

# Regulation of the University of Basel concerning Financial Conflicts of Interest (FCOI) in projects receiving research funds from the U.S. National Institutes of Health (NIH)

dated 4 July 2017

The President's Board agrees:

## 1. General Provisions.

### §1 Basic Principle

<sup>1</sup> Persons, who are involved in or work on projects at the University of Basel funded or financially supported by the U.S. National Institutes of Health (NIH), are required to comply with the terms of these regulations. They are hereinafter referred to as Investigators.

<sup>2</sup> Investigators may be in charge of an NIH project (University of Basel as Main Awardee) or they may be in charge of an NIH sub-project (University of Basel as sub-awardee).

### §2 Prevailing Legal Provisions

<sup>1</sup> In addition to complying with university, cantonal, and national regulations, Investigators must observe the terms of the NIH, which are set out in the *NIH Grants Policy Statement*.

<sup>2</sup> When conducting NIH projects, Investigators of NIH projects must comply with the terms of the U.S. Federal Regulation on Financial Conflicts of Interest, [42 Code of Federal Regulations Part 50 subpart F<sup>2</sup>](#)

### §3 Obligation to report

Investigators must inform the Vice President's Office for Research when they apply for research funding from the NIH. Details about the proposal must be entered in the Grants Tool ([www.grants.unibas.ch](http://www.grants.unibas.ch)) at least six weeks before the submission of the proposal.

## 2. Financial Conflicts of Interest (FCOI)

### §4 Basic Principle

Investigators are required to disclose, to the University of Basel, all financial interests which could be termed a Financial Conflict of Interest as defined in §5 of these regulations.

### §5 Financial Conflict of Interest

<sup>1</sup> A Financial Conflict of Interest is defined as the presence of monetary assets, income or sponsored travel held by or paid to Investigators, their spouses or their dependent children that could directly and significantly affect the design, conduct or reporting of the NIH sponsored research.

<sup>2</sup> Financial interests that are covered by a contractual relationship with the University of Basel are excluded from these terms. Compensation for teaching duties and consulting services for public or non-profit organizations are also excluded from these terms.

## **§6 Tutorial on Financial Conflict of Interest**

Prior to the submission of an application to the NIH, Investigators will complete an online FCOI tutorial. Investigators repeat the FCOI tutorial thereafter at least every four years. Written confirmation of participation must be sent to the Vice President's Office for Research.

## **§7 Reporting Financial Interests**

<sup>1</sup> At the time of application all Investigators of NIH proposals must use the self-declaration form to declare if and which financial interests as defined in §§ 4 and 5 are present.

<sup>2</sup> Investigators of running projects will complete a *self-declaration form* on an annual basis for the duration of the project. If financial interests arise during the course of a project, Investigators must declare them within 30 days to the Vice President's Office for Research by sending an updated *self-declaration form*.

<sup>3</sup> Reports regarding Financial Conflicts of Interest (*self-declaration forms*) are confidential documents. The Vice President's Office for Research may, however, present the form to members of the Presidents Board and the University Council as well as to staff at the University of Basel that have been designated by the aforementioned bodies. In the case of an actual conflict of interest, the self-declaration form may be presented to the *Chief Grants Management Officer* at the NIH (if the University of Basel is the main awardee) or to the institution that is in charge of the project (if the University of Basel is sub-awardee) or to an authorized requestors according to *42 Code of Federal Regulation Part 50 Subpart F*.

<sup>4</sup> The University of Basel will retain reports on financial interests (self-declaration forms) for at least three years after an NIH project has been concluded.

## **§ 8 Procedure for reporting Financial Conflicts of Interest**

<sup>1</sup> If Financial Conflicts of Interest are reported, the Vice President's Office for Research informs the Vice President for Research immediately, who in turn informs the President's Board. A Financial Conflict of Interest is deemed present if the President's Board decides that a financial interest impairs the objectivity of the NIH project. The Vice President for Research reports the Financial Conflict of Interest within 60 days, to the *Chief Grants Management Officer* at NIH (if the University of Basel is the *main awardee*) or to the institution in charge of the project (if the University of Basel is a *sub-awardee*).

<sup>2</sup> The Vice President for Research charges the *Investigator* concerned to forthwith settle or remove the Financial Conflict of Interest. Within 30 days, the Investigator must send a report on the changes to the Vice President for Research for the attention of the President's Board.

<sup>3</sup> If the President's Board reaches the conclusion that the Financial Conflict of Interest has been sufficiently settled the Vice President Research will report to the responsible offices, as described in § 8 sub-section 1.

<sup>4</sup> If the President's Board reaches the conclusion that the objectivity of the NIH project continues to be impaired, or if the Investigator fails to submit a report, the Vice President for Research informs the responsible offices, as described in § 8 point 1. The Vice President for Research

will then take the necessary measures. Such measures include removing individual Investigators from a project or termination of a project.

## **§ 9 University of Basel as Main awardee.**

<sup>1</sup> If the University of Basel is the *main awardee* of an NIH project, it is responsible for ensuring that all participating entities (*sub-awardees*) comply with the terms of the US federal regulations *42 Code of Federal Regulations Part 50 Subpart F*.

<sup>2</sup> All participating sub-awardees are required to set out their own terms concerning financial conflict of interest, which comply with *42 Code of Federal Regulations Part 50 Subpart F*. Participating *sub-awardees* have the obligation to report within 30 days any existing Financial Conflict of Interest in connection with an NIH project to the University of Basel via the Vice President's Office for Research. The Vice President for Research in turn informs the *Chief Grants Management Officer* at NIH.

<sup>3</sup> If a participating *sub-awardee* has no adequate FCOI policy for NIH projects the *sub-awardee* has to establish this policy before the start of the project. In exceptional cases the Vice President for Research can allow a *sub-awardee* to adopt the terms of the University of Basel, as presented in these regulations. Participating *sub-awardees* have the obligation to report any existing financial interests, in connection with an NIH project, to the University of Basel for the attention of the Vice President of Research within 30 days

<sup>4</sup> The participating *sub-awardees* use the *Sub-recipient Financial Conflicts of Interest Certification* Form to confirm in writing to the University of Basel which of the options described in § 9 point 2 and 3 apply. This form must be sent to the Vice President's Office for Research.

## **3. Entry in Force**

### **§10 Entry in Force**

These regulations entered into force retrospective as of 1 January 2017. -

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