

**DIGNITY HEALTH
ADMINISTRATIVE POLICY AND PROCEDURE**

FROM: Compliance Oversight Committee

SUBJECT: Conflicts of Interest – Institutional Review Boards, Facilities, and Investigators

EFFECTIVE DATE: February 22, 2013

REVISED: January 17, 2012, September 1, 2010; February 27, 2009; (100.1.001) March 14, 2006

ORIGINAL EFFECTIVE DATE: (100.1.001) March 14, 2006

REPLACES: (100.1.001) Conflicts of Interest – Institutional Review Boards, Hospitals, and Investigators, March 14, 2006

APPLIES TO: System Offices:	<u>X</u>
Acute Care Entities:	<u>X</u>
Non-acute Care Entities:	<u>X</u>

I. POLICY

It is the position of Dignity Health that participants in the review and conduct of research in Dignity Health facilities must disclose actual and potential conflicts of interest in order to assure the integrity and quality of both the review process and the conduct of the research, to protect human research subjects and to comply with law.

II. PURPOSE

The purposes of this Policy are: (1) to identify and manage potential or actual conflicts of interest in order to assure objectivity in the review, conduct, design, and reporting of research in Dignity Health facilities; (2) to assure that financial interests do not compromise the protection of research subjects; and (3) to prevent intentional or inadvertent participation in the decision-making process by persons having an actual or apparent conflict of interest.

This Policy applies to: (a) members of Dignity Health’s Institutional Review Boards; (b) Dignity Health facilities as institutions in which sponsored research is conducted; and (c) Investigators and staff who conduct research in Dignity Health facilities. (d) Research funded under Public Health Service (PHS) grants, contracts or cooperative agreements (see Appendix 5, Section II). It does not apply to research that is not subject to review by an institutional review board under law.

Dignity Health facilities may establish, in coordination with their Institutional Review Boards, facility-specific policies and procedures consistent with this Policy, to the extent necessary to carry out their responsibilities under this Policy.

For the purposes of 42 CFR Part 50—(Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought) this policy must be posted on a publicly accessible Dignity Health website (See Appendix 5, Section V).

III. DEFINITIONS

- A. For purposes of this Policy, the following definitions apply, provided, however, that the definitions are intended to be consistent with the definitions contained in the Dignity Health Human Research Protection Manual (the “**HPRO Manual**”), published by the Dignity Health Human Research Protections Office (“**HRPO**”):
1. “**Accountable Executive**” means that person, designated in accordance with the HRPO Manual, who is responsible for administrative oversight of research activities conducted within a Dignity Health Facility.
 2. “**Business Position**” means a position (such as an officer, director, employee, advisor, or consultant), whether paid or unpaid, held in the past 3 years by a Covered Individual or Family Member in or with a Research Business Entity.
 3. “**Conflict of Interest**” shall have the meaning set forth in Section B below.
 4. “**Covered Entity**” means Dignity Health and all Dignity Health Facilities.
 5. “**Covered Individual**” means the member(s) and alternate member(s) of the IRB, Investigator(s), Study Coordinators and any other members of a research team, at the discretion of the Accountable Executive.
 6. “**Dignity Health Facilities**” means all Dignity Health hospitals and patient care locations that are owned by Dignity Health or by subsidiaries of Dignity Health that participate in Dignity Health’s self-insurance program.
 7. “**Family Members**” mean a Covered Individual’s spouse; parents (including stepparents); children and their spouses; siblings (including stepbrothers and stepsisters); in-laws (father-, mother-, son-, daughter-, brother-, or sister-in-law); grandparents and their spouses; and grandchildren and their spouses.¹
 8. “**Federal Wide Assurance**” means the assurance executed by Dignity Health and filed with the U.S. Department of Health and Human Services that certifies the compliance of Dignity Health and each of its registered IRBs with the laws governing IRBs and human subjects in research.

¹ 42 CFR 411.351. This definition is consistent with the federal Stark Law.

9. **“Human Subject”** means (a) a living individual about whom an Investigator obtains data through interactions with the individual, or (b) a human being, living or dead, whose protected health information (**“PHI”**), as defined by Dignity Health policies and applicable laws, is obtained or used by an Investigator in the course of conducting a study.
10. **“Institutional Review Board”** or **“IRB”** means a board, committee or other grouping that: (a) is formally organized and designated by Dignity Health or a Dignity Health Facility to assure the rights and protect the welfare of human individuals participating in research, and (b) is identified and registered under Dignity Health’s Federal Wide Assurance (**“FWA”**)[, but excludes any entity that performs the functions of an IRB on behalf of a Dignity Health Facility pursuant to a written contract with Dignity Health or the Dignity Health Facility, such as Western IRB].
11. **“Investigator”** means an individual responsible for the design, conduct, or reporting of the results of work performed or to be performed under the research project, and includes Principal Investigators, Co-Investigators, Sub-Investigators and any other individual who has independent responsibility for designing, conducting, or reporting the results of the research study.
12. **“IRB Members”** mean members and alternate members of an IRB as defined above.
13. **“Material”** or **“material”**, as it applies to Financial Interests and Institutional Financial Interests (as defined in Section B below), means interests of a value of ten thousand dollars (\$10,000) or more in the aggregate, regardless of when it is earned or expected to be earned.² For research funded under Public Health Service (PHS) grants, contracts or cooperative agreements this threshold is Five Thousand Dollars (\$5,000). (See Appendix 5 of this Policy).
14. **“Research”** or **“research”** means the systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, as more specifically defined in the HRPO Manual. The terms “clinical research,” “clinical study,” “study,” “clinical investigation,” “experiment,” “clinical trial” are deemed to be synonymous with research. For purposes of this policy, research includes **“Non-Dignity Health Research”** as that is reviewed by an IRB in accordance with the *Standards for Review of Research by a Dignity Health IRB* as established by HRPO.

² Cal. Health and Safety Code § 24173 (c)(11).

15. **“Research Business Entity”** means a company that is a Sponsor, an Investigator, contract research organization (**“CRO”**), clinical site management organization (**“SMO”**), an employer of an Investigator (other than a Dignity Health entity), or a company that provides goods and services to a Covered Entity in connection with the conduct of research.
16. **“Sponsor”** means either an individual or organization that takes responsibility for and initiates a clinical investigation. The Sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The Sponsor generally does not actually conduct the investigation unless the Sponsor is a Sponsor-investigator.³
17. **“Study Coordinator”** means the person who manages the daily activities of the study, including coordinating the recruitment, enrollment, treatment or testing of Human Subjects.

B. Conflict of Interest Defined. (Please reference Appendix 5, Section III of this Policy for specific definitions that apply to research projects funded under Public Health Service (PHS) grants, contracts or cooperative agreements).

1. **"Conflict of Interest"** as used in this Policy means a direct or indirect Financial Interest or a Business Position held by a Covered Individual, a Family Member or a Covered Entity in a Research Business Entity, and any Other Personal Interest that has the potential to influence or creates the appearance of influencing: (a) the design, conduct, or reporting of research; (b) the rights and welfare of Human Subjects; or (c) the ability of the IRB to make independent decisions in carrying out its responsibilities for the review and oversight of research. The existence of a Conflict of Interest does not reflect on the character of an individual.
2. **“Financial Interest”** means, subject to the exclusions listed in subsection c. below:
 - a) A direct or indirect ownership of stock or proprietary interests in a Research Business Entity (including stock warrants or stock options), or the holding of any debt interests in, any Research Business Entity;

³ 21 CFR. Part 312.3 (b).

- b) Any compensation arrangement between a Covered Individual or Covered Entity and a Research Business Entity, which includes any arrangement involving the exchange of remuneration of any sort, including, without limitation:
- (1) Salaries;
 - (2) Consulting fees;
 - (3) Stipends;
 - (4) Unsecured or below market loans;
 - (5) Honoraria in excess of \$1000 (on an annual aggregate basis);
 - (6) Gifts or entertainment with a value in excess of \$300 (on an annual aggregate basis);
 - (7) Grants, bequests and donations;
 - (8) Payment for the reasonable costs of conducting research;
 - (9) Payment for the conduct of research in excess of reasonable costs incurred, including, without limitation, excessive payments for enrollment of study subjects, milestone achievements or bonuses;
 - (10) Any payments made to a Covered Individual or Covered Entity by a Research Business Entity to support activities of an Investigator, over and above compensation to conduct a particular study, such as a grant to fund ongoing research or to purchase equipment;⁴
 - (11) Any intellectual property rights granted to the Covered Individual or Covered Entity by the Research Business Entity in connection with the research.

⁴ 21 CFR 54.2(f).

c) For purposes of this Policy, a “Financial Interest” does not include the following:⁵

(1) **Publicly-traded securities:** Ownership by a Covered Entity, Covered Individual or Family Member of investment securities, including shares or bonds, debentures, notes or other debt instruments) of a Research Business Entity that at the time they were obtained could be purchased on the open market, provided the equity interests meet all of the following requirements:

(a) are either (1) listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national or regional exchange in which quotations are published on a daily basis, or (2) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; and

(b) are in a corporation that had stockholder equity exceeding \$75 million at the end of the corporation’s most recent fiscal year, or on average during the previous 3 fiscal years; and

(c) are less than \$50,000 in value.⁶

(2) **Mutual Funds:** Ownership, for the account of a Covered Entity, Covered Individual or Family Member, of shares in a Research Business Entity held by a regulated investment company, as defined in Section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

3. **“Institutional Financial Interest”** means any Financial Interest (a) between a Covered Entity and a Research Business Entity, or (b) between a Covered Entity and an Investigator.

⁵ 42 CFR 411.356. These exclusions are consistent with federal Stark Law.

⁶ 21 CFR 54.2(b). The FDA guidelines for “significant equity interest” in a sponsor includes 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 that exceeds \$50,000 during the time the clinical investigator is carrying out the study and for one (1) year following.

4. **“Other Personal Interest”** means any other interest of a Covered Individual that may affect the design, review, conduct or reporting of research. For example, the participation of a Family Member of a Covered Individual as a subject in a study would be a form of Other Personal Interest.

IV. PRINCIPALLY AFFECTED DEPARTMENTS:

The following entities are principally affected by the policy elements and shall receive the required training, as provided in Administrative policy 70.1.003, Compliance Policy Dissemination and Implementation Process:

- Hospitals
- Clinics / Physician Practices
- Any other Dignity Health Facility that sponsors Medical Research

Specifically, the following departments:

- Clinics
 - Management
 - Physician and Non-Physician practitioners
- CMO / VPMA
- Facility Compliance Liaison
- Institutional Review Board (IRB)
- Risk Management
- Facility President / Senior Management

A Dignity Health entity may, in the exercise of its reasonable judgment, determine that other departments are affected by this policy and provide necessary training to the workforce in those departments.

V. GUIDELINES:

A. Disclosure of Conflicts of Interest

1. By Investigators and Study Coordinators

For research funded under Public Health Service (PHS) grants, contracts or cooperative agreements, investigators must complete training regarding financial conflicts of interest prior to engaging in research (See Appendix 5, Section IV).

- a) Disclosure under this Policy is in addition to and supplements any disclosures required in research conducted under the FDA, PHS, or the Common Rule.

- b) Prior to the consideration or review of each research protocol by a Dignity Health IRB, all Investigators (including Principal Investigators, Co-Investigators, and Sub-Investigators) and all Study Coordinators are required to disclose all Financial Interests and any Other Personal Interests that constitute or may appear to constitute Conflicts of Interest with respect to the protocol submitted. The obligation to disclose exists whether or not the Investigator or Study Coordinator believes the Financial Interest or Other Personal Interest has a bearing on the outcome, design, or reporting of the research or on the safety of Human Subjects. Any question as to whether a particular circumstance presents a real or actual Conflict of Interest should be resolved in favor of disclosure.
- c) To implement their obligations above, Investigators and Study Coordinators shall file an *Investigator Conflicts of Interest Disclosure Statement* (in the form approved by the HRPO and appended to this Policy) with each protocol submitted for review, whether a new application or a renewal application. No protocol, whether under a new or renewal application, may be reviewed by the Accountable Executive or the IRB unless all relevant *Disclosure Statements* have been submitted. The inquiry, responses and the disposition or management of any real or potential Investigator Conflicts of Interests shall be recorded in the minutes of the IRB meeting with respect to any protocol before the IRB.
- d) With respect to any open study (including data only studies), Investigators and Study Coordinators shall report any changes to previously filed information by filing an updated *Investigator Conflicts of Interest Disclosure Statement* with the IRB Chair and the Accountable Executive, within 30 days of the event giving rise to the change. The inquiry, responses and the disposition or management of any real or potential Investigator Conflicts of Interests resulting from an updated disclosure shall be recorded in the minutes of the next scheduled IRB meeting. If no action is required on the updated information, the IRB may review the disclosures as information items, or in a consent calendar.
- e) For research funded under Public Health Service (PHS) grants, contracts or cooperative agreements investigators will submit an updated disclosure at least annually. (See Appendix 5, Section VI)

2. By IRB Members and Alternate Members

- a) An IRB Member shall complete and submit an IRB Member Conflicts of Interest Disclosure Statement (in the form approved by the HRPO and appended to this Policy) to both the Accountable

Executive and the IRB Chair: (1) within 30 days of initial appointment; (2) at least once annually thereafter; and (3) within 30 days of a change in information that occurs after the date of the last annual submission. A copy of the Disclosure Statements shall be maintained in the records of the IRB and shall be used by the IRB Chair for the ongoing management of conflicts. The IRB Chair shall share the Disclosure Statements with the Accountable Executive if requested to do so.

- b) Prior to the consideration or review of each research protocol by a the Dignity Health IRB, all IRB Members (including alternate members) are required to disclose any Financial Interests and any Other Personal Interests that constitute or may appear to constitute Conflict of Interests with respect to the protocol submitted. Prior to deliberations on a protocol, the IRB Chair will inquire as to actual or potential conflicts, and IRB Members may respond at that time. The failure of the IRB Chair to make such inquiry does not relieve the IRB Members from making an appropriate disclosure prior to deliberations on the protocol. The inquiry, responses and the disposition or management of any real or potential Conflicts of Interests shall be recorded in the minutes of the IRB meeting.
3. **Continuing Obligation.** It is the continuing responsibility of Investigators or IRB Members to scrutinize their activities to conform to the requirements of this Policy.
 4. **Resources.** The Accountable Executive, the IRB Chair, Investigators and IRB Members may seek advice concerning the application or interpretation of this Policy from the HRPO or the Dignity Health Legal Department.

B. Management of Conflicts of Interests

1. IRB Member Conflicts of Interest

- a) At any time that an actual or potential Conflict of Interest has been identified, whether through the filing of *IRB Member Conflicts of Interest Disclosure Statement* with the Accountable Executive and the IRB Chair, through a voluntary disclosure by the IRB Member, or as a result of a disclosure by an individual other than the IRB Member, the IRB Chair shall perform a review of the circumstances to determine whether or not an actual or potential Conflict of Interest exist. The IRB Chair may consult with responsible Dignity Health Legal Counsel or the HRPO, if necessary.
- b) In the event that the IRB is considering a proposed research study (including any renewals or extensions of existing studies) in which

an IRB Member has a Conflict of Interest, the following procedures shall apply:

- (1) The Conflict of Interest must be fully disclosed to the IRB prior to IRB discussion related to a proposed research study.
- (2) The IRB Chair may, at his or her discretion, arrange for attendance at the IRB meeting of the alternate member designated for the conflicted IRB Member. Any such substitution shall be recorded in the minutes of the meeting.
- (3) The applicable IRB Member may, at the discretion of the IRB Chair, provide information regarding the affected research proposal, so long as such IRB Member is excused from the meeting prior to the discussion, and does not return until discussion and voting on the matter have been concluded.⁷ The IRB must maintain a quorum in order to vote, without including the conflicted IRB Member as part of the quorum.
- (4) If the applicable IRB Member is the Chairperson, he or she may not preside over the meeting at any time in which the affected research proposal is under consideration, during which time the meeting shall be conducted by the Vice Chair or other designee. The IRB must maintain a quorum in order to vote, without including the IRB Chair as part of the quorum.
- (5) The IRB may decline to approve the proposed research, or it may approve the research, with or without modification, that addresses the Conflict of Interest, by a good faith vote of a majority of the IRB Members in attendance without counting the vote of the conflicted IRB Member, and with knowledge of the material facts concerning the IRB Member's conflicting interest, and only if the following findings are made:

⁷ Federal regulation states, "No IRB may have a member 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". 45 CFR 46.107 (e). While the regulation is silent on whether the conflicted member may be in the room during a vote, the Office for Human Research Protections ("OHRP") interprets the regulation to require that the member leave the room prior to the discussion and the vote. OHRP further advises that the IRB must retain a quorum in order to vote while the conflicted member is out of the room.

- (a) The pertinent Conflict of Interest is manageable and will not affect the rights and welfare of Human Subjects;
 - (b) The IRB, without the participation of the conflicted IRB Member, is able to provide objective initial review and continued monitoring of the particular research study;
- (6) Detailed minutes identifying the circumstances creating the Conflict of Interest, describing in detail the above findings and conclusions, and recording the vote, are made and duly recorded.
- (7) In the event that the IRB determines that the proposed research cannot be adequately managed, given the Conflict of Interest, the IRB may elect not to approve the research study.

2. Institutional Conflicts of Interest

- a) The Accountable Executive, in consultation with Dignity Health Legal Counsel, is responsible for determining if there are Institutional Financial Interests that are required to be disclosed to the IRB and to Human Subjects in the written informed consent form. A suggested process is outlined in an Appendix to this Policy. If disclosure is required, the Accountable Executive will disclose the Institutional Conflict of Interest to the IRB prior to its consideration of a new research proposal, or any annual review of or extension of an existing study. Such disclosure shall be reflected in the minutes of the IRB documenting the consideration or review of a proposal.
- b) The IRB, in consultation with the Accountable Executive and Dignity Health Legal Counsel, shall be responsible for:
 - (1) assuring appropriate disclosure of any material Institutional Financial Interests is contained in the informed consent form for the study;
 - (2) determining how to manage, mitigate or eliminate an Institutional Conflict of Interest so as not to affect the rights and welfare of Human Subjects or the quality and integrity of the review, design, conduct or reporting of the research, which may include submitting the protocol to a third party IRB for review and for recommendation on the mitigation or elimination of the conflicts.

3. Investigator Conflicts of Interest

- a. The IRB shall require as part of its review process that Investigators disclose any Financial Interest or Other Personal Interest in a particular research proposal prior to the IRB's consideration of the proposed research, using the process described in Section above. As part of its due diligence process, the IRB may request that the Investigator provide the IRB copies of the financial disclosures Investigator has filed with the Sponsor of the study under submission, such as the FDA 3454 (Certification of Financial Interests and Arrangements of Clinical Investigators) or FDA 3455 Disclosure of Financial Interests and Arrangements of Clinical Investigators), but completion of the approved form of *Investigator Conflicts of Interest Disclosure Statement* is still required.
- b. The IRB shall be responsible for:
 - i. assuring appropriate disclosure of any material Financial Interests of an Investigator is contained in the Consent Form for the study.⁸
 - ii. determining how to manage, mitigate or eliminate an Investigator's Conflict of Interest so as not to affect the rights and welfare of Human Subjects or the quality and integrity of the review, design, conduct or reporting of the research, which may include submitting the protocol to a third party IRB for review and for recommendation on the mitigation or elimination of conflicts.
- c. The IRB will review pertinent research documents and activities that bear directly on the rights and welfare of the subjects of proposed research, including all of the following:
 - i. (i) Review of recruitment methods, particularly with regard to significant enrollment fees that may be deemed improper incentive for enrollment of Human Subjects. IRBs have responsibility and authority to review recruitment methods as related to financial incentives.
 - ii. (ii) Review of the Investigator's or Family Member's financial relationship to the research study Sponsor or Research Business Entity.

⁸ California law requires that the human subject be informed both verbally and within the written consent form of the material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. "Material" means ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned. California Health and Safety Code § 24173 (c)(11).

Appendix 1 – Disclosure Statement – IRB Members

Appendix 1 is available for review through the following link:



70.7.001 Appendix 1

[Double click on icon to open document]

Appendix 2 – Disclosure Statement – Investigators

Appendix 2 is available for review through the following link:



70.7.001 Appendix 2

[Double click on icon to open document]

Appendix 3 - HRPO Guidance #3

Conflict of Interest Disclosures for NIH (Federal) Sponsored Oncology Cooperative Group Clinical Trials.

This guidance is a supplement to Dignity Health Policy 70.7.001 *Conflicts of Interest – Institutional Review Boards, Hospitals, and Investigators*.

Specifically this guidance pertains to Section V, Part 1(a) which states:

Prior to the consideration or review of each research protocol by a Dignity Health IRB, all Investigators (including Principal Investigators, Co-Investigators, and Sub-Investigators) and all Study Coordinators are required to disclose all Financial Interests and any Other Personal Interests that constitute or may appear to constitute Conflicts of Interest with respect to the protocol submitted.

The HRPO recognizes this requirement may create an administrative burden when applied to federally funded cooperative group cancer research in which many of the physicians listed on the IRB application only “participate” by referring potential subjects to the Principal Investigator for enrollment and help manage and/or follow these subjects once enrolled. Participating physicians in this case are not paid by the trial sponsor (NIH) or manufacturers of investigational agents. As such the HRPO recognizes that physicians participating in these trials would not be financially conflicted.

At this time the HRPO will allow the Facility Accountable Executive and Dignity Health Institutional Review Board some flexibility to waive the above requirement as it pertains to Co-Investigators and Sub-Investigators completing COI disclosures for every study prior to AE and IRB review.

Specifically, the HRPO will allow the Facility Accountable Executive and IRB to decide if their facility will allow the waiver in general. If the waiver will be allowed the following criteria must be met:

- The clinical trial is sponsored by the NIH and offered to the site via an NIH funded Oncology Cooperative Group including, SWOG, RTOG, NSABP, CALGB, GOG, ACOSOG, COG, ECOG and CTSU.
- The Physician is not the Principal Investigator
- The Physician is not paid directly by the sponsor (or other entities) to participate.
- The Physician will not seek to publish results of these studies.
- The Physician must maintain a copy of their annual NIH Conflict of Interest Disclosure with the facility Accountable Executive or IRB Office.
- The Physician must be listed on the IRB application.

The Principal Investigator, Co/Sub Investigators (not meeting the criteria above), Clinical Coordinators and other members of the research team are not eligible for this waiver.

HRPO Guidance #3 - *Conflict of Interest Disclosures for NIH (Federal) Sponsored Oncology Cooperative Group Clinical Trials* (Approved by Dignity Health HRPO June 22, 2010).

Appendix 4 – Process for Identifying and Disclosing of Institutional Financial Interests

1. The AE shall assure the informed consent form contains a standard disclosure regarding potential institutional conflicts of interest as set forth in this Appendix, and as from time to time modified by the Dignity Health Human Research Protections Office (HRPO), or at the direction of Dignity Health Legal Counsel: The following language is a sample disclosure to be inserted into the informed consent form:

“Except as stated below, neither Dignity Health nor the Hospital has a material financial interest in the outcome of this Study.

- [In the event that Dignity Health or the Hospital does have a material financial interest in the outcome of the Study, then Dignity Health Legal Counsel shall be contacted to draft a Study-specific disclosure.]
 - [Applicable to studies for which the Hospital receives compensation from the sponsor.] Sponsor compensates the Hospital for Hospital’s services related to the Study. Sponsor may also compensate Dignity Health, Hospital, and other Dignity Health affiliates for services related to other studies or activities.
 - [Applicable to studies with sponsors from which Dignity Health may purchase goods or services.] Dignity Health and Hospital may purchase goods and services from the Sponsor or from an affiliate of the Sponsor in connection with Dignity Health’s and Hospital’s provision of health care services to the public.
 - [Applicable to publicly traded sponsors.] Dignity Health owns investments, which are managed by third party professionals in accordance with Dignity Health’s investment policies. It is possible that Dignity Health’s investments may include stock or other ownership interest in the Sponsor or an affiliate of the Sponsor.
 - [Applicable when Dignity Health employs the Investigator.] Hospital employs the Investigator and the Investigator is supervising the Study within the scope of his or her employment. [The Investigator does not have a financial interest in the outcome of this Study.][The Investigator has a financial interest in the outcome of this Study as follows:]”
2. Whether included in the *Investigator Conflicts of Interest Disclosure Statement* or the IRB Review Application, the AE shall assure that the protocol review process includes an inquiry as to whether Investigator has
 - (a) any arrangement for the sharing of intellectual property related to the Study with the Sponsor, such as development rights, royalties or licenses, and
 - (b) any arrangement for the sharing with Dignity Health of intellectual property related to the Study, such as development rights, royalties or licenses.
 - i. If the Investigator answers affirmatively to 2(a) above, the AE shall assure that the informed consent contains an appropriate disclosure by Investigator of

the arrangement if Investigator's interest from the arrangement equals or exceeds \$10,000. If the Investigator answers affirmatively to (a) above and the Investigator is a W-2 employee of Dignity Health, then the AE, in consultation with Dignity Health Legal Counsel, shall assure that the informed consent contains an appropriate disclosure of Dignity Health's Financial Interest resulting from the employment relationship, if either the Investigator's or Dignity Health's Financial Interest in the sharing arrangement equals or exceeds \$10,000.

- ii. If the Investigator answers affirmatively to 2(b) above, then the AE, in consultation with Dignity Health Legal Counsel, shall assure that the informed consent contains an appropriate disclosure by the Dignity Health Facility of Dignity Health's Financial Interest resulting from the sharing arrangement, if it equals or exceeds \$10,000.

3. If Dignity Health Legal Counsel determines that the clinical trial agreement between a Dignity Health Facility and the Sponsor creates any "Institutional Financial Interest" as defined in this Policy with respect to the Study that is being reviewed by the IRB, then the AE, in consultation with Dignity Health Legal Counsel, shall assure that the informed consent contains an appropriate disclosure by Dignity Health of any Institutional Financial Interest that equals or exceeds \$10,000.

**APPENDIX 5 - INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST
DISCLOSURE POLICY & PROCEDURE FOR FEDERALLY FUNDED RESEARCH**

(42 CFR PART 50.601)

SECTIONS:

- I. PURPOSE**
- II. APPLICABILITY**
- III. DEFINITIONS**
- IV. GENERAL RESPONSIBILITIES OF INVESTIGATORS**
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- VI. INVESTIGATOR DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS**
- VII. HOSPITAL REVIEW AND MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST**
- VIII. APPEALS**
- IX. COMPLIANCE**
- X. FAILURE TO COMPLY**
- XI. RECORDS**
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I. PURPOSE

The purpose of this policy is to ensure objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of Research (as defined herein) funded under Public Health Service (PHS) grants, contracts or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. In order to ensure that Research is conducted with integrity and transparency, and that the rights and interests of human subjects are protected, arrangements involving Investigators who have a financial or fiduciary interest in an outside entity—where such arrangements may represent a source of conflict or an appearance of conflict—must be identified.

Furthermore, this policy is intended to protect Dignity Health’s interest when it is contemplating entering into an agreement or arrangement that might benefit the private interest of an Investigator of the Hospital. This policy (Appendix 5) is meant to supplement Dignity Health policy 70.7.001, *Conflict of Interest – Institutional Review Boards, Facilities, and Investigators*, but not to replace any applicable state and federal laws governing conflicts of interest applicable to nonprofit and charitable organizations.

II. APPLICABILITY

This policy is applicable to each Investigator that is planning to participate in, or is participating in, PHS Research funding by means of a grant, contract, cooperative agreement, sub-award or subcontract.

III. DEFINITIONS

As used in this policy:

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Investigator means the project director or principal Investigator (PD/PI) and any other senior/key personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Investigator responsibilities means an Investigator's professional responsibilities on behalf of Dignity Health, and as defined by Dignity Health in this policy, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. As used in this policy, the term includes any such activity for which any human subjects research funding is available from a PHS awarding component through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Hospital in the grant application, progress report, or any other report submitted to the PHS by the Hospital.

Significant financial interest means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- i. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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;
 - ii. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. This includes: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this policy, the Accountable Executive will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
3. The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Hospital to the Investigator if the Investigator, including intellectual property rights assigned to the Hospital and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

IV. GENERAL RESPONSIBILITIES OF INVESTIGATORS

Each Investigator shall:

1. Read, understand and abide by this policy,
2. Disclose of significant financial interests, and
3. Complete training regarding financial conflicts of interest prior to engaging in Research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - i. Dignity Health revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - ii. An Investigator is new to Dignity Health; or
 - iii. Dignity Health finds that an Investigator is not in compliance with this policy or prescribed FCOI management plan.

V. GENERAL RESPONSIBILITIES OF DIGNITY HEALTH

Dignity Health shall comply with the requirements set forth in 42 CFR Part 50.601 *et seq.* regarding promoting objectivity in research; these requirements include, but are not limited to:

1. Maintaining an up-to-date, written, enforced policy on financial conflicts of interest that complies with 42 CFR Part 50.601 *et seq.*, and make such policy available via a publicly accessible Web site;
2. Informing each Investigator of this policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of the regulations at 42 CFR Part 50.601 *et seq.*;
3. Requiring each Investigator to complete training regarding the same and in accordance with the circumstances noted in section IV.(3) of this policy, above;
4. Taking reasonable steps to ensure that any sub-recipient Investigator complies with this policy;
5. Providing guidelines consistent with 42 CFR Part 50.601 *et seq.* for the [designated institutional official(s)] to determine whether an Investigator's significant financial interest is related to PHS-funded Research and, if so related, whether the significant financial interest is a financial conflict of interest;
6. Taking such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a sub-recipient Investigator, pursuant to 42 CFR Part 50.601 *et seq.*;
7. Providing the PHS Awarding Component financial conflicts of interest reports, as required under the regulations found at 42 CFR Part 50.601 *et seq.*, regarding any Investigator's significant financial interest found by Dignity Health to be conflicting,

and ensuring that Dignity Health has implemented a management plan in accordance with these regulations and this policy;

8. Maintaining records relating to all Investigator disclosures of financial interests, in accordance with section XI of this policy; and
9. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

VI. INVESTIGATOR DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

1. Each Investigator who is planning to participate in the PHS-funded Research must disclose (See Dignity Health Investigator Conflicts of Interest Disclosure Statement) to the facility Accountable Executive for Research his or her significant financial interests (and those of the his or her spouse and dependent children) no later than the time of application for PHS-funded Research.
2. Each Investigator who is participating in the PHS-funded Research must submit an updated disclosure of significant financial interests at least annually, in accordance with the Dignity Health IRB approval date or research budget start date during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Hospital pursuant to section VI.(1) of this policy, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
3. Each Investigator who is participating in the PHS-funded Research must submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
4. Each Investigator who is new to participating in an ongoing PHS-funded research project must submit a disclosure of significant financial interests within thirty (30) days of joining the research project

VII. DIGNITY HEALTH FACILITY REVIEW AND MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

1. Upon disclosure of significant financial interests, the facility Accountable Executive for Research will determine whether an Investigator's significant financial interest is related to PHS-funded Research and, if so related, whether the significant financial interest is a financial conflict of interest.

Note: an Investigator’s significant financial interest is related to PHS-funded Research when the Dignity Health facility, through the facility Accountable Executive for Research, reasonably determines that the significant financial interest could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research. The Dignity Health facility may involve the Investigator in the Accountable Executive for Research determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Dignity Health facility, through its Accountable Executive for Research reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

2. Pursuant to 42 CFR Parts 50.601 et seq., the Dignity Health facility will take actions as necessary to manage any identified financial conflicts of interest. Such actions include development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report. The management plan shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
 - i. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - iv. Modification of the research plan;
 - v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - vii. Severance of relationships that create financial conflicts.

VIII. APPEALS

Appeal of the Accountable Executive’s determination may be made to the Director of the Dignity Health Human Research Protections Office (HRPO). The HRPO will consult with the Investigator and the Accountable Executive for Research and make a final determination.

IX. COMPLIANCE

Each Investigator must certify: [(See Dignity Health Investigator Conflicts of Interest Disclosure Statement)]

1. That the information disclosed in the [Dignity Health Investigator Conflicts of Interest Disclosure Statement] is true and accurate;
2. That if the [Accountable Executive determines a financial conflict of interest exists, the Investigator will adhere to all conditions or restrictions imposed upon the research project, and will cooperate fully with the Dignity Health facility and [HRPO] to monitor compliance with this policy and, if applicable, a prescribed financial conflict of interest management plan.

X. FAILURE TO COMPLY

1. Whenever the Dignity Health facility identifies a significant financial interest that was not, for whatever reason, disclosed timely by an Investigator, the Accountable Executive shall, within thirty (30) days upon discovering the significant financial interest: retrospectively review the significant financial interest; determine whether it is related to PHS-funded Research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.
2. Whenever the Dignity Health facility finds an Investigator fails to comply with a financial conflict of interest management plan, the Dignity Health facility shall, within sixty (60) days of the Dignity Health facility's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
3. If the failure of an Investigator to comply with this policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded Research, the Dignity Health facility will consider the situation and, as necessary, take appropriate action under the Dignity Health facility's policy for dealing with issues of professional or research misconduct. If necessary the Dignity Health facility will, in accordance with 42 CFR Part 50.606(a)—Remedies, promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

Note: The Dignity Health facility may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, regardless of whether a prior disclosure resulted in the Dignity Health facility's determination of a financial conflict of interest.

In any case in which the Dignity Health facility determines that a PHS-funded project of clinical Research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed in accordance with a prescribed management plan or reported by the Investigator as required by this policy, the Dignity Health facility will require the Investigator involved to disclose the financial conflict of

interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

XI. RECORDS

The Dignity Health facility will maintain records relating to all Investigator disclosures of financial interests and the Dignity Health facility's review of, and response to, such disclosures (whether or not a disclosure resulted in the Dignity Health facility's determination of a financial conflict of interest) and all actions under this policy or retrospective review, if applicable, for at least three years from the date the final research expenditures report is submitted to the PHS.

XII. REFERENCE

Dignity Health Policy – Conflict of Interest – Institutional Review Boards, Hospitals and Investigators 70.7.001.

Dignity Health Investigator Conflict of Interest Disclosure Statement (Appendix 2)

42 CFR Part 50—Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought (DHHS Final Rule August 25, 2011)

45 CFR Part 74—Uniform Administrative Requirements for Awards and Sub-awards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations