Cherry Health

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This procedure covers research and related activities conducted under the auspices of or for the benefit of the Cherry Health (Institution). Covered Individuals include all Cherry Health employees, contractors, consultants, and other individuals (e.g. volunteers, students, interns), regardless of pay, with responsibility for the design, performance, or reporting of Institution research. It also includes individuals conducting research at the Institution or using Institution researchers or other Institution facilities or resources for research. Covered individuals at the Institution must comply with the Institution's policies and procedures and all applicable federal and state laws and contractual terms related to conflict of interest.

RESEARCH ACTIVITIES

Completion of the Attestation and Disclosure Form (ADF) is required of all Covered Individuals on an annual basis. In addition to this annual requirement, certain research activities may create the need to file additional or updated information. These situations may include, but are not limited to: substantial changes in external interests and activities; before initiating an activity or external relationship that has a potential for a conflict of interest; when submitting a proposal for research if the current ADF on file does not reflect the current situation; when receiving a contribution that creates or appears to create a conflict of interest; when involved in review or advisory activities; when involved with technology transfer; when communicating with external entities; or when submitting a paper for publication.

The following constitute external interests in research related entities that must be disclosed (non-exhaustive list):

- Covered Individual or immediate family member serving in a fiduciary role (officer, director, or in any other fiduciary role for a financially interested entity, regardless of whether remuneration is received for such service) for a public or private, for-profit or not-for-profit entity.

- Covered Individual or immediate family member receiving remuneration in connection with the research that is not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred.

- Covered Individual or immediate family member receiving remuneration from any publicly traded entity and the value of any equity interest (other than through purchase of mutual funds) in the entity as of the date of disclosure, when aggregated, exceed $5,000.

- Covered Individual or immediate family member receiving any remuneration from any non-publicly traded entity, or the Covered Individual or immediate family member holds any equity interest (e.g., stock, stock option, or other ownership interest).

- Intellectual property rights (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights.

Regarding external interests and activities and the design, conduct, reporting of research activity, the following actions by Covered Individuals are prohibited:

- Using nonpublic research information to buy or sell stock.

- Disclosing nonpublic research information to investment companies or other third parties for personal gain. Note: Individuals who have access to preliminary nonpublic research results related to clinical trials or other research with potential commercial value may be considered insiders for purposes of federal insider trading laws if the research is sponsored by companies with publicly traded stock.

The Chief Medical Officer (CMO) or designee shall ensure that all persons within the Institution who are Covered Individuals are accurately identified, either as defined by this procedure or as individually determined to be involved in research by Principal Investigators. The CMO or designee is responsible to assure that all such Covered Individuals complete the ADF in a timely manner (within 30 days of hire and on an annual basis thereafter).

Research subcontractors or sub grantees, funded from contract or grant awards to the Institution, must provide appropriate assurances that they are in compliance with the Institution's policies relating to financial conflicts of interest in research or that they have the equivalent of these policies and procedures in place, before funds are released. In the case of identified conflicts of interest, the subcontractor/sub grantee must provide the Institution with documentation on the conflict of interest and the approved management plan. On an annual basis, the subcontractor/sub grantee must submit oversight updates to the Institution for the duration of the contract period. The Institution will report the existence of any conflicts of interest and subsequent management plans as required by sponsors.

The Corporate Compliance Officer (CCO) shall be responsible for professional level staff review under this procedure of each ADF submitted to Cherry Health by Covered Individuals in respect to external interests and activities related to research activity, and make appropriate recommendations to the CMO or designee concerning the development of management plans for the elimination, reduction, or management of any potential conflict of interest in research.

The finance department quarterly will generate a list of companies that pay royalties of $5,000 or more per year and of the Department, Clinic, or Unit of the Institution and the Covered Individuals that receive the revenue. The finance department will forward this report to the CCO who will compare that list against a database of research sponsors. If the company is on both lists, the CCO will gather information about the project and forward the matter to CMO or designee to develop a management plan.

The finance department may not release for expenditure funds for a sponsored project in which a significant financial interest has been disclosed until the interest has been reviewed, a determination has been made and a management plan, if required, has been implemented.

Prior to the expenditure of funds, the Institution will report, to the extent required by the research sponsor, the existence of any conflicting interest disclosed and provide assurance that the interest has been managed, reduced or eliminated. If a conflict is identified after this initial report, the covered individual must update the ADF and the Institution will submit a subsequent report in accordance with the requirements of the research sponsor.

REVIEW OF ADFS AND DETERMINATION OF MANAGEMENT PLAN

The CCO will perform an initial review of submitted ADFs and refer appropriate cases to the CMO or designee for review and management determination. The CCO will review each case and make a determination as to whether the disclosed interests create a conflict of interest. In making that determination, the CCO will consider the following issues: the Covered Individual's Institutional responsibilities, the size and nature of the external interest, when the relationship commenced, whether the conditions of the relationship have changed during the past year, the likelihood of actual conflict (will the results of the activity likely be compromised by the external interest), how closely the Institution's research activity is related to the external interest, mechanisms to ensure integrity (peer review, other independent research sites, and independent monitors or controls), the importance of the proposed activity, the participation of human subjects, the availability of alternatives to avoid the conflict or apparent conflict, and any other relevant information. The CCO will consult appropriate individuals, including the Covered Individual, as needed, to ensure a complete understanding of the relationship and its potential impact on Institutional activities and any appropriate management requirements. Based upon this review, the CCO will issue an opinion and, if one is required, the CMO or designee will issue a management plan.

Research activities involving the participation of humans are reviewed with extra scrutiny because of the potential to compromise the welfare of human subjects. The independent IRB has final authority to determine whether the plan adequately protects research subjects and whether the research may proceed.

TRAINING

All Covered Individuals will participate in conflict of interest training upon joining the research activity, and at least every four years after the initial training and immediately under certain circumstances as determined by the CMO or designee.

COMPLIANCE WITH THESE PROCEDURES

Covered Individuals are responsible for knowing, understanding, and complying with this procedure as it relates to their role, position or employment. Breaches of this procedure include, but are not limited to, failing to file an ADF, intentionally filing an incomplete, erroneous, or misleading ADF, failing to provide additional information as required, or failing to follow an approved plan for managing, reducing or eliminating a potential conflict. A violation of this procedure may result in sanctions, corrective measures and appropriate disciplinary actions, up to and including termination.

To the extent required by a research sponsor, the Institution will notify the research sponsor of the violation and any corrective action taken or to be taken. If a research sponsor should report a case of non-compliance by a Covered Individual, the Institution will require the Covered Individual to fulfill all reporting requirements, to the extent required by the research sponsor.

DEFINITIONS

Attestation and Disclosure Form (ADF). Means a Covered Individual's annual attestation to the Standards of Conduct and disclosure of external interests to an Institution.

Covered Individual. Means all Cherry Health (Institution) employees, contractors, consultants, and other individuals (e.g. volunteers, students, interns), regardless of pay, with responsibility for the design, performance, or reporting of Institution research. It also includes individuals conducting research at Cherry Health or using Cherry Health researchers or other Cherry Health facilities or resources for research.

Financial Interest. Anything of monetary value including, but not limited to: an interest in a business consisting of any stock, stock option, or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the Covered Individual does not exercise control; or receipt of, or the right or expectation to receive, any income in one or more of the following forms: a consulting fee, honoraria, salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology or other processes or products, rent, capital gain, or any other form of compensation.

Immediate Family Member. Immediate family member shall mean the Covered Individual's biological, foster or adoptive parent; a stepparent; spouse or an adult in an equivalent relationship; a biological, adoptive or foster child; a step child; a legal ward; a sibling or step-sibling; or an in-law.

Individual Conflict of Interest. A situation that compromises or appears to compromise a Covered Individual's professional judgment in carrying out research because of an external relationship that directly or indirectly affects an external interest of the Covered Individual or an immediate family member.

Manage. Means to take action to address a conflict of interest, which includes reducing or eliminating the conflict of interest, to ensure that affected activity is free from bias or the appearance of bias.

Management Plan. Means a written plan for the management, reduction or elimination of a known or likely conflict of interest. It relies upon good faith disclosures about external interests and activities made in the ADF, as well as other information provided, by the Covered Individual to the Institution. In general, the management plan shall contain provisions appropriate for the purposes intended (e.g. management, reduction or elimination of the conflict), for the identity, nature and any monetary amount of the conflict, and for the other circumstances in question.

Participate. To be part of the Institution research activity in any capacity, including, but not limited to, serving as the principal investigator, co-investigator, research collaborator, research coordinator or assistant, or provider of direct services or patient care. The term does not apply to individuals who provide primarily technical or advisory support and have no direct access to the data or control over its collection or analysis. The term also does not apply to the study participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.

Personal benefits. Includes cash, profits, securities, gifts, performed work, sex, and other benefits.

Personal Gain. Utilize Institution resources for personal commercial purposes or personal commercial financial benefit.

Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Research. Means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, service and testing, and product development. The term includes any such activity for which research funding is available through a grant, cooperative agreement, or contract, such as a research grant, career

development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Sponsored Project. Means research projects involving funds, materials, or other compensation from outside sources under an agreement that binds the Institution to a substantial level of detail (research protocol), requires financial reports, and provides for the disposition of either tangible or intangible properties that may result from the activity.

Vendor. Means businesses and individuals who provide goods and services to the Institution. This term includes pharmaceutical company and medical equipment representatives, as well as equipment and service providers.