

Akron General Health System Financial Conflict of Interest Reference Sheet

Requirements for disclosure and/or a conflict of interest management plan at each level of potential or actual financial conflict of interest, depending on whether the Sponsored Program involves human participants, are provided below. At any point in this process, the Cognizant Official or Investigator may consult with the Research Oversight Committee (ROC) Chairman or request ROC review. **This document is a supplement to and does not replace the Research Conflict of Interest Policy, which should be reviewed prior to using this Reference Sheet.**

The following table is applicable to publicly traded entities only. Any financial interest in a non-public entity must be reviewed by the full ROC.

HUMAN RESEARCH STUDY				
1	2	3	4	5
<\$4,999 or COI eliminated	\$5,000-\$9,999	\$10,000 - \$19,999	\$20,000-\$100,000	>\$100,000
No COI Management Plan	COI Management Plan-Cognizant Official, ROC subcommittee Review	COI Management Plan-Cognizant Official and ROC subcommittee Review	COI Management Plan-Cognizant Official and ROC subcommittee Review	COI Management Plan-Cognizant Office and full ROC Review
AND	AND	AND	AND	AND
Standard Informed Consent Language	Informed Consent Language	Informed Consent Language	Informed Consent Language	Informed Consent Language

NON-HUMAN RESEARCH STUDY				
1	2	3	4	5
<\$4,999 or eliminated	\$5,000-\$9,999	\$10,000 - \$19,999	\$20,000-\$100,000	>\$100,000
No COI Management Plan	No COI Management Plan	COI Management Plan-Cognizant Official	Management Plan-Cognizant Official and ROC subcommittee Review	Management Plan-Cognizant Official and full ROC Review

Definitions:

Conflict of Interest – occurs when there is a divergence between an individual’s private interest and his/her professional obligations to Akron General Health System and its subsidiaries (collectively referred to here as AGHS) such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest arises when a financial interest (anything of monetary value, whether or not the value is readily ascertainable), or other opportunity for personal financial gain, is likely to compromise or influence the objective design, conduct, reporting, or direct administration of research. An apparent or potential conflict of interest arises when there is a reasonable apprehension, which reasonably well-informed persons are likely to have, that an individual’s opportunity for personal financial gain could compromise or influence the design, conduct, reporting, or direct administration of research. Conflict of interest includes a financial conflict of interest.

Significant Financial Interest (SFI) - means an Investigator's monetary interest or relationship, current (i.e. within twelve months) or during the time period a research project is active, related to an Investigator's Institutional Responsibilities including, but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria, or paid authorships from any external entity that exceeds \$5,000 during the 12-months prior to the disclosure when aggregated for the Investigator and their family members). [Note: this does not apply to salary received for teaching at an institution of higher education such as NEOMED]
- Equity interests (e.g., stocks, stock options or other ownership interests in both publicly), if the aggregate exceeds \$5,000, and **any** amount for non-publicly traded entities. [Note: this does not apply to investments, such as retirement accounts, over which the Investigator has no management or control]
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights) upon receipt of income related to such rights and interests.
- Excessive reimbursement for conducting a research study (i.e. per AGHS policy, profit greater than 20% of total budget).
- Any reimbursed travel or sponsored travel related to Institutional Responsibilities. This refers to travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be determined by the Investigator.

Institutional Responsibilities - means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, including activities such as Research, Research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or other internal committees.

A subcommittee of the ROC – will consist of the ROC Chairman, Director Department of Research, Associate Legal Counsel, Chief Compliance Officer and at least one clinician and one PhD researcher with appropriate background.

Management Plan Examples:

- Public disclosure of Significant Financial Interests (when presenting or publishing the Research);
- Review of Research protocol by independent reviewers;
- Monitoring of Research by independent reviewers;
- Modifications of the Research plan;
- Changes of personnel or personnel responsibilities;
- Disqualification from participation in all or a portion of the Research funded;
- Divestiture of Significant Financial Interests;
- Severance of relationships that create Conflicts of Interest; and/or
- Disclosure of financial Conflicts of Interest to participants in research involving human

subjects.

Informed consent language (clauses may be used individually or in any combination depending on the situation):

Standard disclosure of payment by sponsor if profit less than 20%

(used for any informed consent document of a funded study):

The sponsor of this research protocol <insert sponsor name> has contracted with Akron General Medical Center <and investigator if not employed by AGHS> to conduct this study. Financial compensation received by Akron General, above expenses, will go to a fund to support other non-funded research.

Standard disclosure of payment by sponsor if profit greater than 20%

The sponsor of this research protocol <insert sponsor name> has contracted with Akron General Medical Center <and investigator if not employed by AGHS> to conduct this study. Financial compensation received by Akron General, above expenses, will go to a fund to support other non-funded research. Akron General and the investigator could make a profit from participating in this study. Akron General has taken measures to ensure that any financial interest does not result in a conflict of interest that may affect your treatment or the way the study is conducted.

Investigator receives money outside the study

(used for financial conflicts of interest):

The sponsor of this research protocol <insert sponsor name> has contracted with Akron General Medical Center <and investigator if not employed by AGHS> to conduct this study. Financial compensation received by Akron General, above expenses, will go to a fund to support other non-funded research. Akron General and the investigator could make a profit from participating in this study. In addition, <insert investigator name> receives extra money from <insert sponsor name> for work that is not a part of this study. These activities may include consulting, advisory boards, giving speeches, or writing reports.

<Insert investigator name> might receive substantial income for this work. Akron General has taken measures to ensure that any financial interest does not result in a conflict of interest that may affect your treatment or the way the study is conducted.

Investigator has equity interest in sponsor

(used for financial conflicts of interest):

The sponsor of this research protocol <insert sponsor name> has contracted with Akron General Medical Center <and investigator if not employed by AGHS> to conduct this study. Financial compensation received by Akron General, above expenses, will go to a fund to support other non-funded research. Akron General and the investigator could make a profit from participating in this study. <insert investigator name> has an investment in <insert sponsor name>, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the <insert investigator name> could gain or lose money depending on the results of this study. Akron General has taken measures to ensure that any financial interest does not result in a conflict of interest that may affect your treatment or the way the study is conducted.

**Akron General Health System
Research Conflict of Interest Disclosure Form**

Name:

Department:

Study Title:

Sponsor/Funding Agency (if applicable):

- A Conflict of Interest occurs when a financial interest, or other opportunity for personal financial gain, is likely to compromise or appear to compromise or influence the objective design, conduct, reporting, or direct administration of research.
- A Significant Financial Interest refers to an Investigator's monetary interest or other relationship related to his/her Institutional responsibilities.
- Institutional Responsibilities are an Investigator's professional responsibilities on behalf of Akron General Health System and as otherwise defined by Akron General Health System in our Research Conflict of Interest Policy, and includes activities such as research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or other internal boards or committees.
- External Entity refers to any entity outside of Akron General Health System entities.

1. Institutional Responsibilities:

Please list your professional responsibilities on behalf of Akron General Health System. The activities that you identify below will be referred to throughout this form as your "Institutional Responsibilities."

2. Determination of Significant Financial Interests:

Do you or your immediate family (including your spouse and dependent children) have any of the following:

- Y N Compensation paid directly to you or your immediate family member from an External Entity including, but not limited to, salary, paid authorship, honoraria, and consulting compensation.
- Y N Ownership interest, stock options, or other financial interest in an External Entity (this does not include interests and/or income held indirectly through funds, such as mutual funds and pension funds, in which you or your immediate family does not control the selection of investments).
- Y N Proprietary interest or the potential for future proprietary interest, including, but not limited to, a patent, trademark, copyright, or licensing agreement, and royalties from such interest(s).
- Y N Serve as a paid or unpaid member of an advisory or executive board of an External Entity that conducts business in an area related to your Institutional Responsibilities.
- Y N A paid or unpaid executive relationship, consulting agreement, or management responsibilities with an External Entity that conducts business in an area related to your Institutional Responsibilities.
- Y N Sponsored travel paid on your behalf by an External Entity.
- Y N Non-financial interests that reasonably appear to present a conflict of interest with your Institutional Responsibilities or Research activities.
- Y N Other relationships, commitments, or activities that you or a member of your immediate family have or may have that might present or reasonably appear to present a conflict of interest with your Institutional Responsibilities or Research activities.

3. Disclosures:

If you answered “YES” to **any** item in Section #2, please address the following in the space below:

- The name of the company or entity with which the relationship exists;
- A detailed description of the relevant activities in which you are involved;
- Indicate the amount of any payment received during the previous 12 months and/or the anticipated financial gain over the next 12 months; and
- If you answered **YES** to receiving sponsored travel, please describe the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the monetary value (if the monetary value is not known, please provide an estimate).

4. Certification:

In submitting and signing this form, I certify that, to the best of my knowledge, the above information is true and accurate and that I am in compliance with federal and/or state law related to disclosures of conflicts of interest and all AGHS policies related to conflicts of interest, and I agree to the following:

- To update this disclosure:
 - During the award period;
 - On an annual basis; and
 - Within 30 days of discovery of a conflict of interest;
- To cooperate in the development of a resolution plan and subsequent Memorandum of Understanding (MOU), if necessary, to resolve any conflicts of interest; and
- To comply with any conditions or restrictions imposed by AGHS to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Signature: _____

Digital (not typed name) signature stamp is acceptable (Sign using a pen if not using a digital signature stamp).

Completed by (name and credentials): _____

Date: _____

If **YES is checked for **any** item in Section #2, a potential COI exists and Section #5 must be completed.

5. Cognizant Official Review (if applicable):

Cognizant Official: Please check appropriate box below after reviewing items checked **YES** in Section #2 and explanation in Section #3.

An actual or potential conflict of interest has been disclosed, but does not require further action or has been adequately managed. Please explain or attach management plan:

AGHS is being paid by the sponsor to conduct the research. The investigator may be reimbursed for services at fair market value. This will be disclosed on the research study informed consent.

An actual or potential conflict of interest has been identified and not managed or eliminated. This disclosure is being referred to the Research Oversight Committee for review. **Project may not be submitted to the Institutional Research Review Board for review until COI Management plan has been agreed upon.**

Please note that the Cognizant Official may consult with the Research Oversight Committee for assistance with resolution of a conflict of interest or development of a management plan.

Signature: _____

Digital (not typed name) signature stamp is acceptable (Sign using a pen if not using a digital signature stamp).

Cognizant Official (name and credentials): _____

Date: _____

****Please include completed form with IRB submission packet****