



Title:

Financial Conflict of Interest in PHS Funded Research

Document Information:

Doc. Type: Policy	
DCU No.: 0009	
Doc No.: DT-BD-007	Version No.: .01
Supersedes Doc No.: New	
Effective Date: 10/20/2015	

Author:

Name: Mary Katofiasc	Title: Director of Operations
Signature:	Date: 10/2/2015

Revised By:

Name:	Title:
Signature:	Date:

Reviewed and Approved:

Name: Ed Burgard	Title: VP of Operations
Signature:	Date: 10/19/2015
Name: Benny Ward	Title: CEO
Signature:	Date: 10/20/15

Released By:

Name: Mary Katofiasc	Title: Head of Operations
Signature:	Date: 10/21/2015

Financial Conflict of Interest in Funded Research	Document No.Version: DT-BD-07.01
	Replaces Version: New

I. PURPOSE/INTRODUCTION

This policy is designed to comply with Public Health Service (PHS) regulations (42 CFR Part 50 Subpart F, Financial Conflicts of Interest (FCOI) for Grants/Cooperative Agreements; 45 CFR Part 94, Responsible Prospective Contractors). The goal at Dignify Therapeutics (Dignify or Company) is to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will be free from bias resulting from Investigator Financial Conflicts of Interest (FCOI).

II. SCOPE/RESPONSIBILITY

The scope of this policy applies to any Dignify staff member acting as Investigator or Senior/key personnel on a PHS research project and any Sub-recipient of that project. The regulations **do not** apply to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs Phase 1 applications or awards.

III. DEFINITIONS

<p>Company Official means the individual within the Company that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator’s Family related to the Investigator’s Company responsibilities. For the purposes of this policy, the Company Official is designated as Ed Burgard, Vice President of Operations.</p>
<p>Company Responsibilities means the Investigator’s responsibilities associated with his or her Company appointment or position, such as research, teaching, administration, and internal and external professional committee service.</p>
<p>Family means any member of the Investigator’s immediate family, specifically, any dependent children and spouse.</p>
<p>Financial Interest means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable.</p> <p>For Investigators, Financial Interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Company responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.</p>

Financial Conflict of Interest in Funded Research	Document No.Version: DT-BD-07.01
	Replaces Version: New

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from Dignify Therapeutics (including intellectual property rights assigned to the Company, agreements to share in royalties related to such rights, and any ownership interest in the Company);
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or,
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

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.

Investigator means the Project Director (PD) or Principal Investigator (PI) and any other person, 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.

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

Sub-recipient means any party that has entered into an Agreement with Dignify Therapeutics as a subgrantee, subcontractor, collaborator, contractor, or consultant.

Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Company Responsibilities, and is:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
- d) income related to intellectual property rights and interests not reimbursed through the Company.

The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Company to the Investigator if the Investigator is currently employed or otherwise appointed by the Company, including intellectual property rights assigned to the Company and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Company is a commercial or for-profit organization; 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. RESPONSIBILITIES

A. Investigators:

1. Must complete FCOI training prior to engaging in PHS research project and thereafter, every four years if research is still funded. See section F: Training for requirements.
2. Must complete and submit to the Company Official a Financial Conflict of Interest Disclosure Form (DT-RegF-06 Financial Interest Disclosure and if necessary DT-RegF-07 Addendum to Financial Interest Disclosure) prior to working on PHS funded projects.
3. Must update the Financial Conflict of Interest Disclosure Form (DT-RegF-06 and if necessary DT-RegF-07) annually or within 30 days of a change in financial status (acquisition of new financial interest), whichever occurs first.

B. Sub-Recipient

1. Must complete and submit to the Company Official a Financial Conflict of Interest Disclosure Form (DT-RegF-08 Sub-Recipient Financial Disclosure) prior to working on PHS funded projects.
 - a. Subrecipient organization will certify that it currently has a PHS FCOI-compliant policy in place on form DT-RegF-08.
 - b. Subrecipient organization will certify that each Investigator will complete the required training prior to engaging in any PHS-funded grant/contract and any on-going training as necessary on form DT-RegF-08
 - c. If subrecipient organization does NOT have a PHS-compliant policy, it will certify that it intends to have a PHS-compliant FCOI policy in place by the time of award, OR certify that it intends to abide by Dignify's policy on form DT-RegF-08.

Financial Conflict of Interest in Funded Research	Document No.Version: DT-BD-07.01
	Replaces Version: New

C. Company Official (CO)

1. Prior to the Company’s expenditure of any funds under a PHS-funded research project:
 - a. Must review all Financial Conflict of Interest Disclosure Forms from PHS-funded Investigators and Sub-recipients.
 - b. Must determine whether Investigators working on a PHS-funded research project have any FCOI.
 - i. If there is no FCOI or the FCOI is remedied prior to expenditure of grant funds no report needs to be submitted.
 - ii. For any significant FCOI disclosed and not remediated prior to expenditure of funds, a report will be provided to the PHS Awarding Component. The FCOI report will define the financial conflict of interest and detail the Company’s management plan.
 1. Monitors Investigator’s compliance with the FCOI management plan until the completion of the research project.
 2. Submits an annual report to the Awarding Component that shall specify whether the reported financial conflict is still being managed or explain why the financial conflict of interest no longer exists. Annual reports will be submitted for the duration of the project period in the time and manner specified.
2. Subsequent to the initial submission, any new identified FCOI will be reported within 60 days to the Awarding Component.
3. Wherein a FCOI was not disclosed timely, the Company will complete a retrospective review to determine whether any PHS funded research conducted prior to the identification and management of the FCOI was biased in the design, conduct or reporting of such research.
 - a. If bias is found, CO will notify the PHS Awarding Component promptly and submit a mitigation report.
4. Maintains Dignify’s FCOI policy on the Dignify Therapeutics external website.

D. President and CEO

1. Ensures compliance with FCOI policy and determines disciplinary action in the event of non-compliance.
2. In cases where the Company Official determines that a potential FCOI exists, develops and coordinates implementation of FCOI management plan in consultation with the CO. The FCOI management plan must be completed in advance of Dignify expending PHS funds – and a summary of the management plan must be included in the FCOI Report.

E. Retrospective Review

Should a significant financial interest, that was not disclosed timely and was not previously reviewed by the Company Official, be identified, the Company will document the retrospective review. Such documentation shall include but is not limited to these key elements:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;

Financial Conflict of Interest in Funded Research	Document No.Version: DT-BD-07.01
	Replaces Version: New

4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

F. Training

Each Investigator must complete training on this policy:

1. Prior to engaging in research funded by PHS.
2. Every four years thereafter if engaged in PHS funded research.
3. Anytime policy is amended.
4. At the request of the Company Official to reinforce policy compliance.

To document training compliance please:

Complete the NIH tutorial at:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> and forward a copy of the certificate of completion to Dignify Therapeutics' Director of Operations along with the form DT-RegF-05: Regulatory Document Acknowledgement Receipt.

G. Record Retention

The Company Official or designee will maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures for at least three years from the date of the final expenditures report is submitted to the PHS

H. Public Accessibility

Prior to the Company's expenditure of any funds under a PHS-funded research project, the Company shall post this policy to its website. The Company will also ensure public accessibility via written response to any requestor within five business days of a request of information concerning any significant financial interest disclosed to the Company that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by the Senior/key personnel as defined by this subpart;
2. The Institution determines that the significant financial interest is related to the PHS-funded research; and
3. The Institution determines that the significant financial interest is a financial conflict of interest.

Information the Company makes available to a written response to any requestor within five business days of a request shall include at minimum, the following:

1. Investigator's name and title
2. role with respect to the research project
3. name of the entity in which the significant financial interest is held

Financial Conflict of Interest in Funded Research	Document No.Version: DT-BD-07.01
	Replaces Version: New

4. the nature of the significant financial interest; and
5. approximate dollar value of the significant financial interest: (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000),
 - a. or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Form DT-RegF-09 Public FCOI Disclosure may be used for remittance.

I. Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Company may make such information available to an agency funding research of the Company, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Company, if requested or required. If the Company is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

V. REFERENCES

1. Form DT-RegF-06: Financial Interest Disclosure
2. Form DT-RegF-07: Addendum to Financial Interest Disclosure
3. Form DT-RegF-08: Sub-Recipient Financial Disclosure
4. Form DT-RegF-09: Public FCOI Disclosure

VI. ATTACHMENTS

1. Attachment I: Revision History Table

Financial Conflict of Interest in Funded Research	Document No.Version: DT-BD-07.01
	Replaces Version: New

Attachment I: Revision History Table

Approval Date (MM/DD/YYYY)	Revision #	Author	Description of Change (section and description)