RESEARCH CONFLICTS OF INTEREST (RCOI) POLICY

ASSUMPTIONS:

1. The vast majority of investigators are honest and conduct their research with the highest standards and integrity; and
2. For the vast majority of cases, self-regulating structures and processes in science are effective.

APPLICABLE LAW:

This policy supplements applicable law and does not replace it. At all times, applicable law supersedes any conflicting provisions of the policy.

POLICY:

To identify, evaluate, and as appropriate, manage potential conflicts of interests, financial or otherwise, in conducting human subject and animal research, in order to protect human subjects, animals, integrity, and objectivity in the Research conducted at any of the Barnabas Health facilities (BH FACILITY).

Relevant U.S. Food and Drug Administration (FDA) Regulations are available at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=54

Relevant FDA Guidance is available at:
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm

Relevant U.S. Department of Health and Human Services (HHS) Guidance is available at:
http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf
42 C.F.R. Part 50, Subpart F and
45 C.F.R. Part 94
76 Fed. Reg. 53256

Relevant National Science Foundation (NSF) Guidance is available at:
http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510

FINANCIAL INTEREST (FI):

A Covered Person is considered to have a financial interest when he/she, or any of his/her Family Members, has any financial relationships with the developers or manufacturers of Test Articles as well as with the competitors of developers or manufacturers of Test Articles. A Test Article is defined as *"any drug, medical device, biologic (naturally occurring or recombinant), chemical (organic or inorganic), food additive, color additive, electronic product, or any other article subject to regulation by the FDA investigated or tested for any purpose whatsoever in a Research Study."* Family

Member is defined as a "*spouse, domestic partner, parent, sibling, grandparent, child, grandchild, or great grandchild if any of the following apply: (a) the individual lives in research team members household, (b) the research team member manages the financial affairs of the individual, or (c) the research team member is aware without special inquiry that the family member holds a particular interest.*"

A **Conflict of Interest** (COI) is an Interest (as defined below) that is related to the Research and could directly and significantly affect the design, conduct, or reporting of funded research as determined by the Research Conflicts of Interest Committee (RCOIC) and confirmed by the Senior Research Administrator (SRA).

Types of Interests (Interest):

1. Monetary Interest
    a. **Individual Interest** arise from financial interest held personally by an individual or his/her Family Members in or with an outside entity or individual.
    b. **Institutional Interest** arises from financial interests held by the BH FACILITY itself, directly or indirectly, in or with an outside entity.
    c. **Imputed Interest** arise from direct or indirect individual financial interest held by an institutional official (e.g. board member, executive officer, department director) at a BH FACILITY that are imputed to the facility because of the job responsibilities or decision-making authority the individual holds within the BH FACILITY.
2. Associational Interest
    a. **Individual Interest** arise from associational interest held personally by an individual or his/her Family Members in or with an outside entity or individual.
    b. **Institutional Interest** arises from associational interests held by the BH FACILITY itself, directly or indirectly, in or with an outside entity.
    c. **Imputed Interest** arise from direct or indirect individual associational interest held by an institutional official (e.g. board member, executive officer, department director) at a BH FACILITY that are imputed to the facility because of the job responsibilities or decision-making authority the individual holds within the BH FACILITY.

For purposes of Research funded under the Public Health Service of the U.S. Department of Health and Human Services (PHS) and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH), a **Significant Financial Interest (SFI)** is defined as set forth in 45 CFR 50.603 and 45 CFR 94.3.

For PHS funded Research, a **Financial Conflict of Interest (FCOI)** means a SFI that is as determined by the Research Conflicts of Interest Committee (RCOIC) related to PHS funded Research and could directly and significantly affect the design, conduct, or reporting of funded research as determined by the RCOIC and confirmed by the Senior

Research Administrator (SRA). If it is a FCOI in a PHS funded study, then **Appendix D** shall also apply.

APPLIES TO:

This policy applies to any human subject or animal research including, but not limited to, clinical trials, registries and retrospective data evaluations conducted at or involving any BH FACILITY ("Research"). Each person whose responsibilities to a BH Facility (herein, "Institutional Responsibilities") involved participation in the conduct of such Research or evaluation of Research, including but not limited to, Signatory Officials named in PHS funded grant applications, serving on any BH Institutional Review Committees and Investigators as defined under 45 CFR 50.603 and 45 CFR 94.3, and each Institutional Review Board (IRB) member, must abide by this policy ("Covered Persons").

DISCLOSURE OF POLICY:

The policy must be disclosed annually to Covered Persons and posted on the Barnabas Health website beginning August 24, 2012. Covered Persons must review the policy and any updates to the policy.

TRAINING:

The Facility, in its sole discretion, will determine whether any training on this Policy is necessary. However, any Covered Persons involved in any Research relating to any PHS funded grant received on or after August 24, 2012, shall, prior to engaging in such research (i.e. when Notice of Award obtained), or those already under a Notice of Award on or before the next IRB continuing review or December 31, 2012, whichever is sooner, complete training as set forth in **Appendix D** attached hereto and incorporated herein.

PROCESS:

A. The individual Barnabas Health FACILITY Institutional Review Board ("IRB") and /or Institutional Research Committee ("IRC") shall require each Investigator, where applicable, to complete a Protocol Specific Financial Interest Disclosure Form, attached hereto as **Appendix A,** with the research team's submission of any research protocol to the IRB or no later than the time of the application for PHS funded research. For all new research protocols, the IRB shall not fully approve the research protocol submitted until the IRB receives a determination of the conflicts of interest review from the SRA or RCOIC, as defined below. For any continuing review of existing protocols, the IRB shall make its approval contingent upon receiving a determination of the conflicts of interest review from the SRA or RCOIC, as defined below. All information collected must be kept confidential, except as necessary to implement this Policy or as otherwise required by applicable law.

B. In addition, each Barnabas Health FACILITY shall require each Covered Person, including without limitations IRB members, to complete, on an annual basis, an Annual Conflicts of Interest Disclosure Form, attached hereto as **Appendix B**. The IRB shall collect all completed Annual Conflicts of Interest Disclosure Forms. All information collected must be kept confidential, except as necessary to implement this Policy or as otherwise required by applicable law.

C. Additional updates to these disclosure forms must be submitted to the Barnabas Health FACILITY IRB within thirty (30) days following any change in the information disclosed.

D. Each IRB shall send completed disclosure forms and any updates to the SRA or his/her designee at the Barnabas Health Facility.

E. The SRA of the Barnabas Health Facility where the Research will be conducted (and SRA of the Barnabas Health Facility involved in the Research) shall review Disclosure Forms and maintain data regarding each research team member's disclosure.

F. The SRA shall send any completed conflicts of interest disclosure forms that require further review, including any Significant Financial Interests as defined in 45 CFR 50.603 or 45 CFR 94.3 in accordance with the guidelines set forth in **Appendix D** attached hereto and incorporated herein, to the Chair of the RCOIC with a copy to the Senior Vice President of Legal Affairs or his/her designee at BH Corporate Legal Affairs. The RCOIC has been created and operates in accordance with RCOIC policy, attached hereto as **Appendix C**.

G. The RCOIC shall review and evaluate any potential conflicts of interest as the SRA relates to the RCOIC.

For PHS Funded Research: To the extent a Financial Interest is a SFI, the RCOIC will make one of the following determinations.

Is the SFI related to PHS funded research study?

A. If Yes, is it a FCOI?

(i) If Yes, then the RCOIC shall determine one of the following options:

a. **Manageable Conflict:** The RCOIC shall prepare a plan to manage the conflict and require that the research team follow the management plan. If the plan is not followed, the research study cannot proceed. The BH FACILITY

IRB and SRA will monitor adherence to the management plan.

b. **Non-Manageable Conflict:** The RCOIC shall recommend that the research team member divests the interest, or that the research study not proceed. The RCOIC shall communicate its findings in writing to Covered Persons and BH FACILITY IRB, and provide Covered Persons an opportunity to respond.

(ii) If not an FCOI, then the RCOIC shall determine there is no conflict under this policy.

B. If the SFI is not related, then there is no conflict under this policy.

For non-PHS funded research: The RCOIC will determine whether there is a COI:

(i) If yes, then the RCOIC will need to determine whether the COI is either:

a. **Manageable Conflict:** The RCOIC shall prepare a plan to manage the conflict and require that the research team follow the management plan. If the plan is not followed, the research study cannot proceed. The BH FACILITY IRB and SRA will monitor adherence to the management plan.

b. **Non-Manageable Conflict:** The RCOIC shall recommend that the research team member divests the interest, or that the research study not proceed.

The RCOIC shall communicate its findings in writing to Covered Persons and BH FACILITY IRB and SRA, and provide Covered Persons an opportunity to respond.

(ii) If no COI, then no conflict under this policy.

H. The RCOIC shall, as part of its evaluation, may reach out to the Covered Person to obtain information about any Financial Interests reported in its analysis of any COI/ FCOI in accordance with guidelines set forth herein and in **Appendix C**. The Chair of the RCOIC shall communicate its findings to the Covered Person. The Chair of the RCOIC shall also communicate its determination to the Chair of the IRB, the SRA, and the Chair of the BH

Research Committee. The RCOIC Chair shall inquire with the IRB of any individual referred to RCOIC who is already under a management plan, regarding adherence with the management plan.

I. After the RCOIC renders a decision, where the Covered Persons and/or other sources submit any response and RCOIC's review of such responses does not alter RCOIC's position and RCOI so advised Covered Person, Covered Person may appeal to the Barnabas Health Research Committee.
J. The Barnabas Health Research Committee shall review and evaluate the appeal within thirty (30) days. As part of its evaluation, the Barnabas Health Research Committee shall provide written notice and an opportunity for Covered Persons to address the BH Research Committee about the findings before a determination is made.
K. After Covered Persons have addressed the BH Research Committee, the BH Research Committee shall render a decision within five (5) business days. The BH Research Committee shall communicate its determination to the Covered Persons, and notify the RCOIC, BH facility IRB Chair, and SRA.
L. The Barnabas Health Research Committee's decision shall be final.
M. In the event that a Covered Person does not comply with this RCOI Policy, they may be subject to sanctions and/or disciplinary action including, but not limited, to termination of participating in any research activity.

REPORTING

If no FCOI exists for PHS funded Research, then no FCOI report is required. If there is a FCOI for PHS funded Research, then the Facility shall make disclosure of the FCOI to study subjects, publications, and other interested parties, if applicable, as determined by the RCOIC and as set forth in **Appendix D** attached hereto and incorporated herein.

APPENDIX A

FINANCIAL INTEREST DISCLOSURE FORM (PROTOCOL SPECIFIC)

Name: _____

Check one: Principal Investigator _____ Co-investigator _____ Coordinator _____ Other _____

If Other, Please Specify _____

Department: _____

Proposed Study:

Sponsor: _____
_____
_____

Test Article:_____
_____
_____

Description of Study: _____
_____
_____

Any Public Health Services (PHS) funding for the Study (i.e. funding by the NIH, NCI, CDC, HRSA)? If so, who is funding? _____

On behalf of myself and for my Family Members (as defined below), I am disclosing the following financial interests in the _____ (Sponsor Company) and/ or proposed study that may represent, or be perceived to represent, a conflict with respect to outcomes of the proposed study. (Statement must include interests of Family Members)

You should consider your current business and personal relationships and those within the preceding 24 months, including your affiliations with Barnabas Health, in completing this Conflict of Interest Disclosure form.

For purposes of this Disclosure Form:

A **Test Article** is defined as *"any drug, medical device, biologic (naturally occurring or recombinant), chemical (organic or inorganic), food additive, color additive, electronic product, or any other article subject to regulation by the FDA investigated or tested for any purpose whatsoever in a Research Study."*

A **Family Member** is defined as "*spouse, domestic partner, parent, sibling, grandparent, child, grandchild, or great grandchild if any of the following apply: (a) the individual lives in your household, (b) you manage the financial affairs of the individual, or (c) you are aware without special inquiry that the family member holds a particular interest about which this Disclosure Form inquires."*

Please check one:

I. Either I or a Family Member:

Yes	**No**	
___	___	Will, expect to, or have received compensation for participation in the study
___	___	Will, expect to, or have received gifts, consulting fees or honoraria from the study sponsor. If yes, what is the amount? _____
___	___	Will, expect to, or have equity interests that may have value (e.g. stocks, stock options or other ownership interests) from the Sponsor. If yes, what is the amount of equity interest? _____
___	___	Will, expect to, or have proprietary interests in the tested product (e.g. trademarks, licensing or patents)
___	___	Will, expect to, or received payments/ compensation including grants or support of other research conducted by the investigator or the investigator's institution
___	___	Have financial interest in the involved contract research organization, if applicable
___	___	Will, expect to or have other financial interest that could possibly affect, or be perceived to affect, results of the clinical trial
___	___	Have financial interests in the sponsor's company

II. In addition, to the best of my knowledge, I and/or any Family Member:

Yes	No	
___	___	Was involved in the development of a product that directly competes with the Test Article.
____	___	Hold any equity interest in the manufacturer of a product that directly competes with the Test Article.
____	____	Have an uncompensated relationship with the manufacturer of a product that directly competes with the Test Article, for example sitting on a scientific advisory board or a board of directors without pay.
____	____	Have any other relationship to the inventor and/or manufacturer of a product that directly competes with the Test Article.
____	____	Have other relationships which may create any conflict of interest.

If you answered "yes" to any of the questions above, please explain in detail below. Please use additional paper, as necessary, to provide a complete response:

_____

_____

_____

_____

III. For any PHS funded research, please provide the following information for all travel (including any scheduled travel within the next twelve (12) months):

Who paid for or sponsored your travel: _____

Dates of travel: _____

Destination (please specify location, including hotel):_____

Purpose of the trip:_____

Sponsor/organizer of the event: _____

Duration of event: _____

Please use additional paper, if necessary.

I understand that I must update this disclosure during the period of the study, either on an annual basis or as new reportable significant financial interests are obtained.

_____ _____

Signed Date

Name (Please print):_____

Medical Center/ Department:_____

APPENDIX B

ANNUAL RESEARCH CONFLICTS OF INTEREST DISCLOSURE FORM

This Individual Research Conflicts of Interest Disclosure Form must be submitted annually by January 1st of each fiscal year to the Institutional Review Board by all research team members, and other personnel, including Institutional Review Board (IRB) members involved in any research study.

The disclosures reference yours and your Family Members' financial and associational relationships with the developers or manufacturers of test articles as well as with the competitors of developers or manufacturers of test articles.

For purposes of this Disclosure Form:

A **Test Article** is defined as *"any drug, medical device, biologic (naturally occurring or recombinant), chemical (organic or inorganic), food additive, color additive, electronic product, or any other article subject to regulation by the FDA investigated or tested for any purpose whatsoever in a Research Study."*

A **Family Member** is defined as "*spouse, domestic partner, parent, sibling, grandparent, child, grandchild, or great grandchild if any of the following apply: (a) the individual lives in your household, (b) you manage the financial affairs of the individual, or (c) you are aware without special inquiry that the family member holds a particular interest about which this Disclosure Form inquires."*

Please use additional paper as necessary to provide responses below.

YOUR ROLE

1. For any Research in which you are involved, do you serve as a (check all that may apply):

   ☐Principal Investigator
   ☐Co-Investigator
   ☐Sub-Investigator
   ☐Research Coordinator
   ☐ IRB Member
   ☐ IRC Member
   ☐BH Corporate Research Committee Member
   ☐BH Corporate Nursing Research Council Member
   ☐Other (please specify: _____)

YOUR RELATIONSHIP WITH DEVELOPERS OR MANUFACTURERS OF TEST ARTICLES

2. What activities do you perform within Barnabas Health (please check all that may apply):

   ☐ Clinical research
   ☐ Teaching
   ☐Attending physician
   ☐Medical Director
   ☐Department Chair
   ☐ Barnabas Health Committee memberships (please list)

   _____

   _____

   _____

   ☐Other (please specify: _____)

3. Are/were you involved in the development of any Test Articles?
   ☐Yes ☐No (If NO, go to #4)

   If yes, what are/were the involvements?

   _____
   _____

   For what Study (ies)?
   _____

   _____

   If yes, what is the generic and trade names of each Test Article?
   _____
   _____

   For each Test Article, is the Test Article a:
   ☐Drug
   ☐Device
   ☐Biologic
   ☐Other (specify):
   _____

Who manufactures the Test Article? _____
_____
_____
_____
_____
_____

4. Do you or a Family Member hold a direct equity interest in the developer/manufacturer of a Test Article?

☐Yes☐No (If NO, go to #5)
If yes, what is the amount of the equity interest?
_____
If yes, what is the nature of the equity interest? For example, is it in the form of a mutual fund? Blind trust? Individually traded? Stocks? Options? Other ownership interest?
_____
_____
_____
_____
_____
_____

5. Do you or a Family Member receive compensation from the developer/manufacturer of a Test Article?

☐Yes☐No (If NO, go to #6)

If yes, what is the amount of the compensation? _____
_____
_____

If yes, what is the amount and reason for the compensation? For example, are you a paid speaker for the developer/manufacturer? Do you sit on a scientific advisory board? Are you a consultant? Do you receive any honoraria? Paid authorship?
_____
_____
_____
_____
_____
_____

6. Do you or a Family Member have an uncompensated relationship with the developer/manufacturer of a Test Article (for example sitting on a scientific advisory board or a board of directors without pay, intellectual property rights, patents, copyrights)?

☐Yes☐No (If NO, go to #7)
If yes, what is the nature of the uncompensated relationship:
_____
_____
_____
_____

7. Do you or a Family Member have any other relationship to an inventor or manufacturer of a Test Article?
☐Yes☐No
If yes, please explain.
_____
_____
_____
_____
_____
_____
_____

8. Please list all the Research Studies in which you are currently involved (please include
IRB #).

_____
_____

9. If any Research Studies listed above are funded by the Public Health Service (PHS) of the U.S. Department of Health and Human Services, including studies funded by the NIH or COG, then please answer the requested information below; otherwise, please skip to Question 10.

Are you engaged in any travel that is reimbursed or sponsored relating to your any of your responsibilities set forth in questions 1 and 2 above within the preceding twelve (12) months or planned travel within the next twelve (12) months? If No, please skip to Question 10. If Yes, for each such travel, please provide the following (if you have additional disclosures, please use separate paper and attach):

Who paid for or sponsored your travel: _____

Dates of travel: _____

Destination (please specify location, including hotel):_____

Purpose of the trip: _____

Sponsor/organizer of the event:_____

Duration of event: _____

10. If applicable, the Financial Interest Disclosure Forms that you completed with the Institutional Review Board at the commencement of any Research Study are attached. Are there any changes to these forms?

☐Yes☐No ☐ Not Applicable
If yes, please describe and submit a revised Financial Disclosure Form for such Research Study (please use additional paper, as necessary):
_____
_____
_____
_____
_____
_____

I agree that, to the best of my knowledge, the information stated above is true and in the event there is any change in such information, I agree to immediately complete an updated disclosure form to inform the IRB.

By (Signature):_____ Date: _____

Name (print):
_____

Facility/Department:_____

Telephone: _____ Fax: _____

E-mail: _____

APPENDIX C

RESEARCH CONFLICTS OF INTEREST COMMITTEE- CREATION, GOVERNANCE, DUTIES AND FUNCTIONS

A. Creation

I. Formation

a. The RCOIC shall at all times have a Chair and one BH representative from each facility where Research is conducted.
b. At no time may any RCOIC member:
    i. Have a duty to any BH FACILITY that would compromise, or appear to compromise, his/her exercise of independent judgment.
    ii. Have any personal interest in any arrangement under review by the RCOIC (e.g., equity in an industry sponsor or funder of proposed research).
    iii. Be related to or under the control of the persons involved in the arrangement being evaluated.
    iv. Be a member of the any BH FACILITY IRB.
    v. Be an officer of BH FACILITY responsible for investment or significant purchasing decisions.
c. The Chair of the RCOIC shall be appointed by the BH Research Committee, by simple majority vote.
d. Each BH Facility Representative shall be appointed by the President and Chief Executive Officer at such BH FACILITY.
e. Each member shall serve a term of three (3) years, with the exception of the initial RCOIC, in which some BH facility representatives shall serve a staggered term.

Each RCOIC member may be reappointed to one additional three-year term.

II. Removals and Vacancies

a. Resignation: RCOIC members shall give thirty (30) days prior written notice of their intention to discontinue their RCOIC membership. However, a RCOIC member will be deemed to have resigned at the suspension/revocation of their privileges at any BH Facility. RCOIC members serve at the pleasure of the BH Facility President and Chief Executive Officer and may be terminated at any time from serving as an RCOIC member.
b. Termination. The President and Chief Executive Officer may terminate and remove the RCOIC member at any time, with or without cause, including without limitation, for failure to comply with the provisions of

the Conflicts of Interest policy. The termination is final and not subject to appeal.

c. Appointment of an interim replacement. If a RCOIC member resigns, dies, terminates their relationship with BH, or is removed prior to the completion of his/her term (the "departing member"), the RCOIC Chair shall inform the RCOIC member's President and Chief Executive Officer. The President and Chief Executive Officer or his/her designee shall appoint another member to serve as a replacement member (the "Interim Member"). The Interim Member shall possess the same professional capacity of the departing member. The Interim Member shall serve on the RCOIC for the remainder of the departing member's term.

III. Compensation

The RCOIC members shall not receive compensation for their services as members of the RCOIC. However, they shall be reimbursed for reasonable expenses incurred in connection with their service as RCOIC members.

IV. Quorum and Voting

1. The RCOIC shall hold all meetings at the BH corporate offices or over the phone, or other electronic media, in a scheduled conference call/ meeting, unless the Chair of the RCOIC selects a different location.
2. The RCOIC shall meet in person or telephonically as frequently as members deem appropriate to carry out its duties and responsibilities. The RCOIC shall meet on at least a quarterly basis.
3. The presence in person or by conference telephone of a simple majority of the members of the RCOIC constitutes a quorum at any meeting of the RCOIC. Whenever a quorum is not present, the RCOIC Chair shall adjourn the meeting until a quorum can be convened, at which time any matters may be addressed which might have been addressed at the meeting originally called.
4. Each RCOIC Member, including the Chair, is entitled to one (1) vote at any meeting at which the member is present in person or by conference telephone. Proxy voting is not permitted. The act of the majority of the members of the RCOIC present at the meeting at which a quorum is present, and not otherwise disqualified from voting (i.e. because of a Conflict of Interest), will be considered the act of the RCOIC.
5. In the event an urgent or emergent COI review is requested, a subcommittee of the RCOIC consisting of at least three members of the RCOIC may review and evaluate the conflict of interest forms and render a decision (E-RCOIC)

V. Reporting by RCOIC

The Chair of the RCOIC or his/her designee shall periodically report on its activities to the BH Research Committee and CHAIR of the BH FACILITY IRB or his/her designee. Such reporting shall include distribution of a written report and an oral presentation by the RCOIC Chair.

B. Governance

The RCOIC shall serve as the representative of the BH Research Committee in ensuring the objectivity of research conducted at each BH FACILITY.

C. Functions

1. The RCOIC shall review any potential conflicts of interest matters referred to it by the SRA at any BH Facility, or his/her designee, and ultimately report to the BH Research Committee and the Chair of the BH Facility IRB, or his/her designee, pursuant to the COI Research Policy.
2. The RCOIC shall rely on this Conflicts of Interest policy, rules, regulations, guidelines to render its determination.
3. The RCOIC shall maintain written records of its meeting minutes, list of members with their term, votes, recommendations and actions. The records should be retained for the longer of three (3) years, or as consistent with the BH FACILITY record retention policy, or pursuant to applicable law.
4. The RCOIC shall review and evaluate any potential conflicts of interest within thirty (30) days after receiving all relevant information to evaluate any interest and its relationship to the Research. The review may consist of the RCOIC, in its sole discretion, reviewing any resources, requesting more information from the Covered Person or any other individual at a BH Facility familiar with the Covered Person and Covered Person's responsibilities at the Facility to evaluate their disclosure(s).
5. The RCOIC shall communicate its determination in writing signed by the RCOIC Chair to the Covered Persons. If the determination is that a conflict exists, then the RCOIC shall set forth the rationale for its determination and any means to mitigate the conflict and provide thirty (30) days for the Covered Persons to respond.
6. To the extent a conflict is manageable; the RCOIC shall develop and request that the Covered Person agree to a management plan. The RCOIC must oversee and monitor conflict under the management plan and maintain a written record of same.
7. The RCOIC shall review any response and to the extent the RCOIC maintains its denial, then the RCOIC shall automatically refer the matter, along with all documentation received from the Covered Persons to the Chair of the BH Research Committee ("SRC") for review.

APPENDIX D

ADDITIONAL REQUIRMENTS FOR THOSE INVOLVED IN RESEARCH FUNDED BY PUBLIC HEALTH SERVICES (PHS)

I. TRAINING

Each Covered Person shall complete training regarding this Research Conflict of Interest (RCOI) Policy, including the Conflicts of Interest regulations prior to engaging in research related to any Public Health Service (PHS)-funded grant awarded on or after August 24, 2012 and at least every four (4) years, and immediately when any of the following circumstances apply:

(1) This Policy changes in any manner that affects the requirements of Covered Persons;

(2) A Covered Person is new to the Barnabas Health system; or

(3) The Facility finds that a Covered Person is not in compliance with this Policy or management plan (if any).

The BH Facility will provide notice of these trainings on its website or through the BH Research Committee.

II. SUBAWARDS.

When using subcontracts to carry out the PHS-funded research through a sub recipient (e.g., subcontractors or consortium members), the Facility affiliate (awardee institution) shall incorporate in the sub award written agreement with the sub recipient as to terms whether this Policy or that of the sub recipient will apply to the sub recipient's Covered Persons.

(i) If the sub recipient's Covered Persons must comply with the sub recipient's financial conflicts of interest policy, the sub recipient shall certify as part of the sub award agreement that its policy complies with 42 CFR Part 50 and 45 CFR part 94. If the sub recipient cannot provide such certification, the sub award agreement shall state that sub recipient Covered Persons are subject to this RCOI Policy for disclosing Significant Financial Interests that are directly related to the sub recipient's work for any Facility.

(ii) Additionally, if the sub recipient's Covered Persons must comply with the sub recipient's financial conflicts of interest policy, the sub award agreement shall specify time period(s) for the sub recipient to report all identified financial conflicts of interest to the Facility. Such time period(s) shall be sufficient to

enable the Facility to provide timely Financial Conflicts of Interest (FCOI) reports, as necessary, to the PHS as required by applicable law.

(iii) If the sub recipient's Covered Persons must comply with this Policy, the sub award agreement shall specify time period(s) for the sub recipient to submit all Covered Person disclosures of significant financial interests to the Facility. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.

III. ADDITIONAL DISCLOSURES

Covered Persons shall complete any additional disclosures requested on the Annual and Protocol Specific Disclosure forms applicable to any Covered Persons who will engage in Research through any PHS funded grants.

IV. REVIEWS

A. Prior to expenditure of funds under a PHS funded research project, each Covered Person shall abide by the Policy and complete a Protocol specific disclosure form as set forth in Appendix A and an annual disclosure form (if one has not been completed or needs to be revised) as set forth in Appendix B, if they have not already done so. Each Facility Senior Research Administrator (SRA) shall evaluate these disclosures in accordance with the Policy.

B. In the course of on-going PHS funded research project, any new Covered Person to the project shall complete the Protocol Specific Disclosure Form and Annual Disclosure Form (if one has not been completed or needs to be revised). The Facility through its SRA shall review, evaluate and determine within sixty (60) days whether the financial interest is a Significant Financial Interest (SFI). If so, then the SRA shall refer the matter to the Chair of the RCOIC for review and evaluation. The RCOIC shall have sixty (60) days to review and determine:
    - Whether the SFI is related to the PHS funded research
    - Whether a FCOI exists; if so, then the RCOIC shall put in; place an interim management plan and specifically state in the plan actions taken, and those that will be taken, to manage the conflict.

C. In the event a FCOI is identified after the expenditure of funds under a PHS funded research project, then the facility shall perform a retrospective review of the Covered Person's activities related to the PHS funded research project within one hundred and twenty (120) days of the Facility's determination of a FCOI that either the Covered Person failed to report, Facility failed to manage, or Covered Person's failure to comply with a management plan was already in place for such FCOI.

The RCOIC, as requested in writing by the SRA, shall review and evaluate whether the PHS funded research project was during the period of noncompliance either:

a. Biased in design;
b. Biased in conduct; or
c. Biased in the reporting of the research.

If yes, then the SRA shall document the retrospective review and maintain the following information:

1. Project number (IRB #)
2. Project title
3. Name of Principal Investigator (s)
4. Name of Covered Person(s) with the FCOI
5. Name of entity with which the Covered Person(s) has the FCOI
6. Reason(s) for the retrospective review
7. Details of the review, including review methodology, composition of the review panel, and documents reviewed
8. Findings of the review
9. Conclusions of the review.

If no, then no reporting required.

In the event bias is found, the SRA shall report to the PHS Awarding agency information as required under 42 CFR 50.605 (3)(iii) and 45 CFR 49.

V. REPORTING

The Facility will report any finding of FCOI to the PHS awarding agency and, upon written request by a member of the public, disclose the name and title of any Senior/ Key Personnel of the Facility within five (5) business days. A member of the public should contact the BH Facility as posted on the BH System website. For purposes of this Policy, "Senior/ Key Personnel" are the Principal Investigator or Program Director of a PHS funded project, and individuals identified as the senior/ key personnel on the PHS funded grant application, progress report or any other documentation submitted to the PHS by the Facility.

Any report of a FCOI to the PHS, as required under 42 CFR 50.605 and 45 CFR 49.5, shall contain the following information:

(i) Project number;

(ii) Name of Principal Investigator or Program Director;

(iii) Name of the Investigator with the financial conflict of interest;

(iv) Name of the entity with which the Investigator has a financial conflict of interest;

(v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

(vi) Value of the financial interest (dollar ranges are permissible as follows: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000–$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of the Facility's management plan, including:

(A) Role and principal duties of the conflicted Investigator in the research project;

(B) Conditions of the management plan;

(C) How the management plan is designed to safeguard objectivity in the research project;

(D) Confirmation of the Investigator's agreement to the management plan;

(E) How the management plan will be monitored to ensure Investigator compliance

Any report requested in writing by the public shall contain the following information:

- Name of the Investigator
- Title of the Investigator and role in research project
- Name of entity in which the SFI is held
- The nature of SFI
- The approximate range of the dollar value held as follows:
  - $0-$4,999
  - $5,000-$9,999
  - $10,000-$19,999
  - $20,000-$100,000 by increments of $20,000

- Amounts above $100,000 by increments of $50,000, or
- A statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

The information shall be subject to at least annual updates and within sixty (60) days of the Facility's finding of a new FCOI.

In accordance with the regulations, we will provide financial interest information that meets a specific standard and are a FCOI for those that we are required to disclose such information to a member of the public who makes a written requests for such information addressed to the contact set forth on the BH website.