries out PHS-funded research through a subrecipient (e.g. subcontractors), Covenant Health must take reasonable steps to ensure that the subrecipient Investigators will comply with 42 CFR 50 Subpart F and 45 CFR 94 by incorporating one of the following into the subcontract agreement:

- Statement that the subrecipient will comply with their own financial conflict of interest policy which complies with 42 CFR 50 Subpart F and 45 CFR 94. The agreement will specify the time periods for the sub recipient to report all identified financial conflicts of interest to the awardees institution (Covenant Health). Time periods for reporting to Covenant Health must be sufficient to allow Covenant Health to complete the review, management, and reporting of subrecipient

Financial Conflicts of Interest which are related to PHS-funded research.

OR

- Statement that the subrecipient will comply with this Policy (Covenant Health's Investigator COI Policy) which complies with 42 CFR 50 Subpart F and 45 CFR 94. The agreement will specify the time periods for the subrecipient to report all Investigator disclosures of significant financial interest to the awarded institution (Covenant Health). Time periods for reporting to Covenant Health must be sufficient to allow Covenant Health to complete the review, management, and reporting of subrecipient Financial Conflicts of Interest which are related to PHS-funded research.

PHS FUNDING APPLICATION CERTIFICATION

In accordance with 42 CFR 50 Subpart F and 45 CFR 94, Covenant Health will meet the following PHS expectations when applying for PHS-funding:

Certification. Covenant Health must certify, in each grant application for PHS-funded, that Covenant Health;

- Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS:

- Shall promote and enforce Investigator compliance with the requirements under 42 CFR 50 Subpart F and 45 CFR 94 (as applicable), including those pertaining to disclosure of significant financial interest;

- Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component;

- Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and Covenant Health's review of, and response to, such disclosure, whether or not the disclosure resulted in Covenant Health's determination of a FCOI; and

- Shall fully comply with the requirements of 42 CFR 50 Subpart F and 45 CFR 94.

REVIEW AND MANAGEMENT OF POTENTIAL COI

Institutional Official: In accordance with 42 CFR 50, Subpart F, Covenant Health designates an Institutional Official responsible for soliciting and reviewing disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, research. Disclosures must be made, in writing, to the Research Administrative office prior to the submission of each application for PHS funding, in accordance with Covenant Health's published Investigator COI Disclosure form(s). Covenant Health will provide initial and ongoing FCOI reports to the funding agency, if any, in accordance with the funding agency's policies.

Covenant Health will provide guidelines consistent with 42 CFR 50, Subpart F and 45 CFR 45 CFR 94 for the Institutional Officials to determine whether an Investigator's significant financial interest is related to the research, and it so, whether the significant financial interest constitutes a "financial conflict of interest." A "financial conflict of interest" occurs when the designated Institutional Official reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of research. Covenant Health may not rely solely upon an Investigator's determination to decide whether a Significant Financial Interest or Financial Conflict of Interest is related to research. The Institutional Official or COI Committee may, however, request information and feedback from the Investigator regarding relatedness to research and/or Institutional Responsibilities.

Appeals. Any Investigator who disagrees with a final decision of the COI Committee may appeal in writing to the Institutional Official within ten (10) calendar days of a final decision. The COI Committee must review and consider all appeals, and vote to either retain its original findings or to revise its recommended actions. The final decision regarding management of an actual or potential COI in research under this Policy rests with the COI Committee, though investigator feedback is encouraged.

COMPLIANCE, NON-COMPLIANCE AND INSTITUTIONAL ENFORCEMENT

All persons subject to this Policy are expected to comply fully and promptly. An Investigator who submits a complete and accurate COI Disclosure and complies with conditions required by the COI Committee shall be deemed to be in compliance with this Policy. Failure to fully and accurately disclose a Conflict of Interest or failure to comply with conditions or management plans imposed by the COI Committee shall constitute non-compliance with this Policy.

Covenant Health encourages Investigators who are aware of an unreported Conflict of Interest to bring the COI to the attention of the Institutional Official who

will consult with the COI Committee regarding possible enforcement actions to be taken. If the COI Committee determines that an Investigator has failed to comply with any aspect of this Policy, the COI Committee shall submit a report in writing to Covenant Health's Executive Vice President for Hospital Operations. The report shall include all material facts and recommendations for enforcement actions, if any.

The Executive Vice President for Hospital Operations shall make final decisions regarding enforcement actions, up to and including termination of employment or legal action.

Covenant Health will complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner. Such reviews will be documented consistent with the regulation.

In instances where the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with an FCOI that was not managed or reported by Covenant Health as required by the regulation, Covenant Health shall require the investigator involved to:

a) Disclose the FCOI in each public presentation of the results of the research, and
b) To request an addendum to previously published presentations.

REVIEW AND MANAGEMENT OF CONFLICT OF INTERESTS

Mitigation

For PHS-funded research, Covenant Health must notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above, and a description of the impact of the bias on the research project, as well as Covenant Health plan of action to eliminate or mitigate the effect of the bias. Thereafter Covenant Health shall submit FCOI reports to the PHS Awarding Component annually. Depending on the nature of the FCOI, Covenant Health may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS –funded research project between the date that the FCOI or noncompliance is determined, and the completion of Covenant Health's retrospective review. The COI Committee will be responsible for generating all appropriate documentation, including when the retrospective review finds no bias, and the basis for such a finding.

PUBLIC ACCESSIBILITY

Prior to the expenditure of any funds under any PHS-funded research projects, Covenant Health will ensure public accessibility of information concerning any Financial Conflicts of Interest (FCOI) disclosed to Covenant Health. Covenant Health will ensure such accessibility by responding to any requestors within five (5) business days of a request, or posting on Covenant Health's external website, when the following criteria are met:

- A Significant Financial Interest (SFI) was disclosed and is still held by the senior/key personnel as defined in 42 CFR 50, Subpart F and 45 CFR 94.
- The designated Institutional Official and/or COI Committee has determined that the SFI is related to the research and:
- The COI Committee determines that the SFI is a FCOI.

The information that Covenant Health must make publicly available includes, at a minimum:

- Investigator's name
- Investigator's title and role with respect to the Externally-funded project
- The name of the entity with which the significant financial interest (SFI) is held
- The nature of the SFI
- The approximate value of the SFI (dollar ranges are permissible as follows: $0-$4,999; $5,000-$9,999; $10,000-$19,999: $ amounts between $20,000-$100,000 in increments of $20,000; amounts above $100,000 in increments of $50,000)
- When the value of an SFI cannot be readily determined through reference to public prices or other reasonable measure of fair market value, a statement stating so.
- A statement that the information is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor. Covenant Health is not responsible for continually updating previous requests. The requestor must make a new request to obtain updated information.

Information concerning conflicts for which the above criteria are met must be available to written requestors for at least 3 years from the date that the information was last updated.

REPORTING TO PHS AWARDING COMPONENTS:

For PHS-funded research, Covenant Health will provide the PHS Awarding Component with a FCOI report regarding any Investigator's significant financial interest found to constitute FCOI, and to ensure that Covenant Health has implemented a management plan in accordance with 45 CFR 94 and 42 CFR 50.

For subsequent FCOI findings during the period of award (e.g. participation of a new Investigator), Covenant Health shall, within 60 days, provide the PHS Awarding Component with a FCOI report regarding the financial conflict and ensure that Covenant health has implemented a management plan in accordance with 45 CFR 94 and 42 CFR 50. Where such a FCOI report involves a significant financial interest that was not disclosed timely by the Investigator, or which was for whatever reason not previously reviewed or managed by Covenant Health, Covenant Health is also required to complete a retrospective review as referenced above. If bias is found, Covenant Health is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

All FCOI reports to PHS Awarding Components must include sufficient information to enable the PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of Covenant Health's management plan. The FCOI report shall include, but is not limited to:

- Project number
- PD/PI or Contact PD/PI if multiple PD/PI model is used
- Name of Investigator with the FCOI
- Name of the entity with which the Investigator has the FCOI
- Nature of the financial interest (e.g. equity, travel reimbursement, honoraria)
- Value of the interest (ranges are allowed a cited in the Public Accessibility section of this Policy
- A description of key elements of Covenant Health's management plan, including:
    - Role and principal duties of the conflict Investigator in the research project
    - Conditions of the management plan
    - How the management plan is designed to safeguard objectivity in the research project
    - Confirmation of the Investigator's agreement to the management plan
    - How the management plan will be monitored to ensure Investigator compliance, and
    - Other information as needed.

For any FCOI previously reported by Covenant Health with regard to an ongoing

PHS-funded project, Covenant Health will provide the PHS Awarding Component an annual FCOI report that addresses the status of the FCI and any changes to the management plan. This reporting shall continue throughout the period of funding in the time and manner specified by the PHS Awarding Component. The annual FCOI report shall specify whether the FCOI is still being managed, or explain why the FCOI no longer exists.

MANTENANCE OF RECORDS. Covenant Health shall maintain records regarding Investigator COI Disclosures, and Covenant Health's review of, and response to, such disclosures (whether or not the disclosure resulted in the Institutional Official's determination of a financial conflict of interest related to research) and all actions relating to elimination, management, mitigation, and retrospective reviews (if applicable) for at least three (3) years after final payment on any Externally-funded project to which the potential or actual COI relates; or three years after the resolution of any funding agency action involving those actions, whichever is longer.

PART II – FDA Regulated Industry Sponsored

PURPOSE:

The purpose of this policy is to promote the identification, disclosure and, if required, resolution or management of conflicts of interest (COI) when conducting industry sponsored clinical research.

Any person engaging in a research activity has an obligation to avoid conflicts of interests. Individuals engaging in research activities are required to make voluntary and timely disclosures to ensure the necessary steps to avoid the appearance of a conflict of interests.

DEFINITIONS:

Applicant means the party who submits a marketing application to FDA for approval of a drug, device, or biologic product. The applicant is responsible for submitting the appropriate certification and disclosure statements required in this policy.

Clinical Investigator means only a listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child or the investigator.

Compensation Affected by the Outcome of Clinical Studies means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

Covered Clinical Study means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the applicant or FDA relies on to establish that the product is effective (including studies that show equivalence to a effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety. This would, in general, not include phase 1 tolerance studies or pharmacokinetic studies, most clinical pharmacology studies (unless they are critical to an efficacy determination), large open safety studies conducted at multiple sites, treatment protocols, an parallel track protocols. An applicant may consult with FDA as to which clinical studies constitute "covered clinical studies" for purposes of complying with financial disclosure requirements.

Propriety Interest in the Tested Product means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement.

Significant Equity Interest in the Sponsor of a Covered Study means any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation that exceeds $50,000 during the time the clinical investigator is carrying out the study and for 1 year following completion of the study.

Significant Payments of Other Sorts means payments made by the sponsor of a covered study to the investigator or the institution to support activities of the investigator that have a monetary value of more than $25,000, exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and or 1 year following the completion of the study.

Sponsor of the Covered Clinical Study means the party supporting a particular study at the time it was carried out.

POLICY

Individuals engaged in industry sponsored research are to complete a Conflict of Interest Questionnaire (COIQ) at the following times:

- at the time of submitting a contract packet to the Research Administration Office for the purpose of entering into any sponsored clinical research agreement

- at the time of submitting a continuing review application to the IRB

Procedure

Upon receipt of the COIQ the Research Administrator will review the disclosure in conjunction with the study budget and verify that payments to the investigator or research center are considered "reasonable compensation" for the services and procedures required by the research. *Reasonable Compensation is defined by the IRS as:*

- *"The value of services is the amount that would ordinarily be paid for like services by like enterprises (whether taxable or tax-exempt) under like circumstances (i.e., reasonable compensation)."*

Specific restrictions will not be placed on the compensation received by an individual as long as such compensation meets this definition. Covenant Health relies on the personal integrity, professional discipline and alert common sense of individuals in the conduct of their external activities when conducting clinical research.

Disclosing a financial conflict of interest does not automatically mean the financial interest is inappropriate or improper, it means only that disclosure and evaluation, and in some cases, approval and oversight of the research will be necessary.

The Research Administrator will notify the COI Administrator of reports of Significant Financial Interests. The COI Administrator will consult with the Chair of the COIC to determine if the COI committee should be convened for resolution of the conflict before the research contract can be considered for approval.

The following disclosure will require automatic convening of the COI committee:

- Research where an investigator involved in the project holds a license for the patent or invention under study

Confidentiality

Disclosures of financial interests shall be maintained in a careful and discreet manner and made available only to those within Covenant Health who have a need to see them. In addition, the appropriate hospital or entity within Covenant Health is obligated to advise the applicable government agency with respect to financial interests and how they are being managed, reduced, or eliminated to protect the research from bias. The hospitals or entities within Covenant Health also have a responsibility to keep the applicable agency fully informed if they are unable to adequately manage an actual or potential conflict of interests. A regulatory body or government agency may at any time request submission of, or review on site, all records pertinent to the certification by the appropriate hospital or entity within Covenant Health.

Conflicts of Commitment

Individuals who are employed by Covenant Health are expected to devote their primary professional loyalty, time, and energy to their medical practice, research, patient care,

and service to the Covenant Health facility in which they are employed. Outside activities must be arranged so as not to interfere with the importance of these commitments. In keeping with this policy, it is the practice of Covenant Health to permit individuals to devote some of their time toward external activities, provided that the individual's work for the hospital or other entity within Covenant Health is not negatively affected.

Conflicts Identified by the IRB at Continuing Review

The IRB will notify the COI Administrator of any conflicts identified by the IRB at the time of continuing review. The COI Administrator, in consultation with the COI Chair, will determine if the COI committee should be convened.

The IRB will be informed of any recommendations made to manage the conflict by the COI committee. The recommendations and actions will become a part of the research application and continue for the duration of the research study.

Part 1 and Part 2

Conflict of Interest Committee (COIC)

The COI Committee membership shall consist of:
* the Institutional Official,
* a representative from the Integrity/Compliance Office
* the Chairman of the IRB and
* a medical staff representative to be selected by the COI membership listed above

Minutes shall be taken at each committee meeting and maintained by the COI Administrator.

The conflicts committee will:

- Determine if there are compelling circumstances which are sufficient to allow the research to continue in the face of the conflict.
- Determine the appropriate strategies to properly oversee and manage potential conflict(s), taking into consideration the possible remedies as outlined below.
- Inform the investigator and the IRB of the actions taken and decisions made by the committee.

For research that is permitted to go-forward by the COI committee, the IRB will be informed of the nature of the conflict, and any recommendations made to manage the conflict by the COI committee. The recommendations and actions will become a part of the research application and continue for the duration of the research study.

The COI Committee responsibilities include the following:

a. Review of any request by a financially interested individual to rebut the presumption that he or she may not conduct human subject's research.

b. Documentation of the Committee's findings and the bases for any recommendation to permit or to recommend against permitting a financially interested

individual to conduct human subjects research. In either case the COI Committee will prepare a summary report describing the nature and amount of the financial interest and the Committee's recommendations. This summary report shall be made available to the Covenant Health IRB. When the COI Committee has recommended that a financially interested individual be permitted to conduct human subject's research and the Covenant Health IRB has approved the research and the individual's participation, the summary report should be provided to research subjects or the public, upon request.

c. The COI Committee shall encourage the financially interested individual to minimize the potential for conflict of interest by reducing or eliminating the interest or the individual's direct involvement in the research. The COI Committee should specify the monitoring procedures or other conditions to be imposed when a financially interested individual will be permitted to conduct human subject's research. Such procedures may include: (i) public disclosure of the researcher's conflict, (ii) monitoring of a study, (iii) disqualification of a researcher from taking part in research, (iv) compelled divestiture of a researcher's ownership interest in an outside firm or corporation, or (v) severance of a researcher's business relationship with an outside firm or corporation. Mitigation plans will be monitored by the COI Committee and others as designated by the Chair of the COI Committee.

d. The COI Committee shall notify each researcher within ten (10) business days of its findings with regard to the existence of a conflict of interest and the action it deems appropriate to manage, eliminate, or reduce the conflict of interest.

e. The COI Committee will communicate summary information about the nature and amount of any significant financial interest in human subjects research, along with the Committee's findings and recommendations concerning requests by financially interested individuals to conduct such research to the Covenant Health IRB, the facility CAO, and to Covenant Health Officials.

Process.

a. The Covenant Health IRB and responsible institutional officials shall be alerted whenever a financially interested individual proposes to conduct human subject's research;

b. At the time of continuing review, the IRB Administrator will report the ongoing status of the continuing review process to the COI Administrator prior to IRB review.

c. Prior to the Covenant Health IRB's final approval (whether initial or continuing approval) of human subjects research, the COI Committee shall inform the Covenant Health IRB and responsible institutional officials of any significant financial interests held by financially interested individuals who will conduct the research, as well as the COI Committee's findings and recommendations concerning the same;

c. When financially interested individuals are permitted to conduct human subject's research, the financial interests in question shall be disclosed in accordance with Covenant Health's COI policies.

d. The COI Committee shall maintain records of all financial disclosures and all actions

taken by the institution with respect to any conflict of interest for at least three years from the date of submission of the final expenditures report (for each cited project), or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

Rebuttable Presumption that Financially Interested Individuals May Not Conduct Human Subjects Research. This policy establishes the presumption that, in the absence of compelling circumstances, a financially interested individual may not conduct human subject's research. This presumption should be rebuttable when compelling circumstances exist.

a. This policy allows the COI Committee, after it reviews the relevant facts and circumstances and documents the compelling circumstances, to recommend that a financially interested individual be permitted to conduct the research, and to make recommendations for appropriate monitoring and oversight.

b. A summary report indicating the nature and amount of the financial interest and COI Committee recommendations shall be transmitted to the Covenant Health IRB and to responsible institutional officials.

Monitoring. Procedures for internal, and, when deemed necessary, external monitoring when a financially interested individual is permitted to conduct human subjects research, include (but are not limited to):

a. The Research Administrator and the IRB Administrator will conduct audits of billing records and research records every 6 months and report summary findings to the COI Committee and to the IRB at time of continuing review.

Continuing Review of Studies. When an industry sponsored research proposal is submitted to the Covenant Health IRB for continuing review, each covered individual who will conduct the research shall submit the COI Questionnaire to the Covenant Health IRB with the continuing review form. The IRB Administrator will report the ongoing status of the continuing review process to the COI Administrator prior to IRB review. The Covenant Health IRB shall forward any information that it receives concerning a significant financial interest in human subject's research to the COI Committee. The COI Committee will make a determination regarding the status of the research and will forward that information to the IRB prior to the IRB meeting.

Disclosure of Significant Financial Interests.

a. This policy shall require disclosure of the existence of significant financial interests in human subjects research as follows: to federal agencies when applicable, as required by statute or regulation; to research funders or sponsors; to the editors of any publication to which a covered individual submits a manuscript concerning the research;[1] and in any substantive public communication of the research results, whether oral or written.

b. Research consent forms should, as a matter of Covenant Health's COI policy, disclose the existence of any significant financial interest held by a covered individual who is conducting the human subject's research. The precise wording of disclosure in the consent form will be determined by the Covenant Health IRB.

Prohibition on Payments for Results. This policy prohibits payments from Covenant Health or the research sponsor to a covered individual, if such payments are conditioned upon a particular research result or are tied to successful research outcomes.

Process of Review and Non-Compliance. The investigator must agree in writing to follow the mitigation plan outlined by the COI Committee. The IRB Administrator and Research Administrator will conduct audits every 6 months for compliance with the research plan. Findings will be reported to the IRB and COI Committee if not in compliance with the mitigation plan. Information will be reported to the COI Committee for review to determine if the research can continue.

REGUALTIONS ADDRESSED:

42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought

45 CFR 94, Section 94.4 Institutional Responsibility Regarding Conflicting Interest of Investigators

National Institutes of Health Grants Policy Statement, Part II: Terms and Conditions of NIH Grant Awards

45 CFR 46 (HHS regulations governing IRB members and investigators)

21 CFR 54 (FDA regulations governing Financial Disclosures by Investigators)

21 CFR 56 (FDA regulations governing IRBs)

Treas. Reg. § 53.4958-4(b)(1)(ii)