

Conflict of Interest Policy of SAKK

1 BACKGROUND

SAKK is a non-profit organization active in clinical cancer research. With trials supported by a core grant from the Swiss State Secretariat of Education and Research and other grants from pharmaceutical companies and foundations, SAKK researches therapies and their optimization for frequently occurring cancer types.

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 or conflict of interest 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 cause that the design, conduct, or reporting of research in connection with SAKK will be biased by any conflicting interest of an individual directly involved in SAKK research activities.

Furthermore, a conflict of interest may damage the personal reputation and that of SAKK.

This Conflict of Interest Policy (CoIP) helps to identify and disclose conflicts of interest and it determines appropriate measures in order to minimize or avoid any bias when disclosure has been made. In order to do so, all persons concerned (p. 2) are requested to fill out the Conflict of Interest Declaration (CoID, p. 5).

2 PRINCIPLES

2.1 Who is concerned?

This CoIP is applicable to the following functions:

- Members of the Board; members of the International Scientific Advisory Board; members of the Scientific Committee; members of the Patient Advisory Board; members of the Project Groups/Working Groups/Sections;
- Members of the Executive Committee;
- Head of Clinical Project Management; Head of Monitoring & Clinical Project Management; Head of Clinical Project Development; Head of Clinical Data Management; Head of Statistics;
- Coordinating Investigator; supporting Coordinating Investigators; Principal Investigators; Leaders of subprojects (all together "Investigators").

The concerned members of the bodies and committees and the concerned employees of SAKK (as defined above) shall complete the CoID at the time they are elected or appointed to the body or committee or at the time concluding the employment contract.

Investigators have to complete the CoID when they are involved in a study, trial or other research project for the first time in such a function.

An update of the CoID is required every three years or on their initiative if relevant circumstances change as long as they are fulfilling one of the above mentioned function.

2.2 What is a 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 a person bound by this CoIP or a closely related person¹ has an interest that conflicts or may conflict, be perceived as conflicting, or be inconsistent with the individual duties, responsibilities, or exercise of judgment in SAKK research activities and that leads, may lead or seems to lead to a situation in which this person gives less weight to the interests of SAKK, the patients' welfare or research

¹ Closely related persons are the person's concerned family members, those living in the same household as the person concerned or someone with whom the person concerned has a personal relationship of an intimate or romantic nature. There may be situations where other person not defined as a "closely related persons" hold a financial or other interest such that a perceived conflict may exist. In such situations, disclosure is required.

validity than to his/her own or is improperly influenced in its business judgments, decisions or actions.

All persons subject to this CoIP are obliged to avoid conflict of interest and to disclose them in a CoID as soon as possible if a conflict occurs nevertheless.

2.3 Who takes which measures?

Conflict of Interest must be disclosed to the Conflict of Interest Subcommittee of SAKK (CoI Subcommittee). The CoI Subcommittee consists of a Legal Counsel, the Chief Operations Officer and Chief Quality & Compliance Officer. If a member of the CoI Subcommittee discloses a conflict of interest, he or she is represented in the CoI Subcommittee by the Chief Executive Officer.

The CoI Subcommittee is responsible for taking appropriate measures, if a conflict of interest is disclosed, and may take all necessary and proportionate measures to minimize or eliminate conflicts of interest or the appearance thereof (including the exclusion of persons from a research project or the suspension of voting rights on a particular issue).

The CoI Subcommittee will contact the disclosing person should any action be taken.

2.4 What happens if conflicts of interest are not disclosed?

Failure to disclose a conflict of interest as required in this CoIP could result in different measures e.g. the loss of privileges to participate in the bodies and committees or research activities of SAKK or also a termination of employment (if employees of SAKK are concerned). In the event of a suspected breach, the CoI Subcommittee will decide what next steps shall be taken. Upon discretion of the CoI Subcommittee critical constellations or possible breaches of this policy will be brought to the attention of the SAKK Board for action. The CoI Subcommittee will also report any breaches of this policy to the Swiss Ethics Committee, to which the respective research projects or clinical trials have been submitted to.

The CoI Subcommittee may seek advice from external advisors in case of a breach or in the administration of this CoIP and is therefore allowed to disclose the related personal data to persons outside the company.

3 EFFECTIVE DATE

This CoIP was accepted by the General Assembly of SAKK on 16.11.2022 and is effective as of that date. It shall replace all previous CoIPs.

Appendix: Conflict of Interest Disclosure Form

Basel, 17.11.2022



Prof. Dr. Miklos Pless
SAKK President



Prof. Dr. Sacha Rothschild
SAKK Vice-President a.i.



CONFLICT OF INTEREST DECLARATION

Name _____
Function _____
Affiliation _____
Telephone _____
E-Mail Address _____

Please disclose all situations that may give rise to a conflict of interest as explained in the Conflict of Interest Policy of SAKK (CoIP) dated 16.11.2022. Possible categories of conflicts of interest could be the following (non-exhaustive list):

- Employment or leadership position: Any full- or part-time employment or the function as an officer or board member for any outside entity² having an investment, licensing, or other commercial or strategic interest in the research activities of SAKK.
- Advisory role: Any consultant or advisory arrangements within the last 2 years with an outside entity having an investment, licensing, or other commercial or strategic interest in the research activities of SAKK.
- Honoraria: Receipt of more than CHF 5'000 within the last 2 years for speeches, seminar presentations, mandates or appearances from any outside entity having an investment, licensing, or other commercial or strategic interest in the research activities of SAKK.
- Research funding: The receipt of any personal research funding within the last 5 years from an outside entity having an investment, licensing, or other commercial or strategic interest in the research activities of SAKK.
- Stock ownership: Any ownership interest (except when invested in a diversified fund not controlled by the concerned individual) in a company having an investment, licensing, or other commercial or strategic interest in the research activities of SAKK.

² Any entity, not being member of SAKK (especially any biotechnology, pharmaceutical, bioinformatics, diagnostic or other related company) will be considered an outside entity for disclosure purposes.

- Other remuneration: The receipt of any trip, travel, gifts, or other in kind payments within the last 2 years by an outside entity having an investment, licensing, or other commercial or strategic interest in the research activities of SAKK. These payments exclude research-related costs and travel. The minimum payments totalling less than CHF 1'000 are excluded from these disclosure requirements.

Are there any circumstances that lead, may lead or seem to lead to a (potential) conflict of interest?

- NO
- YES: please specify below

Entity name	Reason for the conflict	Payments/values

Comments: _____

I have read and understood the CoIP and I represent and warrant to the best of my knowledge that I: a) have disclosed all (potential) conflicts of interest; b) have filled in this Conflict of Interest Disclosure Form truthfully and c) will bring any relevant changes of it to the attention of the Col Subcommittee immediately.

In addition, I am aware and I agree that SAKK will report it (incl. details) to the ethics committees if the Col Subcommittee concludes that there is a conflict of interest with respect to a study in which I am involved as investigator.

Place and Date: _____ Signature: _____