Cook Children's
Health Care System

Subject:	Section:	Policy Number:	Page:
CONFLICTS OF INTEREST IN RESEARCH	Research	RS 175	1 of 18
	Application: System Wide	Date of Issue: December 2018	
	Contact Person: Director, Human Subject Protection	Supersedes: August 2016	
Recommended: James C. Cunningham, M.D. Chief Medical Officer	Approved: Rick W. Merrill President and Chief Executive Officer		
Source of Policy: Regulatory: Federal	Review: Initial/Date		

PURPOSE

Cook Children's Health Care System (CCHCS) believes that all research should be conducted with the highest degree of ethical conduct and integrity and should not be affected in any manner by financial or other conflicts of interest. The purpose of this policy is to establish a process and procedure for disclosing, reporting and evaluating conflicts of interest and to assist CCHCS Investigators (and key study personnel) conducting research at CCHCS, the Conflict of Interest (COI) Official and COI Committee (when applicable) as well as the CCHCS Institutional Review Board (IRB) in managing, eliminating, or reducing any financial interests that may exist in which they are involved.

The following sections describe the procedures by which this responsibility is carried out.

DEFINITIONS

Key Study Personnel (KSP) - Individuals that contribute to the conduct of the study, scientific development or execution of the research in a substantive, measurable way, (whether or not they receive salaries or compensation under the protocol). KSP are also considered to be individuals who intervene or interact directly with human subjects (including the recruitment or consenting thereof), or who analyze data.

Institutional Official (IO) – The Chief Medical Officer (CMO), who serves as the IO, is responsible for ensuring that the Human Research Protection Program (HRPP) at CCHCS has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects' research. The IO is legally authorized to represent the institution, is the Signatory Official for all Assurances, and assumes the obligations of the institutions Federal-wide Assurance. The IO is responsible for ensuring that any identified conflicts of interest in research are evaluated, appropriately managed, or eliminated. This responsibility has been delegated to the COI Official, COIC (when warranted) and the IRB.

Conflict of Interest (COI) - Any situation in which financial, professional, or personal obligations may compromise or present the appearance of compromising an individual's judgment in designing, conducting, analyzing, or reporting of research activities or findings. Federal regulations at Title 21 Part 54 and Title 42 Part 50 of the Code of Federal Regulations (CFR)

require the disclosure and management of conflicts of interest in research. Federal human subject protection regulations at 21 CFR 56.107(e) and 45 CFR 46.107(e) require IRB members to be free of any conflict. Examples of possible types of conflicts of interest are:

A. For KSP:

1. Financial incentives related to the research;
2. Coercion/Undue influence to participate in research if the investigator is also the individual's treating physician;
3. Enrollment bonuses; or
4. Publication requirements/career advancement.

B. For The Institutional Official:

1. Participating in decisions affecting resources in which they have personal financial or professional interests; or
2. Participating in decisions affecting resources in which the institution has significant financial or other interests that may influence conduct or outcomes of the research.

C. For IRB Members/IRB Chair:

1. Serving as an investigator on research being considered by IRB;
2. Playing a substantial role in planning or conducting research at CCHCS or the strategy of such at CCHCS;
3. Where an investigator reports to the IRB Chair/IRB member or vice versa; or
4. Where IRB Chair/IRB member competes for research with an Investigator whose proposal is being considered by the IRB.

Conflict of Interest (COI) Official - CCHCS Official that is responsible for evaluating Principal Investigator and KSP financial conflicts of interest information and determining whether a financial COI is present. The COI Official has full authority to investigate potential conflicts of interest and to enforce all CCHCS COI policies in all human subject research utilizing CCHCS facilities or resources or conducted by CCHCS personnel. The COI Official may also evaluate potential institutional COI. For the purposes outlined in this policy, the CCHCS COI Official, reports directly to the CCHCS Chief Executive Officer (CEO).

Conflict of Interest Committee (COIC) - The COIC is a committee that is utilized to review and evaluate COI Official determinations when an Investigator or KSP does not accept or makes an appeal requesting re-review of the COI management plan. The COIC may also evaluate potential institutional COI.

Financial Interest Related to the Research – Financial interest in the sponsor, product, or service being tested, or competitor of the sponsor or product or service being tested.

Financial interest includes:

A. Anything of monetary value that could reasonably appear to affect, or to be affected by, the research; or

B. Anything of monetary value in entities whose interests could reasonably affect, or be affected by, the research. The latter includes membership in partnerships or group practices that could reasonably affect, or be affected by, the research;

C. Any financial arrangement whereby compensation to the investigator could influence, or be influenced by, the outcome of the study;

D. Salary and other payments for services (e.g., consulting fees, honoraria, etc.);

E. Payments of other sorts from the sponsor of the research (e.g., a grant to fund other ongoing or additional research, compensation in the form of equipment, retainer for on-going consultation, etc.);

F. Equity interests (e.g., stocks, stock options, or other ownership interests). Please note that equity interests does not include interests held indirectly through mutual or pension funds, in which the investigator or research personnel member does not directly control the selection of investments;

G. Proprietary interests or intellectual property rights (e.g., patents, trademarks, copyrights, licensing agreements, royalties, etc.); and/or

H. Non-cash items such as travel expenses or business gifts.

Financial interest does not include the following:

A. Salary, royalties, or other remuneration from CCHCS for purposes unrelated to the research in question;

B. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; and/or

C. Income from service on advisory committees or review panels for public or nonprofit entities.

Ownership Interest - Ownership interest 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 non-publicly traded corporation), or any equity interest in a publicly traded corporation during the time the Investigator is carrying out the research and for one year following completion of the study.

Compensation - Compensation means payments made by an organization to the Investigator or the institution exclusive of the costs of conducting the research during the time the Investigator is carrying out the study and for one year following completion of the research. This includes, but is not limited to:

A. Income from seminars, lectures, or teaching engagements.

B. Income from service or advisory committees or review panels.

C. Grants to fund ongoing research.

D. Compensation in the form of equipment.

E. Retainers for ongoing consultation.

Patent - An official written document which secures an inventor's exclusive right to make, use, or sell an invention for a limited period of time.

Royalty - A royalty is compensation for an invention.

Immediate Family Member - An immediate family member is a person that has a relationship (whether by blood, law or marriage) to a person as a spouse, parent, child, grandparent, grandchild, stepchild, or sibling.

Non-Financial Conflict of Interest - Non-financial conflict of interest may exist when an individual serves dual roles, such as health care provider and Investigator. Other interests such as publication or promotion can also become conflicts of interest that may affect an individual's judgment. Membership in oversight committees such as the IRB as well as positions of authority may pose potential conflicts of interest. Any position that includes responsibilities for the review and approval of research projects or contracts other than his/her own may potentially affect the design of, decisions made, and/or action taken surrounding a specific study.

INVESTIGATOR AND KSP RESPONSIBILITIES RELATED TO DECLARING AND DISCLOSING CONFLICTS OF INTEREST

Background - Department of Health and Human Services (HHS) regulations at 42 CFR Part 50 Subpart F require institutions to develop mechanisms to manage, eliminate, or reduce any financial conflicts of interest in research. The regulations require CCHCS to appoint a specific official to implement and ensure compliance with conflict of interest requirements and procedures on behalf of the organization.

Investigators and KSP (whether or not employed by CCHCS) are required to declare and disclose any financial conflicts of interest associated with themselves and any immediate family members by completing the COI process in iMedRIS. The COI process should be completed upon submission for initial or continuing IRB review or as possible conflicting interests are identified or acquired during the course of the research. The COI process and corresponding declaration and disclosure forms, attached hereto in the appendix as Attachment A, will be used for this purpose. If necessary, a plan to manage identified conflicts of interest will be approved by both the COI Official and the IRB (as set forth in this policy), and will be in place before any research activities involving human subjects are initiated. Updated COI declarations and disclosures (if applicable) will be submitted at least annually and will accompany the application for continuing IRB review.

INSTITUTIONAL RESPONSIBILITIES RELATED to IDENTIFICATION and MANAGEMENT of CONFLICTS of INTEREST

CCHCS Conflict of Interest (COI) Official - The CCHCS Vice President of Compliance serves as the CCHCS COI Official. The federal regulations associated with conflicts of interest in research require that CCHCS appoint a specific official to implement and ensure compliance with conflict of interest requirements to manage, eliminate, or reduce any financial conflicts of interest in research. The COI Official has full authority to investigate possible financial conflicts of interest and to enforce all CCHCS COI policies in all human subject research utilizing CCHCS facilities or resources or conducted by CCHCS Investigators and KSP.

The COI Official reviews information submitted by Investigators and KSP and determines whether particular Investigators or KSP have financial conflicts of interest requiring management. Where financial conflicts of interest (or the appearance of financial conflicts) are identified, the COI Official recommends how best to manage or eliminate such conflicts and reports his/her findings and recommendations to the IRB. The COI Official can appoint an appropriate Designee to make COI determinations in this policy when unavailable.

Before proposed human subject research may begin at CCHCS, the COI Official (or CCHCS COIC if applicable) and the IRB must approve any management plan in identical form, and the affected individual must accept it as a condition for IRB approval. The IRB will review studies submitted for initial or continuing review, but will not grant approval until a conflict of interest determination has been made by the COI Official and any identified COI management plans have been accepted and enacted. If an Investigator or KSP does not accept or would like to appeal the COI Official's determination and COI management plan, an appeal can be made to the COIC.

The CCHCS COIC is a committee that is utilized to review COI Official determinations when an Investigator or KSP does not accept or makes an appeal requesting re-review of the COI management plan. Please see the "COI Management Plan Appeal Process" section for more information.

CCHCS COIC

A. Function - The COIC will only be convened as described above.

B. Composition - The COIC shall be appointed by the President/CEO of CCHCS. The COIC will consist of at least three individuals - at least one of whom will be a physician. A majority of the members will be individuals not involved with research or research related activities. COIC Members will not be members of the IRB or admissible personnel with duties related to the HRPP, the IRB or the Research Administration Office.

C. Quorum and Voting - The presence of a simple majority of the members will constitute a quorum necessary to conduct business. Decisions will require at least a majority of the COIC members attending the meeting.

D. The COI Official will prepare and submit a report at least annually to the CEO summarizing CCHCS COI activities. The COI Official or the CCHCS Legal Counsel may take conflict of interest matters directly to the CCHCS Board of Trustees or its designated committee should the need arise.

COI Official Determination Process, Basis for Making Determinations, Notification of Determinations, and Storage of COI Information

1. The COI Official will receive and review declarations and disclosures (as applicable) relating to the financial interests of Investigators and KSP via the iMedRIS system.
2. The COI Official recognizes that such information may be sensitive and highly confidential and will treat such information in a confidential manner.
3. The COI Official and COIC are guided by Department of Health and Human Services (DHHS) regulations at 42 CFR Part 50 Subpart F and by Food and Drug Administration regulations at 21 CFR part 54 when evaluating potential conflicts of interest. These regulations require institutions to develop mechanisms to manage, eliminate, or reduce any financial conflicts of interest in research.
4. The COI Official will consider the information submitted and render a reasonable decision as to whether the financial interest of the affected Investigator or KSP could significantly affect the research activities directly or indirectly.
5. The COI Official may seek consultation from any source necessary to assist in making his/her findings or determination or in the design, implementation, and monitoring of any mechanism or plan for managing conflicts of interest.
6. If the COI Official reaches a decision that no financial conflict of interest exists, the COI Official will notify HRPP personnel of that determination. In turn, HRPP personnel will complete processing of the COI determination and notify the Investigators and KSP via the iMedRIS system.
7. If the COI Official reaches a decision that a financial conflict of interest exists, the COI Official will propose a management plan for the specific conflict. The COI Official will notify HRPP personnel of the management plan via iMedRIS.
8. HRPP personnel will notify the Principal Investigator, the affected individual and the study contacts of the COI determination as well as the proposed plan to manage the conflict in the following manner:

    a. By imposing stipulations and notifying the Principal Investigator, the affected individual and study contacts (listed on the study) of these stipulations via iMedRIS.

    or

b. By sending study related correspondence to the Principal Investigator, affected individual, and study contacts (listed on the study) via iMedRIS.

9. Completed COI forms for declaring and disclosing interests and all associated documentation and files will be kept in a locked filing cabinet in the COI Official's locked office, if the forms were completed prior to implementation of the iMedRIS system (pre-March 1, 2009). Destruction of these forms will follow CCHCS policy CC 827 - Records Management.

10. Electronic information will be managed in accordance with CCHCS policy CC 827 - Records Management. If these forms were completed post-iMedRIS implementation, these forms will be retained in the iMedRIS system indefinitely. However, only the COI Official, and specific HRPP personnel will be able to access the electronically completed forms.

B. Examples of Management Plans

1. The COI Official has complete discretion and authority in designing and approving a management plan.

2. Examples of management plans include, but are not limited to, the following:

a. Public disclosure of financial interests;

b. Monitoring of the research by independent reviewers or establishing a research monitoring process, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the research and CCHCS;

c. Modification of the research plan;

d. Reducing or otherwise modifying the financial (equity or royalty) stake involved;

e. Increasing the segregation between the decision-making regarding the financial and the research activities;

f. Complete divestiture of interests in the sponsor, product, or entity under study;

g. Selection of another investigator or research staff person to perform the research or research-related function;

h. Modifying the role of a particular research staff person or implementing a change in location for certain research activities, e.g., a change of the person who obtains consent;

i. Requiring an independent data and safety monitoring committee or similar monitoring body;

j. Disclosure of the conflicting interest in the informed consent document and any manuscripts or oral presentations based upon the research in question; or

k. Severance of relationships that create actual or potential conflicts.

C. COI Management Plan Appeal Process

1. The affected individual will be required to comply with all stipulated changes necessitated by the COI management plan prior to the release of IRB approval. IRB approval is contingent upon complete satisfaction of all stipulated changes imposed by the COI management plan. Before the proposed human subject research may

begin, the COI Official and the IRB must approve the management plan in identical form, and the affected individual must accept it as a condition for IRB approval.

2. If the affected individual does not accept the COI management plan, the individual may appeal by requesting a formal meeting with the COI Official to present an alternate plan. Following consideration of the alternate plan, the COI Official may adopt the original plan, adopt the individual's alternate plan, or adopt a modified plan. The COI Official will then notify the HRPP of the decision, and in turn, HRPP personnel will notify the PI, the affected individual and study contacts of the decision via iMedRIS. Before the proposed human subject research may begin, the COI Official and the IRB must approve the management plan in identical form, and the affected individual must accept it as a condition for IRB approval.

3. If the affected individual does not accept the decision of the COI Official, the affected individual may appeal and request a review by the CCHCS COIC. The COIC will review the disclosure, the proposed management plan, and any other information presented by the affected individual and COI Official. The COIC will then determine if the proposed management plan previously adopted by the COI Official should be revised and shall inform the COI Official and the HRPP of such a decision. HRPP personnel will then notify the PI, the affected individual and study contacts of the COIC's decision as well as any further stipulations that may need to be imposed due to re-review of the plan via iMedRIS. Once any applicable, additional stipulations have been addressed, the IRB will then review and approve the revised management plan prior to implementation of the research protocol.

RECRUITMENT INCENTIVES

Payment arrangements among sponsors, organizations, investigators, and those referring research participants may place participants at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective participants from researchers (physicians) ("finder's fees") is not permitted. Similarly payments designed to accelerate recruitment that is tied to the rate or timing of enrollment ("bonus payments") are also not permitted.

RESPONSIBILITIES OF THE IO/INSTITUTIONAL COI AND THE COI COMMITTEE

The IO is responsible for ensuring that any identified conflicts of interest in research are evaluated, appropriately managed, or eliminated. This responsibility has been delegated to the COI Official, COIC (where an appeal of the COI's official determination has been requested by an Investigator or KSP) and the IRB.

The policy of CCHCS is to ensure that the welfare of human subjects and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations.

This policy and associated procedures apply to all CCHCS Investigators and KSP (whether or not employed by CCHCS), IRB members, HRPP staff, Institutional leadership and the IO.

Institutional financial interests may be created by gifts, payments, royalty income, equity, and other benefits from or interests in for-profit organizations. Institutional financial interests also are created by financial and fiduciary interests of the IO.

The COI Official (or the COIC in cases of appeal) will be responsible for evaluating potential institutional conflict of interest and will take actions as required to avoid, or to appropriately manage, apparent institutional COI. These actions may involve referral to appropriate advisors outside the facility or obtaining advisement from CCHCS Legal Counsel. If used, outside advisors will be individuals who have sufficient seniority, expertise, and independence to evaluate the competing interests at stake and to make credible and effective recommendations. All outside advisors will be independent of the management of oversight for the Human Research Protection Program (HRPP) within the institution. The utilization of outside advisors will increase the transparency of the deliberations and enhance the credibility of determinations.

After reviewing any financial interest issues related to the research, the COI Official (or the COIC in cases of appeal) will communicate its conclusions, along with any management arrangements to be imposed, to the IRB. All relevant conflicts will be disclosed to research participants in a form to be determined by the IRB. The COI Official (or the COIC in cases of appeal) also will communicate conclusions and COI management strategies to the Institutional Official and the PI.

To eliminate possible conflicts of interest among institutional leadership associated with the Research and Human Subject Protection Program, the CCHCS Chief Research Officer, the CCHCS Director of Nursing Research, the CCHCS Vice President of Compliance, and the CCHCS IO will not serve as voting members of the CCHCS IRB.

RESPONSIBILITIES OF IRB MEMBERS/IRB CHAIR

Background - The Office for Human Research Protections (OHRP) interprets the HHS regulations to prohibit IRB members from participating in the deliberative discussion or vote relative to any research in which they participate in any way, including but not limited to study planning and design, conduct of the study, data analysis, subject recruitment, subject consent, and authorship. IRB members are likewise prohibited from participating in the deliberative discussion or vote relative to any research in which they have, or may appear to have, a financial, personal, or professional conflict.

Procedure

A. If the IRB member believes that a conflicting interest might impact, or appear to impact, IRB deliberations or the protection of human subjects, the member will declare the presence of the conflict to the IRB. IRB members with a potential conflict of interest will absent himself or herself from any deliberative IRB discussion and/or vote on the research. There are no exceptions from this requirement.

B. In most cases, it is not necessary for the IRB member to disclose to the IRB the details of any conflict of interest for which the member voluntarily absents herself or himself from the IRB's deliberative discussion and vote, and limits him/herself to answering questions posed by the IRB. However, there may be circumstances in which it is in the best interests of the individual, the institution, and/or the human subjects involved for the member to make a complete, written disclosure to the HRPP Director, the COI Official and/or Committee. IRB members are expected to use their best judgment to ensure that all IRB deliberations take place without any appearance or possibility of conflict of interest.

C. IRB members are required to complete and submit the IRB Member Conflict Of Interest Declaration form before each meeting. This form addresses both financial and non-financial conflicts of interest, attached hereto as Exhibit D. IRB members who declare a possible conflict of interest will leave the meeting during the IRB's deliberative discussion

or vote on the relevant action. HRPP personnel maintain and store all IRB Member Conflict of Interest Declaration forms from each IRB meeting in a secure fashion, i.e., in the locked IRB offices. At the beginning of every meeting, the HRPP Director and/or the IRB Chairperson will review the agenda and make note of any possible conflicts of interest that have not already been identified to the Chair or HRPP personnel.

D. Members found to have any interest (financial or non-financial) in the research under consideration will be recused from participation in or voting on the initial or continuing review of research. The member may be present to answer questions posed by the IRB, but any other IRB activity – including the final discussion in which a determination is made as to how the IRB will vote on the protocol – must be conducted without the presence or participation of the conflicted IRB member.

E. All recusals/absences of IRB members for conflict of interest will be noted as such in the official IRB minutes, and a determination will be made as to whether the recusal affects quorum requirements or other such issues.

F. If the absence of the conflicted member results in a majority of the IRB members no longer being present at the meeting, no IRB actions or determination can take place until a majority of IRB members have again joined the meeting.

G. If the (now absent) conflicted member was the only non-scientist member present at the meeting, no IRB actions or determinations can take place until an additional non-scientist member has joined the meeting.

REFERENCES

CCHCS policy Records Management (CC 827)

Code of Federal Regulations (CFR), Title 21 Part 54, and 56.107(e), Title 42 Part 50 and Subpart F, Title 45 46.107(e)

End of Policy

Attachment A

Cook Children's
Declaration Regarding Financial Interests Form

Date:

Conflict of Interest Policy Information:

Research reviewed by the CCHCS IRB must be accompanied by disclosure of all researchers and their immediate family members of any Financial Interest in the research under review. An immediate family member is a person that has a relationship (whether by blood, law, or marriage) to a person as a spouse, parent, child, grandparent, grandchild, stepchild, or sibling. Financial Interest means (i) anything of monetary value that could reasonably appear to be affected by the research, or (ii) anything of monetary value in entities whose interests could reasonably be affected by the research. Financial Interest includes, but is not limited to, (i) salary and other payments for services (e.g., consulting fees or honoraria); (ii) equity interests (e.g., stocks, stock options or other ownership interests); and (iii) intellectual property rights (e.g., patents, copyrights and royalties from such rights). Disclosure is required prior to the submission of an application or proposal for external funding or at the time of application for IRB review, whichever comes first.

General Information:

Please complete the following information:

IRB#
Title of Study:
Principal Investigator:
IRB File number
Study Sponsor or Entity Providing Support:

Declaration Regarding Financial Interest Information:

Please choose one of the following:

☐	I hereby declare that I, my spouse, and immediate family members have NO FINANCIAL INTEREST in the research described above.
☐	I hereby declare that I do have a potential financial conflict of interest associated with this study and that the following "Disclosure of Financial Interests" section adequately represents any and all such interests held by myself, my spouse, and immediate family members in the above referenced research.

Attachment A (continued)

Disclosure Regarding Financial Interests Information:

Please complete the following questions as applicable:

I, my spouse, or immediate family members:

- ☐ Own stock or have stock options or other equity interests in the sponsor or product (Do not include stock held in a mutual fund)

Please indicate the number of shares of stock that you, your spouse, or immediate family members own and indicate the monetary amount that the stock is estimated to be worth.

- ☐ Serve in a managerial position with the sponsor
- ☐ Act as a paid consultant for the sponsor
- ☐ Serve as member of an advisory or administrative board of the sponsor
- ☐ Receive payment(s) of any type from the sponsor or any other party (e.g., grants, consulting fees, salary, payments for board membership, honoraria, retainers, etc.) (Do not include payment to CCHCS or salary paid to you by CCHCS)

a. If you do expect to receive payment from the sponsor, please indicate below what this payment is for, i.e., grants, consulting fees, salary, payments for board membership, honoraria, retainers, etc.

b. If you do receive payment from the sponsor, how much did you receive in the last twelve months:

c. How much do you expect to receive in the next 12 months?

- ☐ Have intellectual property rights, patents, trademarks, copyrights, royalties, or other financial or proprietary interests in the research
- ☐ Have any of the relationships noted above occurred with a competitor of the sponsor?

Attachment A (continued)

☐ Have equity interests, intellectual property rights, patents, copyrights, proprietary interests, financial interests, or commitments of any kind, in addition to what was disclosed above, which may be perceived as a conflict of interest, as affected by the result of this research, or as incompatible with your commitments to CCHCS and your functioning as described in this protocol

Please provide further information relating to any intellectual property rights, patents, copyrights, or proprietary interest agreements currently in place with the sponsor company. Also, if you, your spouse, or immediate family members have equity interests or financial interests in the sponsor company (which has not already been disclosed previously), please disclose this information in the box below. In addition, please indicate the monetary amount that these interests are estimated to be worth.

Please describe any steps taken to minimize conflict or bias. If no steps are being taken to manage the financial interests disclosed above, explain clearly why you think such steps are not needed. If a previously approved plan remains in effect, so indicate.

Attachment B

CookChildren's
Health Care System

Declaration Regarding Financial Interests In Human Subject Research

Conflict of Interest Policy

Research reviewed by the CCHCS IRB must be accompanied by disclosure of all researchers and their immediate family members of any Financial Interest in the research under review. An immediate family member is a person that has a relationship (whether by blood, law, or marriage) to a person as a spouse, parent, child, grandparent, grandchild, stepchild, or sibling. Financial Interest means (i) anything of monetary value that could reasonably appear to be affected by the research, or (ii) anything of monetary value in entities whose interests could reasonably be affected by the research. Financial Interest includes, but is not limited to, (i) salary and other payments for services (e.g., consulting fees or honoraria); (ii) equity interests (e.g., stocks, stock options or other ownership interests); and (iii) intellectual property rights (e.g., patents, copyrights and royalties from such rights). *Please note that equity interests do not include those interests held indirectly through mutual or pension funds, in which there is not direct control over the selection of investments. Disclosure is required prior to the submission of an application or proposal for external funding or at the time of initial (or continuing) application for IRB review, whichever comes first.

General Information

Date:

1. **Name (Please print):**
2. **Telephone Number & E-mail Address:**
3. **IRB Number:**
4. **Role in Project:**
5. **Title of Project:**
6. **Principal Investigator (Please print):**
7. **Sponsor or Other Entity Providing Support:**

Declaration Regarding Financial Interest

Please check as appropriate.

☐ **I hereby declare that I and my immediate family members have NO FINANCIAL INTEREST in the research described above.**

☐ **I hereby declare that the ATTACHED DISCLOSURE OF FINANCIAL INTERESTS accurately represents any and all such interests currently held by myself and my immediate family members in the above-referenced research.**

I will promptly update this Declaration should the relevant Financial Interests of myself and my immediate family members change during the conduct of this research.

Signature_____ **Date:** _____

Attachment B (continued)

Cook Children's
Health Care System

Conflict of Interest Official Action

Name (Please print):

Title of Project:

FOR COI OFFICIAL USE ONLY

- ☐ No Conflict of Interest Exists -- Research May Be Reviewed by the IRB
- ☐ Conflict of Interest Exists -- Previously Approved Plan Remains Sufficient
- ☐ Conflict of Interest Exists – Management Plan Approved by COI Official Attached
- ☐ Conflict of Interest Exists – Research May Not Be Conducted at CCHCS

Comments:

Signature of COI Official: **Date:**

Attachment C

CookChildren's
Health Care System

IRB Member Conflict of Interest Declaration

In accordance with FDA regulations at 21 CFR 56.107(e) and DHHS regulations at 45 CFR 46.107(e), no CCHCS Institutional Review Board (IRB) member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. CCHCS interprets the regulations to prohibit IRB members from participating in the deliberative discussion or vote on any research in which they (i) participate in any way, including but not limited to study planning and design, conduct of the study, data analysis, subject recruitment, subject consent, and authorship; or (ii) have, or may appear to have, any personal, professional, or financial conflict.

If an IRB member believes that a conflicting interest might impact, or appear to impact, IRB deliberations or the protection of human subjects, the member must declare the conflict to the IRB and absent himself or herself from any deliberative IRB discussion or vote on the research. There are no exceptions from this requirement.

Conflict of Interest Declaration:

I have reviewed the agenda for the IRB meeting to be held on: _____

☐ **I hereby declare that I AM NOT INVOLVED IN, and HAVE NO PERSONAL, PROFESSIONAL, and OR FINANCIAL CONFLICTS REGARDING, any of the research to be reviewed. I will promptly update this declaration should I discover such a conflict during the IRB meeting.**

☐ **I will absent myself during any deliberative IRB discussion or vote on the research listed below, in which I AM INVOLVED, or HAVE A PERSONAL, PROFESSIONAL, OR FINANCIAL CONFLICT. I hereby declare that I AM NOT INVOLVED IN, and HAVE NO PERSONAL, PROFESSIONAL, OR FINANCIAL CONFLICTS REGARDING, any other research to be reviewed. I will promptly update this declaration should I discover such a conflict during the IRB meeting.** List relevant protocol number(s) below.

Signature_____ **Date:** _____

Attachment D

Sample Informed Consent Language for Disclosure of Potential Conflicts of Interest

The following language is provided as a sample for disclosure in the informed consent document of potential conflicts of interest. **It is not mandatory to use this language.** Language should be modified to fit the specific facts and circumstances. The appropriate language for disclosure will vary based on individual circumstances, and the final determination of what language to include in the informed consent document will be made by the CCHCS Institutional Review Board (IRB).

This research study is paid for by [*name of sponsor*] which owns the product being tested and thus has a financial interest in the outcome of the research study. Payments are made to CCHCS. These funds are used to cover the expenses of the research study and related activities of the institution, and . . .

do not increase the income of the investigators or other members of the research team.
may also increase the income of the investigators or other members of the research team.

The investigators and CCHCS do not have any financial interest in the outcome of the research study.

The investigator, Dr. _____, owns equity (stock) in the company which is paying for this research.

The investigator, Dr. _____, personally receives consulting or other payments from the company which is paying for this research study.

CCHCS and/or one of its affiliated hospitals and/or associated Foundations owns equity (stock) in the company which is paying for this research study.

If you require further information regarding the financial arrangements described in this paragraph, you should discuss the matter with the investigator, Dr. _____, phone number _____ or with the Chairperson of the Conflicts of Interest Committee, phone number _____.

Attachment E

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014.
Expiration Date: May 31, 2009.
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS ATTACHED.

☐ CURRICULUM VITAE ☐ OTHER STATEMENT OF QUALIFICATIONS

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES).

6. NAMES OF THE SUBINVESTIGATORS *(e.g., research fellows, residents, associates)* WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S).

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR.

FORM FDA 1572 (5/06) PREVIOUS EDITION IS OBSOLETE. **PAGE 1 OF 2**

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8. ATTACH THE FOLLOWING CLINICAL PROTOCOL INFORMATION:

☐ FOR PHASE 1 INVESTIGATIONS, A GENERAL OUTLINE OF THE PLANNED INVESTIGATION INCLUDING THE ESTIMATED DURATION OF THE STUDY AND THE MAXIMUM NUMBER OF SUBJECTS THAT WILL BE INVOLVED.

☐ FOR PHASE 2 OR 3 INVESTIGATIONS, AN OUTLINE OF THE STUDY PROTOCOL INCLUDING AN APPROXIMATION OF THE NUMBER OF SUBJECTS TO BE TREATED WITH THE DRUG AND THE NUMBER TO BE EMPLOYED AS CONTROLS, IF ANY; THE CLINICAL USES TO BE INVESTIGATED; CHARACTERISTICS OF SUBJECTS BY AGE, SEX, AND CONDITION; THE KIND OF CLINICAL OBSERVATIONS AND LABORATORY TESTS TO BE CONDUCTED; THE ESTIMATED DURATION OF THE STUDY; AND COPIES OR A DESCRIPTION OF CASE REPORT FORMS TO BE USED.

9. COMMITMENTS:

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR:

1. Complete all sections. Attach a separate page if additional space is needed.
2. Attach curriculum vitae or other statement of qualifications as described in Section 2.
3. Attach protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND ATTACHMENTS TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. SIGNATURE OF INVESTIGATOR	11. DATE

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (HFD-143)
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (HFM-99)
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please DO NOT RETURN this application to this address.