

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 defines areas of conflict of interest, identifies who has to disclose a potential conflict of interest, when disclosure has to be provided and determines appropriate actions in order to minimize any bias. 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.

II DEFINITIONS

2.1 Board

The SAKK Board will hereinafter be referred to as Board.

2.2 Conflict of Interest

Conflict of interest is defined as "a set of conditions in which professional judgement concerning a primary interest (such as patients' welfare or the validity of research) tends to be unduly influenced by a secondary interest" (DF Thomson, NEJM, 1993)

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.

2.3 Coordinating Investigator

The term Coordinating Investigator includes also supporting Coordinating Investigators

2.4 Immediate Family Member

Immediate family member includes a person related straight down to the third line or related in marriage or a person connected through marriage or partnership, 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.

2.5 Investigator

The term Investigator shall include Principal Investigators as well as any Leaders of sub-projects.

2.6 Outside Entity

Any entity, not being member of SAKK, such as any biotechnology, pharmaceutical, bioinformatics, diagnostic or other related company will be considered an outside entity for disclosure purposes.

2.7 Policy

This SAKK Conflict of Interest Policy will be referred to as Policy.

2.8 Research Activities

Research activities include any research study or clinical trial protocol, investigation or analysis of a drug, technique, treatment or technology, and any correlative biological investigations related to such research study or clinical trial protocols, investigations or analyses, including publication or other public disclosure of the results.

2.9 SAKK Conflict of Interest Subcommittee

Members of the SAKK Conflict of Interest Subcommittee (hereinafter referred to as the Subcommittee) are the SAKK Chief Executive Officer, the SAKK Chief Operations Officer, the SAKK Chief Scientific Officer and the Head of Quality Assurance of SAKK

III REQUIRED DISCLOSURES

3.1 The following persons have to fill out a Conflict of Interest Disclosure Form:

The *Conflict of Interest Disclosure Form (COIDF)* has to be completed by the following persons at the beginning of each term:

- Members of the SAKK Board
- Presidents of the SAKK Project Groups, Sections and Working Groups

Update of the CIODF is required every three years res. promptly if relevant circumstances change

The COIDF has to be completed by the following persons before the initial assessment of the trial proposal by the SAKK Board res. in the event of a change of Coordinating Investigator (CI), Supporting CI or Principal Investigator during the conduct of the trial and before the submission of a manuscript for publication.

- Designated Coordinating Investigators (incl. Supporting Coordinating Investigators)
- Principal Investigators
- Leaders of a scientific subproject

Collaborators of the SAKK Coordinating Centre who are directly involved in SAKK research activities (e.g. Chief Executive Officer, Chief Operations Officer, Chief Scientific Officer; Head of Statistics, Head of Clinical Project Management,) have to complete the COIDF every three years. If relevant circumstances change, the disclosure form has to be updated promptly.

3.2 The following interests or relationships have to be disclosed:

Employment or Leadership Position

Any full- or part-time employment, mandate or service as an employee or board member for an Outside Entity having an investment, licensing, selling 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, selling 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 two 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, selling 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 two years by an Outside Entity having an investment, licensing, selling or other commercial interest in the research activities of SAKK.

Research Funding and Sponsoring

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

Other Remunerations

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 two years, must be disclosed. The minimum payments totalling less than CHF 200.- are excluded from disclosure requirements. These payments exclude research-related costs and travel.

IV REFRAIN FROM INFLUENCE

This Policy states tolerated and prohibited conflict of interests. All conflict of interest have to be made transparent to the Subcommittee. Any prohibited conflict of interests requests total refrain from influence, some designated conflicts of requests need further safety measures, being defined accordingly.

4.1 Not allowed

Board members

- Having an equity interest in an Outside Entity that will benefit from the investigation or sale of the product, technology or know-how
- Having a leading role (head/chair) in an advisory role for an Outside Entity (paid and unpaid consulting service)
- Being co-founder of a start-up company (oncology related)
- Having an interest in a patent or licence (oncology related)

Coordinating Investigators

- Influencing the study design to push professional achievements
- Knowing the data from the interim analysis (chair review)
- Interpreting the data, whether an endpoint is reached or not
- Having an equity interest in an Outside Entity that will benefit from the investigation or sale of the product or technology in the field of oncology
- Having a leading role (head/chair) in an advisory role for an Outside Entity (paid and unpaid consulting service) in the field of oncology

4.2 Allowed with restrictions

Board members

- A Board member and a Coordinating Investigator who submitted a proposal work for the same legal entity
- A Board member and a Coordinating Investigator who submitted a proposal work within the same department (under the supervision of the same unit head)
- A Board member is active in the respective Project Group or Section
- Leading a research project funded with over CHF 50'000.- by an Outside Entity, whose products are to be tested in a clinical (sub-)trial
- Leading a research institute receiving more than CHF 100'000 by an Outside Entity, whose products are to be tested in a clinical (sub-)trial
- Receiving local sponsoring by an Outside Entity whose products are to be tested in a clinical (sub-)trial

In these cases, the board member is not allowed to vote on the proposal, but may give scientific advice according to roles for the board.

- A Board member has an advisory role for an Outside Entity (paid or unpaid) consulting service

Any payment for consulting goes directly to a non-profit organization. Furthermore, no chair or head function in advisory board is allowed.

Coordinating Investigators and Principal Investigators

- A Coordinating Investigator res. Principal Investigator has an advisory role for an Outside Entity (paid and unpaid consulting service).

Any payment for consulting goes directly to a non-profit organization. Furthermore, no chair or head function in advisory board is allowed.

4.3 Allowed when made transparent

Coordinating Investigator

- The Coordinating Investigator (incl. Supporting Coordinating Investigator) works for a university hospital. The associated university (two separate legal entities) holds a patent or license for the study drug/medical device.

V 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. Critical constellations or possible

breaches of this policy will be brought to the attention of the SAKK Strategic Board for action. Parallely the Subcommittee will report any breach of this policy to the Swiss Ethics Committee, to which the respective research projects or clinical trials have been submitted to. In the event of a suspected breach, the Subcommittee will decide what next steps shall be taken.

VI ADMINISTRATION OF THE POLICY

This Policy shall be administrated by the Subcommittee, which shall be responsible for the following:

- a) Reviewing the declarations and receiving disclosures from all defined persons to fill in the COIDF;
- b) Forward once a year the COIDF of SAKK Managing Board Members to the SAKK President;
- c) Maintain a list with the regular update of COIDF;
- d) Store electronically all filled COIDF;
- e) Ensure the regular update of the COIDF;
- f) Reporting to the Board any critical cases or when any breaches are discovered;
- g) Be point of contact for any indications of breaches of this Policy;
- h) Decide how to proceed in case of suspected breaches of this Policy;
- i) Reporting to the Ethics Committee when any breaches are discovered within research projects or clinical trials submitted to the Swiss Ethics Committee.

The Subcommittee may seek advice from outside advisors in case of a breach or in the administration of this Policy. The Board/General assembly shall have the authority to review operation of this Policy and make changes from time to time, as it may deem appropriate.

VII EFFECTIVE DATE

This policy was accepted and updated by the SAKK General Assembly on 05.05.2021 and is effective as of that date.

This policy replaces version 2, activated on 18 June 2009



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 entity, not being member of SAKK, such as any biotechnology, pharmaceutical, bioinformatics, diagnostic or other related 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 RENUMERATION

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 minimum 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: _____