

Conflict of Interest Certification form

Project/proposal title:_____

NIH Award number (when applicable):______

This form is designed to comply with US department of Health and Human Service (HHS)¹ requirements concerning Financial Conflict of Interests (FCOI)

. This form needs to be filed and signed regardless if a conflict of interest exists. The form shall be signed by the PI at the time of application and by all other involved in a grant/contract/solicitation that falls under the HHS regulation.

I am a:

- Principal investigator to the above mentioned proposal. By signing below I am aware that I am also responsible to ensure that, in case an award is made, all participants within the project sign this form.
- Principal Investigator to the above mentioned and awarded project. By signing below I am aware that I am also responsible to ensure that all participants within the project sign this form. (annual update)
- □ Principal Investigator to the above mention ongoing project, whose FCOI status has changed
- □ Participant/co-researcher to the above mention and awarded project.
- □ Participant/co-researcher to the above mention and ongoing project who's FCOI status has changed.

By signing this form I certify that I have read and understood Appendix A - Significant Financial Interest (SFI), to this form and that the information stated below is complete and accurate to the best of my knowledge.

I also confirm that I am aware that any false, fictitious or fraudulent statements, information or omission may subject me to criminal, civil or administrative penalties according to Swedish and US regulation. I am also aware that signing this document does not liberate me form the normal

¹ Concerning among others, but not only, proposals/projects within the NIH program.

reporting requirements of Swedish regulations as an employee in a public authority (jäv and bisysslor)

By signing this form I am aware that any information listed below will be subject to the Swedish Public act and the 45 CFR part 94, 42 CFR part 50 (Federal Register vol 76/no 165- 2011) and can be made public upon request.

- □ I have read and understood appendix A to this form and hereby confirm that I do not have any significant financial interest to report
- □ I have read and understood appendix A and would like to report the following significant financial interest ;

Please describe the significant financial interest:

Size of the financial interest: ______

Name	Date	Signature



Financial Conflict of Interest -report (to be concluded by KTH UF)

Comments/decision:

Management plan:

Mitigation plan:

Name KTH UF	Date	Signature

I hereby confirm my adherent to the above management- and mitigation plan.

Name PI/Participant	Date	Signature
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Appendix A - Significant Financial Interest (SFI):

Reasoning: Ensure objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Significant Financial Interest (SFI):

(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 excluded sources provided in regulation

SFI does not included

- Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institution held by the Investigator, if the Institution 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, Institution of higher education as defied 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.

<u>A financial conflict of interest (FCOI) is an SFI that could directly and significantly affect the design,</u> <u>conduct, or reporting of NIH-funded research</u>.

For more information regarding the specific HHS regulation please go to <u>http://qrants.nih.qov/qrants/policy/coi/</u>