

Deutsches Krebsforschungszentrum (DKFZ)
Policy on Financial Conflicts of Interest (FCOI)
(effective date: 01 January 2020)

I. Introduction

In 2011 the regulations with regard to the responsibility of applicants for promoting objectivity in research (42 CFR¹ Part 50 Subpart F) in the United States have been revised. The purpose of the revised regulations is to promote objectivity in research by establishing standards, so that it can be reasonably expected that the design, conduct, and reporting of research performed under Public Health Service (PHS) funding will be free from bias resulting from Investigator financial conflicts of interest. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation and applies to each grant or cooperative agreement with an issue date of the Notice of Award that is subsequent to 24 August 2012.

Institutions applying for or already receiving PHS Funding by means of a grant or cooperative agreement, as well as all Investigators (as defined in section "II. Definitions") planning to participate or already participating in such research, have to be in compliance with the revised FCOI regulations.

The present FCOI Policy describes the respective administrative procedure at DKFZ to identify and manage FCOI, and gives an overview about the required FCOI training of the investigators and other requirements in the FCOI regulation.

The above-mentioned Investigators as defined in the next section are obliged to comply with the requirements of this FCOI Policy.

II. Definitions

Disclosure of significant financial interests

SFI disclosure means Investigator's disclosure of significant financial interests to DKFZ, in general by means of the form "Significant Financial Interest (SFI) Disclosure Form".

Financial conflict of interest (FCOI)

A FCOI exists if the responsible Institutional Official reasonably determines that a certain SFI could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report

FCOI report means DKFZ's report of a financial conflict of interest to a PHS Awarding Component.

¹ CFR = Code of Federal Regulations in the USA

Financial interest

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

HHS

HHS comprises the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution

In general, Institution means with regard to FCOI regulations any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding; in this policy it means DKFZ.

Institutional officials

The members of the Grants Office are designated by the Management Board of DKFZ as Institutional Officials, i.e. persons in charge with regard to FCOI topics (e.g. together with the Management Board responsible for the review of SFI disclosures, determination of SFI relation to PHS-funded research, etc.).

Institutional responsibilities

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of DKFZ, which may include for example: 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.

Investigator

Investigator means the project director or principal investigator 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.

Manage

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

Management plan

The Management plan shall specify the actions that have been, and shall be, taken to manage such FCOI; it shall include role and principal duties of the conflicted Investigator in the research project, conditions of the management plan, how the management plan is designed to safeguard objectivity in the research project, confirmation of the Investigator's agreement to the management plan, how the management plan will be monitored to ensure Investigator compliance; and other information as needed.

Mitigation report

This report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and DKFZ's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

PD/PI

These abbreviations mean a project director or principal investigator of a PHS-funded research project; the PD/PI is included in the definitions of Senior/key personnel and Investigator under the FCOI regulation.

PHS

PHS comprises 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).

PHS Awarding Component

This term means the organizational unit of the PHS that funds the research that is subject to the FCOI regulation (e.g. the National Institutes of Health).

Public Health Service Act or PHS Act

That means the statute codified at 42 U.S.C. 201 et seq.

Research

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. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in the FCOI regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a

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

Retrospective review

Whenever a FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI that is determined by DKFZ to constitute an FCOI; failure by DKFZ to review or manage such a FCOI; or failure by the Investigator to comply with an FCOI management plan, DKFZ shall, within 120 days of DKFZ'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.

Senior/key personnel

Senior/key personnel mean the PD/PI and any other person identified as senior/key personnel by DKFZ in the grant application, progress report, or any other report submitted to the PHS by DKFZ under the FCOI regulation.

Significant financial interest (SFI)

SFI 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**:
 - a) With regard to any publicly traded entity, an SFI 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;
 - b) With regard to any non-publicly traded entity, an SFI 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

- c) 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 his/ her spouse or dependent children not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. The disclosure is only required when the aggregate value in the last 12 months provided by any single entity exceeds US \$5,000. Moreover, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a U.S. Federal, state, or local government agency; or 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 located in the U.S. This disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this FCOI policy, the Institutional officials 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 SFI **does not include** the following types of financial interests: salary, royalties, or other remuneration paid by DKFZ to the Investigator if the Investigator is currently employed or otherwise appointed by DKFZ, including intellectual property rights assigned to DKFZ 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 U.S. 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 located in the U.S.; or income from service on advisory committees or review panels for a U.S. Federal, state, or local government agency; or 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 located in the U.S.

III. Responsibilities

1. DKFZ:
- complying with the FCOI regulation, including developing, maintaining and communicating a written and enforced FCOI policy;
 - promoting and enforcing Investigators' compliance with the FCOI regulation, e.g. by implementing this policy, regular trainings, or publishing notes within the intranet;
 - collecting SFI disclosures of participating investigators;

- reviewing the disclosure and determining which SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI;
- managing, reducing, or eliminating these FCOI (development and implementation of a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI, perhaps including interim measures, and considering any FCOI of subrecipient Investigator; retrospective review, if necessary); and
- reporting FCOI to the PHS;
- retaining all disclosures of SFIs as well as the respective reviews for three years from the date the final expenditure report is submitted to the PHS;
- maintaining confidentiality of reported information as far as is practicable and consistent with legal obligations. All information provided for review is shared only with staff who are involved in the processing and review of the information, as well as those who create and implement management plans. Other individuals receive this information only on a need-to-know basis. Individuals with access to confidential personal information have an obligation of confidentiality.

2. Investigator:

- complying with DKFZ's policies and procedures;
- disclosing the required information to DKFZ in a timely manner.

IV. Enforcement mechanisms / Sanctions

The non-compliance of an Investigator with this policy may result in one or more of the following sanctions:

- The Institutional officials will report the failure to comply with the FCOI regulation to the Management Board;
- The Investigator will be deemed ineligible to maintain principal investigator status on sponsored projects;
- The individual will be deemed ineligible to enter into technology transfer agreements;
- The Management Board shall be responsible for enforcing this policy, and shall take reasonable steps to respond appropriately to violations, including, but not limited to suspending expenditures on a research account or instituting disciplinary measures.

V. Identification of FCOIs

1. Who identifies FCOI?

DKFZ has designated Institutional officials in the Grants Office to solicit and review disclosures of SFI.

In accordance with this FCOI policy, the Institutional officials 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.

2. When are FCOIs identified?

- Each Investigator must disclose SFI (and those of Investigator's spouse and dependent children) no later than the time of application to the Institutional officials
- SFI disclosure must be updated at least annually during the period of the award (around ten months after the Institutional officials have received the SFI disclosure, the Investigator is requested to provide the update, if necessary);
- In case of acquired SFI, Investigators participating in PHS-funded research must submit an updated disclosure within 30 days of acquiring (e.g. through purchase, marriage, or inheritance).

3. How are FCOIs identified?

- The disclosure forms are sent to the Institutional Officials for review.
- The Institutional Officials review the disclosure forms.
- An Investigator's SFI is related to PHS-funded research when DKFZ, through its Institutional officials, reasonably determines that the SFI could affect the PHS-funded research; or is in an entity whose financial interest could be affected by the research.
- The Investigator may be involved in the Institutional officials' determination of whether an SFI is related to the PHS-funded research.
- An FCOI exists when DKFZ, through its Institutional officials and in close collaboration with the Management Board, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research
- In any case, Investigators are informed about the determination and the consequences are clarified.

4. Procedure in case of subrecipients

In case of subrecipients of DKFZ, DKFZ must take reasonable steps to ensure that Investigators working for these entities comply with the FCOI regulation, either by requiring those Investigators to comply with DKFZ's policy or by requiring the entities to provide assurances to DKFZ that will enable DKFZ to comply with the FCOI regulation. The procedures with regard to addressing subrecipient requirements are decided case by

case, depending on the project partner, and always in accordance with the FCOI regulation.

VI. Management of FCOIs

1. Prior to the expenditure of any funds under a PHS-funded research project, the Institutional officials of DKFZ shall
 - review all Investigator disclosures of SFIs;
 - determine whether any SFI is related to PHS-funded research;
 - determine whether an FCOI exists; and, if so,
 - develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such FCOI;
 - monitor the Investigator's compliance with this management plan.

2. In case of an FCOI, the following conditions might be imposed to manage the FCOI (the list is not limited):
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
 - Modification of the research plan;
 - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
 - Severance of relationships that create FCOI.

3. Whenever an FCOI is not identified or managed in time, DKFZ shall within 120 days of DKFZ'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 noncompliance, was biased in the design, conduct, or reporting of such research.
 - a) The documentation of this retrospective review shall include:
 - Project number;
 - Project title;
 - PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;

- Name of the entity with which the Investigator has a FCOI;
 - Reason(s) for the retrospective review;
 - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - Findings of the review; and
 - Conclusions of the review.
- b) The next steps after the retrospective review shall be
- an update of the previously submitted FCOI report, if necessary;
 - a specification of the plan to manage the FCOI;
 - in case of found bias, the prompt notification of the PHS Awarding Component as well as the submission of a mitigation report to the PHS Awarding Component including the key elements documented in the retrospective review mentioned above and a description of the impact of the bias on the research project and the action plan of DKZ to eliminate or mitigate the effect of the bias (e.g. impact on the research project).
4. Furthermore, the management of FCOI requires that, prior to the expenditure of any funds under a PHS-funded research project by DKFZ, information concerning any SFI disclosed to DKFZ is made available via written response to any requestor within five business days of a request under the following conditions:
- The SFI was disclosed and is still held by the senior/key personnel;
 - DKFZ determines that the SFI is related to the PHS-funded research; and
 - DKFZ determines that the SFI is an FCOI.

This information by DKFZ shall include:

- the Investigator's name;
- the Investigator's title and role with respect to the research project;
- the name of the entity in which the SFI is held;
- the nature of the SFI;
- the approximate dollar value of the SFI (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), 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; and
- the note that the information provided is current as of the date of the correspondence and is subject to updates, on an annual basis and within 60 days of the identification by DKFZ of a new FCOI, which should be requested subsequently by the requestor.

VII. Reporting of FCOIs

1. Prior to the expenditure of any funds under a PHS-funded research project, DKFZ shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by DKFZ to be conflicting and ensure that DKFZ has implemented a management plan in accordance with the FCOI regulation. The report is only necessary, if such an FCOI has not been eliminated prior to the expenditure of PHS-awarded funds.
2. In case of FCOIs identified subsequent to the initial DKFZ FCOI report during an ongoing PHS-funded research project (e.g. upon the participation of an Investigator who is new to the research project), DKFZ shall provide to the PHS Awarding Component, within 60 days, an FCOI report and ensure that a management plan has been implemented in accordance with the FCOI regulation.
3. In a nutshell, there are initial and ongoing FCOI reports; they must be sent:
 - Prior to the expenditure of funds;
 - Within 60 days of identification for an Investigator who is newly participating in the project;
 - Within 60 days for new, or newly identified, FCOIs for existing Investigators;
 - At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
 - Following a retrospective review to update a previously submitted report, if appropriate.
4. The FCOI reports shall include the following:
 - Project number;
 - PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - Name of the Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - Value of the 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), 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;

- A description of how the financial interest relates to the PHS-funded research and the basis for DKFZ's determination that the financial interest conflicts with such research; and
 - A description of the key elements of the management plan of DKFZ, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.
5. Any FCOI reported to the PHS Awarding Component must be updated by means of an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the project period. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Such annual FCOI reports DKFZ provides to the PHS Awarding Component for the duration of the project period (including extensions with or without funds).
 6. In addition to FCOI reports, a mitigation report must be submitted to the PHS Awarding Component in cases where a retrospective review was required and bias was found.
 7. If a written request to make information concerning identified FCOIs is received, the Institutional officials provide feedback in close collaboration with the Investigator and the Management Board.
 8. After an FCOI is reported to PHS, it is reviewed to determine if additional information is needed. After considering the additional information provided, the PHS may decide that further action is needed to ensure the objectivity of the research, or that DKFZ has not managed, reduced, or eliminated the FCOI in accordance with the regulation. The PHS may determine that suspension of funding is necessary until the matter is resolved.

VIII. Remedies

1. In case of non-compliance of Investigators with this policy, DKFZ shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The same applies if an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to DKFZ for further action, which may include directions to DKFZ on how to maintain appropriate objectivity in the

PHS-funded research project. PHS may, for example, require DKFZ to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

2. The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the DKFZ review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in DKFZ's determination of an FCOI. DKFZ is required to submit, or permit on-site review of, all records pertinent to compliance with the FCOI regulation. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that DKFZ has not managed the FCOI in accordance with the FCOI regulation. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.
3. In any case in which the HHS 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 an FCOI that was not managed or reported by DKFZ as required by the FCOI regulation, DKFZ shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

IX. FCOI Training for Investigators

This policy will be listed as one of the important documents newcomers must read when starting at DKFZ. Prior to engaging in research related to any PHS-funded grant, it is pointed out that Investigators must comply with this policy. At least every four years, Investigators must be trained with regard to the FCOI regulation, as well as in cases of modifications of the regulations or responsibilities, and in cases of non-compliance with the policy or management plan.

The procedure for informing Investigators of the policy, the respective responsibilities, CFR etc.: Scientists are directly addressed and receive a link to the training documents that are published in the intranet. The Institutional officials will provide the necessary information to ensure compliance.

X. Forms, Links, and other information

1. The respective forms with regard to FCOI topics are available in the Intranet of DKFZ.

2. Please find below the links to the FCOI regulation as well as the corresponding FAQs:
 - [42 CFR Part 50 Subpart F \(FCOI regulation\)](#)
 - [FAQs to the FCOI regulation](#)

3. Several other regulations and policies apply to the FCOI regulation. They include, but are not necessarily limited to:
 - 2 CFR part 376—Nonprocurement debarment and suspension (HHS)
 - 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
 - 45 CFR part 16—Procedures of the Departmental Grant Appeals Board
 - 45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations
 - 45 CFR part 79—Program fraud civil remedies
 - 45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State, local, and tribal governments