

Directives on financial conflicts of interest in projects funded by the U.S. Department of Health and Human Services

The University Board of Directors,

on the basis of Article 39 par. 1 item b of the law governing the University of 5 September 1996 (UniG) decrees:

Preamble

Truthfulness and integrity are core elements of research and scientific work. They are also a prerequisite for scientific credibility and justify the right to freedom in research. The University does not tolerate any form of bias resulting from financial conflicts of interest. These directives establish standards to assure that the design, conduct and reporting of research is objective and free from such bias. They comply with U.S. Code of Federal Regulations on Promoting Objectivity in Research (42 CFR Part 50 Subpart F) and Responsible Prospective Contractors (45 CFR Part 94).

I. General Provisions

Art. 1 Applicability

¹ These directives apply to the principal investigator (PI) and any other person, hereafter referred to as "Investigator", regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the U.S. Department of Health and Human Services (HHS; such funding agencies as the National Institutes of Health, Centers for Disease Control and Prevention, and U.S. Food and Drug Administration). This includes collaborators, subrecipient PIs and consultants, where applicable.

² These directives constitute a minimum applicable standard. If a faculty has its own regulations on financial conflicts of interest that are stricter than these directives, the faculty shall apply its own regulations. However, if the regulations of the faculty are not compatible with these directives, the regulations included in this document shall apply.

³ These directives do not cover any questions relating to moral, ethical, or political issues that might arise in connection with the research projects themselves.

Art. 2 Definitions

¹ A *financial interest* means anything of monetary value, whether or not the value is readily ascertainable.

² A *significant financial interest* (SFI) means one or more of the following interests of the Investigator and the Investigator's spouse / registered partner and any dependent children that relates to the Investigator's institutional responsibilities (e.g., research, consultation, teaching, membership or service on institutional committees and boards):

- a remuneration received from a publicly traded entity in the 12 months prior to the SFI disclosure and any equity interest at the date of disclosure that exceeds US\$5,000 when aggregated. Remuneration includes salary and any payment for services (e.g., consulting fees, honoraria, paid authorship). Equity interest includes any stock, stock options, or other ownership interest.
- b remuneration received from a non-publicly traded entity in the 12 months prior to the SFI disclosure that exceeds US\$5,000 when aggregated, or any equity interest at the date of disclosure.
- c receipt of income from intellectual property rights and interests (e.g., patents, copyrights) in the 12 months prior to the SFI disclosure that exceeds US\$5,000 when aggregated.
- d reimbursed or sponsored travel (i.e., paid on behalf of the Investigator and not reimbursed to the Investigator) in the 12 months prior to the SFI disclosure that exceeds US\$5,000 when aggregated.

³ An SFI does not include the following types of financial interests:

- a salary, royalties or other remuneration paid by the University of Bern to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the University of Bern and agreements to share in royalties related to such rights,
- b income from seminars, lectures or teaching engagements sponsored by a government agency, institution of higher education, academic teaching hospital, or medical center / research institute affiliated with an institution of higher education,
- c income from serving on advisory committees or review panels for a government agency, institution of higher education, academic teaching hospital, or medical center / research institute affiliated with an institution of higher education,
- d travel that is reimbursed or sponsored by a government agency, institution of higher education, academic teaching hospital, or medical center / research institute affiliated with an institution of higher education.

⁴ A *financial conflict of interest* (FCOI) exists when the University of Bern, through its designated FCOI Officer (cf. Art. 5), determines that an SFI is related to an HHS-funded research project and could directly and significantly affect the design, conduct or reporting of the HHS-funded project.

II. Requirements

Art. 3 Training

¹ Each Investigator shall complete FCOI training, regardless of whether or not an FCOI exists:

- a prior to engaging in research on an HHS-funded project,
- b immediately if the Investigator joins the University of Bern with an ongoing HHS-funded project,
- c at least every four years during an HHS-funded project,
- d immediately if the University of Bern revises its FCOI procedures in any manner that affects the Investigator,
- e immediately if it is determined that the Investigator is not in compliance with the University of Bern's FCOI policy.

Art. 4 Disclosure of SFIs

¹ Each Investigator shall disclose their own SFIs and those of their spouse / registered partner and dependent children, or certify that no such SFIs exist:

- a* no later than the time of application for HHS-funded research,
- b* annually during the HHS-funded project,
- c* within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) an SFI.

² The Investigator makes the SFI disclosure or certifies that no SFIs exist by completing a disclosure form. If an SFI is disclosed, specific details are provided on an additional form.

³ The disclosure of an SFI shall include:

- a* for remuneration, the name and address of the entity, and the nature and amount of remuneration received in the 12 months prior to the disclosure,
- b* for equity interest, the name and address of the entity, and the nature and value of the equity interest at the date of the disclosure,
- c* for travel, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration, as well as the monetary value, if known.

III. FCOI Officer

Art. 5

¹ The University Board of Directors appoints an FCOI Officer.

² The FCOI Officer serves a 2-year term and may be reappointed.

³ The FCOI Officer is responsible for coordinating the implementation of the University of Bern's FCOI policy and procedures. This includes:

- a* soliciting and reviewing disclosures of SFI of Investigators (and the Investigators' spouse / registered partner and dependent children),
- b* determining if an FCOI exists,
- c* developing and implementing plans to manage an SFI determined to be an FCOI,
- d* timely reporting to the relevant funding agency.

⁴ The FCOI Officer is also the point of contact for reports of noncompliance of a University of Bern Investigator by other persons (cf. Art. 8).

IV. Procedures

Art. 6 Determination and management of FCOIs

¹ If the SFI disclosure form contains an SFI, the FCOI Officer shall use the additional form with detailed information on the SFI to promptly determine if the SFI relates to the HHS-funded project and whether an FCOI exists.

² An Investigator's SFI is related to the HHS-funded project if the FCOI Officer reasonably determines that the SFI:

- a* could be affected by the HHS-funded research, or
- b* is in an entity whose financial interest could be affected by the research.

³ An SFI that is related to the HHS-funded project is an FCOI if the FCOI Officer reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the HHS-funded research.

⁴ The FCOI Officer may request additional information from the Investigator and may involve the Investigator in the determination of the FCOI.

⁵ If an FCOI is identified, the FCOI Officer will communicate the determination to the Investigator and any other University of Bern administrative units as needed.

⁶ The FCOI Officer will undertake all actions deemed necessary to reduce or eliminate the FCOI, including developing and implementing a management plan, to ensure to the extent possible that the design, conduct, and reporting of research will be free from bias. For an FCOI disclosed or identified in an ongoing project, this process shall be completed within 60 days of the date of disclosure or of the FCOI Officer becoming aware of an FCOI that was not disclosed or not previously reviewed. For an FCOI disclosed during application submission, this process shall be completed before project start.

⁷ Examples of conditions or restrictions that might be imposed to manage an FCOI include:

- a* public disclosure of an FCOI when presenting or publishing the research,
- b* disclosure of an FCOI to participants if the project involves human subjects,
- c* appointment of an independent monitor to protect the research against bias,
- d* modification of the research plan,
- e* change of personnel or personnel responsibilities, or prohibiting personnel from participation in a portion of the research,
- f* reduction or elimination of the SFI (e.g., through sale of an equity interest),
- g* severance of relationships that create an FCOI.

⁸ Depending on the nature of the SFI, the FCOI Officer may determine that interim measures are necessary with regard to the Investigator's participation in the HHS-funded project between the date of disclosure and the completion of the determination.

⁹ The Investigator must agree in writing to the proposed management plan before any related HHS-funded research can be undertaken or continued.

¹⁰ If the funding agency decides that a particular FCOI will bias the objectivity of the research to such an extent that further corrective action is needed, or that the University of Bern has not managed the FCOI adequately, they may impose specific award conditions or other enforcement actions, or suspend funding until the matter is resolved.

¹¹ If the funding agency determines that an HHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has an FCOI that was not managed or reported by the University of Bern as required, the Investigator shall be required to disclose the FCOI in every public presentation of the research results and to request an addendum to previously published presentations.

Art. 7 Reporting and monitoring of FCOIs

¹ If an FCOI is identified before project start, the FCOI Officer shall provide a report to the funding agency and ensure that a management plan has been implemented prior to the expenditure of funds. If an FCOI was identified and eliminated before project start, a report shall not be submitted.

² If an FCOI is identified during an ongoing HHS-funded project, the FCOI Officer shall provide a report to the funding agency within 60 days and ensure that a management plan has been implemented or updated.

³ In addition, whenever an FCOI has not been disclosed, reviewed, or managed in a timely manner, or whenever an Investigator fails to comply with a management plan, the FCOI Officer shall complete a retrospective review within 120 days to determine whether the design, conduct, or reporting of the

HHS-funded research conducted prior to the determination of the FCOI or during the period of non-compliance was biased.

⁴ If bias is found during the retrospective review, the FCOI Officer shall promptly notify the funding agency and submit a mitigation report that details the review, describes the impact of the bias on the research project, and the plan of action taken to eliminate or mitigate the effect of the bias. Depending on the nature of the FCOI, the FCOI Officer may determine that interim measures are necessary with regard to the Investigator's participation in the HHS-funded project between the date of disclosure and the completion of the review.

⁵ The information submitted in an FCOI report shall include as a minimum:

- a* the project number,
- b* the name of the project PI or contact PI,
- c* the name of the Investigator with the FCOI,
- d* the name of the entity in which the SFI is held,
- e* the nature of the SFI (e.g., equity, consulting fee, travel reimbursement, honorarium),
- f* the value of the SFI (given as a range: \$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 SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value,
- g* a description of how the SFI relates to the HHS-funded research and the basis for the determination that the SFI conflicts with such research,
- h* a description of the key elements of the management plan, including the role and principal duties of the conflicted Investigator, the conditions of the plan and how it is designed to safeguard objectivity, confirmation of the Investigator's agreement to the plan, and details of how the plan will be monitored to ensure Investigator compliance.

⁶ The FCOI Officer shall periodically review the research project and monitor its compliance with the management plan.

⁷ An updated FCOI report that addresses the status of any FCOI and any changes to the management plan shall be submitted annually for the duration of the project, in the time and manner specified by the funding agency.

Art. 8 Noncompliance

¹ It shall be considered a violation of University of Bern policy subject to disciplinary action if an Investigator:

- a* refuses to undergo FCOI training,
- b* fails to disclose an SFI as required herein,
- c* provides false information,
- d* fails to provide timely information as required herein,
- e* fails to comply with an established FCOI management plan.

² The FCOI Officer shall report any violation of policy to the University Board of Directors.

³ The University Board of Directors shall assess the violation and decide on the imposition of sanctions and/or further administrative measures. The Investigator is given the opportunity to comment.

⁴ Any sanctions or measures imposed will be in accordance with the applicable University and personnel laws.

⁵ If the noncompliance appears to have biased the design, conduct, or reporting of the HHS-funded research, the FCOI Officer shall promptly notify the relevant funding agency of the corrective action taken or to be taken.

Art. 9 Public accessibility, confidentiality and record retention

¹ The FCOI Officer shall ensure that information regarding an ongoing FCOI is made available in writing to any requestor within 5 business days of a request.

² The information regarding an ongoing FCOI that is made available shall include as a minimum:

- a* the Investigator's name,
- b* the Investigator's title and role with respect to the research project,
- c* the name of the entity in which the SFI is held,
- d* the nature of the SFI (e.g., equity, consulting fee, travel reimbursement, honorarium),
- e* the value of the SFI (given as a range: \$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 SFI is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

³ The completed SFI disclosure form is available to University of Bern administrative units as needed (e.g., audit) and a copy may be requested by the Investigator's superiors.

⁴ The additional form with detailed information on the SFI is confidential and shall only be released by the FCOI Officer to the University Board of Directors, funding agency or audit authority officials if required. In such an event, the Investigator shall be informed.

⁵ All records relating to disclosure and review of SFIs, the response to such disclosures (whether or not it resulted in a determination of an FCOI), and the actions under the FCOI policy must be kept for 3 years from the date of submission of final expenditure reports to the funding agency, with the following exceptions:

- a* If any legal or administrative action (e.g., audit) is started before the expiration of the 3-year period, the FCOI documents and records must be retained until the action has been resolved.
- b* If a funding agency, audit authority or pass-through entity (main awardee) notifies the University of Bern in writing to extend the retention period.

⁶ Information on the FCOI shall remain available for responses to written requests for at least 3 years from the date that the information was most recently updated.

V. Effective date

Art. 10 These directives take effect immediately and replace the *Directives of the University Board of Directors concerning the handling of grants from the US National Institutes of Health to research projects of entities of the University of Bern* of 21 October 2014.

Bern, 17 November 2020

On behalf of the
University Board of Directors:



Prof. Dr. Christian Leumann, Rector