

SAKK – Conflict of Interest Policy

I BACKGROUND

The scientific credibility and the general acceptance of the results of a clinical investigation clearly depend on the integrity and objectivity of all individuals involved in SAKK research activities. Even the perception that an individual has a bias may cast doubt on the validity of the results. The intention of this policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research sponsored by SAKK will be biased by any conflicting interest of an individual involved in SAKK research activities.

This policy will define areas of conflict of interest and will identify when disclosure should be provided. Following disclosure using the *Conflict of Interest Disclosure Form*, the SAKK Conflict of Interest Subcommittee will determine, on a case by case basis whether any limitations will be placed on participation in SAKK activities.

The *Conflict of Interest Disclosure Form* has to be completed by the members of the SAKK Board, the Presidents of the SAKK Project Groups and Sections, designated Coordinating Investigators or Leaders of a scientific subproject and collaborators of the SAKK Coordinating Center who are directly involved in SAKK research activities (e.g. CEO, Head of Statistics, Head of Clinical Trial Management, Head of Clinical Project Management, Head of Innovation and Development, Clinical Project Manager). Members of the SAKK Board and the Presidents of the SAKK Project Groups and Sections have to complete the *Conflict of Interest Disclosure Form* at the beginning of their term. An update is required every second year. Coordinating Investigators or Leaders of a scientific subproject have to complete the *Conflict of Interest Disclosure Form* before the Trial proposal form or the Translational Research Proposal form or the Protocol or Synopsis of a collaborative groups is submitted to the SAKK Board and before the submission of a manuscript for publication. Collaborators of the SAKK Coordinating Center have to complete the *Conflict of Interest Disclosure Form* yearly. If relevant circumstances change the disclosure form has to be updated promptly.

II DEFINITIONS

Conflict of Interest

A conflict of interest may exist whenever an individual involved in SAKK research activities or a member of his or her immediate family has a direct or indirect interest or relationship, financial or otherwise with an outside entity that may conflict, be perceived as conflicting, or be inconsistent with the individuals duties, responsibilities, or exercise of judgment in SAKK research activities.

Immediate Family Member

Immediate family member includes a spouse and a dependent child. There may be situations where other family members not defined as an “immediate family member” hold a financial or other interest in an outside entity such that a perceived conflict may exist. In such situations, disclosure is required.

Outside Entity

Any biotechnology, pharmaceutical, bioinformatics, or other similar company will be considered an outside entity for disclosure purposes.

Research Activities

Research Activities include any trial protocol, investigation or analysis of a drug, technique, treatment or technology, and any correlative biologic investigations related to such trial protocols, investigations or analyses, and includes publication or other public disclosure of the results.

III REQUIRED DISCLOSURES

The following interests or relationships should be disclosed:

Employment or Leadership Position

Any full- or part-time employment or service as an officer or board member for an outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK must be disclosed.

Advisory Role

Consultant or advisory arrangements with an outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK must be disclosed if consultation was performed or payments made for such consultation within the last 2 years.

Stock Ownership

Any ownership interest (except when invested in a diversified fund not controlled by the covered individual) in a start-up company, the stock of which is not publicly traded, or in any publicly traded company must be disclosed if the company is an entity having an investment, licensing, or other commercial interest in the research activities of SAKK.

Honoraria

Honoraria are reasonable payments for specific speeches, seminar presentations, or appearances. Disclosure of honoraria is required when paid directly to the covered individual

within the last 2 years by an outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK.

Research Funding

All payment associated with personal funds received for research within the last 5 years from an outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK.

Other Remuneration

Other instances in which an individual or an immediate family member has an affiliation, relationship, or additional interest, such as intellectual property rights, or the receipt of trips, gifts and incentives within the last 2 years, must be disclosed. De minimus payments totalling less than CHF 200.- are excluded from disclosure requirements. These payments exclude research-related costs and travel.

IV ENFORCEMENT

Failure to disclose a conflict of interest as required above could result in the loss of privileges to participate in the bodies of SAKK or SAKK research activities. Possible breeches of this policy will be brought to the attention of the SAKK Board for action.

V EFFECTIVE DATE

This policy was accepted by the SAKK General Assembly on June 18, 2009 and is effective as of that date.

CONFLICT OF INTEREST DISCLOSURE FORM

Name _____

Function _____

Affiliation _____

Telephone _____

E-Mail Address _____

Please, provide a description of any proprietary or financial interest related to an outside entity for you or any member of your immediate family. An outside entity is any biotechnology, pharmaceutical, bioinformatics, or other similar company. Immediate family member includes a spouse and a dependent child. There may be situations where other family members not defined as an “immediate family member” hold a financial or other interest in an outside entity such that a perceived conflict may exist. In such situations, disclosure is required. If you have no financial interests and/or affiliation to declare, indicate by checking the applicable No-box in each paragraph.

A. FINANCIAL INTERESTS OR RELATIONSHIPS REQUIRING DISCLOSURE

Employment or Leadership Position

Are you in any full- or part-time employment or do you serve as an officer or board member for any outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK?

No

Entity Name	Position	Amount of Payment

B. ADVISORY ROLE

Do you have any consultant or advisory arrangements with an outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK?

No

Entity Name	Nature of Arrangement	Amount of Payment

C. STOCK OWNERSHIP

Do you have any ownership interest (except when invested in a diversified fund not controlled by the covered individual) in a start-up company, the stock of which is not publicly traded, or in any publicly-traded company, having an investment, licensing, or other commercial interest in the research activities of SAKK?

No

Entity Name	Ownership Type	Current Value

D. HONORARIA

Did you obtain any reasonable payments within the last 2 years for specific speeches, seminar presentations, or appearances from any outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK?

No

Source	Nature of arrangement	Amount of Payment

E. RESEARCH FUNDING

Did you obtain any personal research funding within the last 5 years from an outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK?

No

Source	Nature of Research	Amount of Payment

F. OTHER REMUNERATION

Did you obtain any trip, travel, gifts, or other in kind payments not directly related to research activities within the last 2 years by an outside entity having an investment, licensing, or other commercial interest in the research activities of SAKK? These payments exclude research-related costs and travel.

De minimus payments totalling less than CHF 200.- are excluded from these disclosure requirements.

No

Source of compensation	Nature of arrangement	Estimated current value

I have read the *SAKK - Conflict of Interest Policy*, and I represent and warrant that to the best of my knowledge that I am and I will continue to be, in compliance with this disclosure policy.

Place and Date: _____ Signature: _____