NAME_____

Griffin Hospital Institutional Review Board
Human Subjects Research-Related
Conflict of Interest

I. POLICY

A. Introduction

All members of the Griffin Hospital research community need to be sensitive to the potential impacts of financial interests and/or non-financial relationships with commercial sponsors or other external entities on the conduct of research and the participation and protection of human research subjects. In compliance with recent federal guidelines as well as review of pertinent peer reviewed literature, the IRB at Griffin Hospital considers such relationships and determines whether they might influence or appear to influence the outcome of a research project involving human subjects, the objectivity of the investigator during the performance of such a project, or the investigator's interactions with research subjects who participate in the project. Accordingly, the IRB solicits and reviews relevant information regarding the financial interests of all investigators and key study personnel participating in a protocol involving human subjects prior to approving or re-approving that protocol.

B. Definitions

1) "***Key study personnel"*** means those persons involved in the design, conduct, and/or the data analysis of the research involving human subjects.

2) "***Financial interests"*** that may be considered to be conflicts include, but are not limited to, the following:
    a) Ownership of stocks, bonds, options, patent or royalty interests
    b) Receipt of consulting, honoraria or speaking fees
    c) Salary
    d) Subject accrual awards and/or penalties
    e) Loans
    f) Lectureships
    g) Memberships on boards of directors or scientific advisory boards
    h) Any of the above related to any close family members of the key study personnel

C The Role of the IRB

The IRB is the primary authority at Griffin Hospital responsible for ensuring that human research subjects are protected in accordance with federal regulations, hospital policies and ethical principles. One of the primary responsibilities of the IRB is to ensure that human subjects receive all information needed to enable the prospective subject to make an informed decision

concerning study participation. The IRB's consideration of investigator's financial interests is intended to ensure

1) that the informed consent process provides the subjects with all the facts necessary to make a knowledgeable and sound decision as to whether they wish to participate in the study, and
2) that no conflict exists that would otherwise compromise the protection of human subjects.

In the ***Human Subjects Research-Related Conflict of Interest*** review process conducted by the Griffin Hospital Institutional Review Board as part of its evaluation of a new or pre-existing protocol submitted for approval or reapproval respectively, the confidentiality of investigators and other key study personnel will be respected. Financial disclosure forms will be kept in confidential files and information will be shared only an extremely limited basis.

D. Instructions for Investigators and Key Study Personnel

1. For new protocols: For all new protocols submitted to the IRB, **each participating investigator and key study person** must read this ***Human Subjects Research-Related Conflict of Interest Policy*** and complete the questionnaire in the ***Conflict of Interest Disclosure*** section. **Each participating investigator and key study person** must sign the ***Griffin Hospital IRB Protocol for Research Involving Human Subjects*** form in the space noted for ***Conflict Of Interest***, date, and check "yes" or "no" as appropriate. A signature in this space indicates that you have read the ***Griffin Hospital IRB Human Research-Related Conflict of Interest Policy***, completed the questionnaire in the ***Conflict of Interest Disclosur****e* part of the form, and provided all documents needed to explain or support the responses to the questions posed in the questionnaire.

2. For re-approval of current protocols: For all applications submitted to the IRB for protocol reapproval (continuing review), each **participating investigator and key study person** must read this ***Human Subjects Research-Related Conflict of Interest Policy*** and complete the questionnaire in the ***Conflict of Interest Disclosure*** section. **Each participating investigator and key study person** must sign the ***Griffin Hospital IRB Request for Reapproval of a Protocol for Research Involving Human Subjects*** form in the space noted for ***Conflict Of Interest***, date, and check "yes" or "no" as appropriate. A signature in this space indicates that you have read the ***Griffin Hospital IRB Human Research-Related Conflict of Interest Policy***, completed the questionnaire in the ***Conflict of Interest Disclosur****e* part of the form, and provided all documents needed to explain or support the responses to the questions posed in the questionnaire.

E. IRB Process

Before the IRB meeting at which a new protocol or reapproval is scheduled for consideration, the IRB Chairman will review the questionnaire in the ***Protocol-Related Conflict of Interest Disclosure*** part of the ***Conflict of Interest*** form to determine if there are actual or potential conflicts of interest on the part of the investigator or key study person. The Chair will evaluate such conflicts and, if necessary, provide a summary to the full IRB Committee. The Committee will

0) discuss the degree to which such actual or potential conflicts may impact on the conduct of the research protocol with regards to the protection of human subjects, and

1) discuss what remedies will be recommended to the investigator in order to reduce or eliminate such actual or potential conflicts

F. Guidelines

The IRB considers certain relationships and behaviors on the part of an investigator or other key study person to either have the appearance of or actually constitute a conflict of interest. The IRB will review all disclosures related to potential or real conflicts of interest and determine whether or not these rise to the level of significance suggesting that these may impact on the ethical manner in which the research is to be conducted. The IRB will consider a failure to disclose the existence of a significant past or current relationship with a present study sponsor to be problematic. Questions regarding what constitutes 'significant' should be addressed to the Chairman of the IRB. Behaviors or relationships which would concern the IRB include but are not limited to

1. serving as an officer, director, or maintaining any official position, whether or not there is direct compensation, within the company sponsoring your research
2. being involved in research on a drug, device, or other product created or invented by you or by a member of your immediate family
3. owning equity shares in the company sponsoring your research valued at more than $10,000
4. purchasing any new equity shares in the company sponsoring your research during the time period in which the research is being planned, conducted, evaluated or at any time prior to the results of the research entering the public domain
5. providing lectures, talks, grand rounds, etc., on behalf of or at the request of the company sponsoring your research for which you are compensated more than $10,000 during any 12 month period during which the study is being planned, implemented, evaluated or submitted for publication
6. having a financial relationship with the study sponsor which provides you with any type of 'recruitment incentive' or bonus related to the speed of subject recruitment
7. compensating physicians who refer to you potential study subjects
8. providing the company which sponsors your research with any materials or information other than the data specifically described in the contract between the investigator and the sponsor and described in the protocol, the informed consent and the HIPAA Research Authorization
9. having a past significant monetary or non-monetary relationship with a company that is presently sponsoring your research
10. 'encouraging' or 'persuading' one's own patients to enroll in your research

II. Conflict of Interest Disclosure

A. Questionnaire

1. Are you or any family member (defined as spouse, child, domestic partner, parent, in-law, sibling) the inventor of any item (defined as drug, device, program, method, etc) being evaluated in this research project? **____yes ____no**

2. Do you (or any family member) presently have or have had within the past 5 years:
   a. any financial interest or relationship with the sponsor of this research project *other than direct compensation for your involvement in the conduct of the current study?* This would include but would not be limited to letters a, b, d, e, f, g and h of the *Financial interests* section under Definitions on page 1 of the COI Policy or numbers 1-9 of the Guidelines noted above. **____yes ____no**
   b. any securities or equity in the company sponsoring your research? If you own mutual funds and do not know the specific composition of the funds or if a professional investor is independently managing your investments, you may answer this question "no." We assume that neither you nor any members of your family will purchase any equity shares in the company sponsoring your research until the results of the study enter the public domain. **____yes ____no**
   c. any financial relationship with the manufacturer of any item being evaluated in this research project *other than direct compensation for your involvement in the conduct of the study*? **____yes ____no**
   d. any financial interest or relationship with a competitor of the sponsor of this research project that might be affected by this research project? **____yes ____no**
   e. any other financial interest or relationship that might be affected by this research project? **____yes ____no**

3. Do you (or any family member) have any non-monetary incentives or interests that may affect or be affected by the conduct of this research project and that may affect the protection of the human subjects involved in this research project? Examples may include serving as an officer, director or other fiduciary role in the sponsor. **_____yes _____no**

4. If you have seen the contract with the sponsor, does the arrangement with the sponsor include financial bonus payments related to the speed of enrollment or any milestones in recruitment? **_____yes _____no _____have not seen contract**

5. Will a company in which you have an interest receive materials from this research project? **_____yes _____no**

6. Do you plan to pay referring physicians or other persons a "finder's fee" or present them with a "gift-in-kind?" **_____yes _____no**

7. Do you plan on recruiting your own patients to enroll in your research?

____yes ____no

If the answer is "yes," how do you intend to address the issue of counseling the patient regarding the study and obtaining appropriate informed consent without unintentionally coercing patients to enroll in the study? Some possible ways to reduce or eliminate the potential for coercion in recruiting one's own patients are

a. utilize other personnel to review the particulars of the study with the prospective subject using a recruitment flyer or information sheet
b. utilize other trained personnel to perform the consenting process
c. utilize a recruitment monitor such as a member of the IRB or someone designated by the IRB to witness the consenting process
d. utilize personnel outside of your office for pre-screening to answer basic questions regarding the study

If you answered "yes" to any of these questions, please explain. You may use additional sheets if necessary. Please submit copies of pertinent documents such as contracts with sponsors, agreements for honoraria, equity information, patent or royalty information, etc. Please note that the IRB must receive from the Principal Investigator a complete budget detailing how funds will be allocated during the conduct of the study.

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Signature

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Date Signed