EASTERN CONNECTICUT HEALTH NETWORK

Institutional Review Committee

Conflict of Interest Policy

IRC MEMBERS AND PRINCIPAL INVESTIGATORS

SECTION 1. Purpose of Policy on Conflict of Interest.

Real, potential and apparent conflicts of interest ("Conflict(s)") occur from time to time in the course of conducting the affairs of the Institutional Review Committee ("IRC") of Eastern Connecticut Health Network ("ECHN"). The purpose of this policy is to provide guidelines to the IRC for addressing Conflicts in a manner that will allow it to fulfill its responsibility of safeguarding the rights and welfare of the persons participating in research projects ("Research Subjects") within ECHN.

1.1. Definitions.

(a) An "Interested Person" includes an IRC member, a principal investigator ("PI") or immediate family of such IRC member or PI. Immediate family includes spouse and dependent children.

(b) "Conflict(s)" exist under this policy when an Interested Person has a Significant Financial Interest (as defined below), or any other professional or personal relationship (a "Relationship"), which may make it difficult for the Interested Person to exercise independent judgment in safeguarding the rights and welfare of Research Subjects. More specifically, Conflict(s) exist under this policy when an "Interested Person" has a direct or indirect Significant Financial Interest (as defined below) in:

(i) the sponsor of any research project which the IRC is reviewing;

(ii) the provider of any product being investigated through any research project which the IRC is reviewing;

(iii) other entities whose financial interests would reasonably appear to be affected by the outcome of any research which the IRC is reviewing.

For purposes of this policy, the IRC's review includes all aspects of review, including but not limited to the review of new protocols, renewal requests, adverse event reports, and similar reports.

(c) "Significant Financial Interest" means anything of monetary value, including, but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and

intellectual property rights (eg., patents, copyrights and royalties from such rights). The term does not include:

1) salary, royalties, or other remuneration from the Eastern Connecticut Health Network;

2) income from seminars, lectures, or teaching engagements sponsored by public or non profit entities;

3) income from service on advisory committees or review panels for public or non-profit entities;

4) An equity interest (eg., stocks, stock options, or other ownership interests, but excluding any interest arising solely by reason of investment in a business by a mutual fund, pension, or other institutional investment fund over which the "Interested Person" does not exercise control) that when aggregated for the PI or IRC Member and his/her immediate family meets both the following tests: Does not exceed $10,000.00 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity.

5) Salary, royalties or other payments that when aggregated for the PI or IRC Member and his/her immediate family are not expected to exceed $10,000.00 over a 12 month period. Salary, royalties or other payments that when aggregated for the PI or IRC Member and his/her immediate family that are expected to equal or exceed $10,000.00 over a 12 month period must be disclosed. (For the purposes of calculating such payments, any payments made to the PI or IRC Member as reimbursement for administrative expenses that the PI or IRC Member incurred in conjunction with conducting the clinical study may be excluded).

SECTION 2. Policy Statement.

As a consequence of the potential for Conflicts to arise and the significance of Conflicts, ECHN's affirmative policy shall be to require that (a) all direct and indirect Relationships which may pose a potential Conflict be disclosed promptly and fully to all necessary parties, and (b) all direct and indirect Significant Financial Interests be disclosed promptly and fully to all necessary parties including, but not limited to, the IRC Chairperson. It shall also be ECHN's affirmative policy to prohibit involvement, except as set forth in this policy, in the IRC's review of the specific research project forming the basis of the Conflict by persons having such a Conflict.

SECTION 3. Implementation of Policy.

IRC members and PIs shall complete the annual disclosure questionnaire as required in Section 4 of this policy. IRC members and PIs shall also disclose all current Conflicts to IRC members at meetings of the IRC. An IRC member shall not participate in the IRC's review of any research project in relation to which the IRC member has a Conflict, except to provide information requested by the IRC, if any.

3.1. IRC Disclosure Required.

Each Relationship or Significant Financial Interest must be presented to the Chairperson of the IRC and to a designated representative(s) of the ECHN IRC Administrative Office for review. This shall be done by completing and/or updating the questionnaire. The Chairperson of the IRC and the representative(s) of the IRC Administrative Office shall determine whether a Conflict exists or can reasonably be construed to exist.

If a Conflict is deemed to exist, the following procedures shall be followed:

(i) The disclosing person shall make a prompt, full, and frank disclosure of his/her Conflict to the IRC prior to its action on the research project forming the basis of the Conflict;

(ii) An IRC member shall not participate in the IRC's review of any research project in relation to which the IRC member has a Conflict, except to provide information requested by the IRC, if any. Specifically, the IRC member shall not participate in discussions and/or votes relating to the research project forming the basis for the Conflict;

(iii) The IRC shall determine any action to be taken on the research project in question by a vote of the non-interested members present;

(iv) The IRC shall take appropriate disciplinary action against any IRC member who violates this policy to protect ECHN's best interests; and

(v) The minutes of all IRC meetings involving Conflicts shall include the names of the persons who disclosed the existence of a Conflict. In addition, the minutes shall set forth the names of the persons who were present for discussions and/or votes relating to the research project forming the basis of the Conflict; the content of those discussions; and a record of the vote.

(vi) The IRC shall maintain records of all financial disclosures, the completed Conflict of Interest Questionnaire and a record of all actions taken by the IRC or ECHN with respect to conflicting interests, for no less than three (3) years from the date of submission of such information or the date such action was taken, respectively.

3.2. Direct or Indirect Involvement Prohibited.

IRC members and PIs are prohibited from being directly or indirectly involved in any research project where a Conflict exists. This includes discussions with other IRC members regarding the research study and voting. This section shall not be construed to prohibit IRC members who are also principal investigators with regard to a particular study from presenting such study to the IRC and interacting with the IRC as required for the protection of Research Subjects.

Any other exceptions to this Section 3.2 may be made on a case-by-case basis only by the IRC.

SECTION 4. Annual Disclosure.

Each year, the ECHN IRC Chairperson and designated representative of the ECHN Administrative Office shall prepare and submit a Conflict of Interest Questionnaire to all PIs and IRC members. Each person who receives a questionnaire shall submit the completed questionnaire to the IRC Chairperson or Administrative Office for review by the IRC Chairperson and the designated representative of the ECHN Administrative Office. The IRC Chairperson and designated representative of the ECHN Administrative Office shall determine which issues and situations constitute a Conflict for any particular IRC member or PI. If, after the submission of a completed questionnaire, an IRC member or PI learns of additional information responsive to the questionnaire or otherwise experiences a new or additional conflict not already reported, such IRC member or PI must provide all information necessary to accurately update his/her responses on the questionnaire last submitted.

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Revised 02/04
Revised 04/04
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Revised 01/11

EASTERN CONNECTICUT HEALTH NETWORK

Conflict of Interest Questionnaire

On an annual basis, or more frequently if there is a change, every member of the Eastern Connecticut Health Network Institutional Review Committee (IRC) and the Principal Investigators (PIs) shall submit a completed Conflict of Interest Questionnaire to the IRC Chairperson. These requirements are pursuant to the Eastern Connecticut Health Network Institutional Review Committee Members Policy on Conflicts of Interest.

For the purposes of this questionnaire, Conflict(s) exist under this policy when an IRC member or PI has a "Significant Financial Interest", or any other professional or personal relationship (a "Relationship") which may make it difficult for the IRC member or PI to exercise independent judgment in safeguarding the rights and welfare of Research Subjects. More specifically, Conflict(s) exist under this policy when an IRC member, PI or his/her immediate family (spouse and dependent children) have a direct or indirect "Significant Financial Interest" in: (i) the sponsor of any research project which the IRC is reviewing; (ii) the provider of any product being investigated through any research project which the IRC is reviewing; (iii) other entities (e.g. biotechnology, medical device, pharmaceutical) whose financial interests would reasonably appear to be affected by the outcome of any research which the IRC is reviewing; (iv) "Significant Financial Interest" also includes intellectual property rights (e.g. patents, copyrights, and royalties from such rights). Please refer to the attached ECHN Conflict of Interest Policy for complete details.

For the purpose of this disclosure, IRC review includes all aspects of review, including but not limited to the review of new protocols, renewal requests, adverse event reports and similar reports.

Financial Interest Disclosure - *Based on the attached Conflict of Interest Policy, answer the following questions*:

1. I, or my immediate family, own interest in a publicly traded company (excluding any interest arising solely by reason of investment in a business by a mutual fund, pension, or other institutional investment over which I, or my immediate family, does not exercise control), as a result of which there may be a potential Conflict.

   ☐ No

   ☐ Yes – Please Specify:

   _____

   _____

   _____

2. I, or an immediate member of my family, own interest in a non-publicly traded company, as a result of which there may be a potential Conflict.

☐ No

☐ Yes – Please Specify:

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3. I, or an immediate member of my family, hold a position as employee, director, officer, partner or any other position of management, as a result of which there may be a potential Conflict.

☐ No

☐ Yes – Please Specify:

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4. I, or an immediate member of my family, have or will receive income (e.g. consulting, salary) from a person or entity, as a result of which there may be a potential Conflict.

☐ No

☐ Yes – Please Specify:

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5. I, or an immediate member of my family, have received or anticipate receiving a loan from a person or entity, as a result of which there may be a potential Conflict.

☐ No

☐ Yes – Please Specify:

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6. I, or an immediate member of my family, have received or anticipate receiving gifts from a person or entity, as a result of which there may be a potential Conflict.

☐ No

☐ Yes – Please Specify:

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7. I, or an immediate member of my family, has a personal or professional relationship with an individual or entity, as a result of which there may be a potential Conflict.

☐ No

☐ Yes – Please Specify:

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8. I, or an immediate member of my family, currently have or have submitted an application to acquire intellectual property rights for a product (please specify below), as a result of which there may be a potential Conflict.

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B. Certification

I certify that I have read, understand and will comply with the Eastern Connecticut Health Network Institutional Review Committee Conflict of Interest Policy.

Dated: _____

By:_____
(Signature)

_____

(Print Name)