

GUIDELINES REGARDING POTENTIAL CONFLICTS OF INTEREST

All IFOM employees are required to avoid any situation which could give rise to a conflict of interest and to refrain from personally profiting from business opportunities which they may encounter through their work and/or position.

In order to maximise research results and to promote processes to pursue the "Studying Cancer to find a Cure" mission, IFOM encourages its researchers to collaborate with industry and with profit-making organisations – in the broadest sense. Those relationships can give rise to a – potential or actual – conflict of interest, namely between the interests of individuals or IFOM itself and the interest that IFOM and its researchers are working for. Conflicts of interest refer to any potential personal gain, which is mainly financial.

Such potential personal gain can adversely impact the judgement or objectivity of researchers or directors, thus jeopardising their main mission and the commitment to the research institute's values, and also the research activities and specialised training conducted by the institute. It should be noted that there need not occur an actual conflict of interest, as even an apparent conflict relating to research could negatively affect the overall trust in the institute as a whole.

This issue can be more pressing in cases involving clinical testing of medicinal products, agents and/or medical instruments, or in general, any testing involving patients given that it is such a sensitive field and moreover that the results can have immediate commercial consequences. Although IFOM does not carry out that kind of research, the issue may arise should IFOM be involved in any way in this kind of activity in the future.

The opportunity for scientific personnel to receive additional monetary or other remuneration is acceptable provided that it does not unduly affect their objectivity, integrity or professional commitment to IFOM and the scientific activities they carry out. Therefore, as regards the relationship between research and industry, being party to a situation which offers personal gain is not necessarily unacceptable; it is crucial that any potential encouragement of unacceptable conduct is correctly handled.

More complex Conflicts of Interest can arise in the research field when two positive results, or processes for obtaining such results, are not compatible. However if a result or a process for obtaining the result appear to be clearly flawed and inconsistent with principles, duties and/or generally accepted rules, the solution is a lot simpler. That is why IFOM has undertaken to establishing policies, rules and procedures for managing, reducing or indeed eliminating conflicts of interest (or conflicts of commitments), whether actual or potential.

Those policies, rules and procedures are based on the values upon which IFOM has founded its activities.

The institute's founding values are:

- IFOM pursues excellence in oncology research based on genomic and post-genomic technologies, building relationships with public and private institutes in Italy and internationally;
- IFOM's research activities are characterised by the respect for fair scientific competition, and seek to identify and punish any scientific conduct that is fraudulent, plagiaristic or incorrect in any way;
- IFOM is aware of the social and ethical impact of its activities.

As a result, the institute's scientists must adhere to the following main principles:

- A genuine involvement in IFOM's scientific research, training and all related activities.
- An intellectual autonomy and academic freedom
- Unhindered communications and sharing of knowledge
- Capacity, objectivity and integrity in research and training
- Public spirit

Defining a Conflict of Interest

A Potential Conflict of Interest refers to a financial interest of any company or legal body which could compromise or would be able to compromise the planning, the performance and/or the disclosure/presentation of research activities or services, and the use of financial and/or human resources within the Institute.

The term "**financial interest**" means:

- Salary, fees, remuneration and any other kind of payment for consultancy and/or teaching;
- Intellectual property rights, including patents, patent applications, copyright, royalties and any entitlement to royalties;
- Shareholdings, including options to subscribe shares and any other stock options/entitlements;
- Directors positions, managerial roles and other relationships with legal entities which offer the potential for personal gain.

Any such financial interest must be disclosed, however it may not necessarily be deemed to pose an issue.

Usually a financial interest is held to be a significant financial interest ("**Significant financial interest**") if:

- It entails shareholdings or similar interest exceeding the value of €10,000 or represents more than 1% of a company or corporation's capital, with respect to an individual researcher and his/her family members; or
- It involves salary, royalties or similar payments from any company or organisation exceeding the value of €10,000 in any year, with respect to an individual researcher and his/her family members.

Family members include: spouses, parents, children, siblings, spouse's children and the spouse of any researcher's dependants.

Defining a Conflict of Commitment

A further conflict may arise involving researchers and their external activities, which is referred to as a Conflict of Commitment. Such a situation may arise when the commitment of a researcher to an external activity compromises his/her commitment to the responsibilities with the Institute. In general, this kind of conflict is easy to identify given that it usually entails an individual having less time and energy to dedicate to such responsibilities with the Institute.

It should be noted that throughout a researcher's career, an individual may be involved in numerous external academic activities, which may include seminars and conferences in other institutes, taking part in scientific and academic committees for non profit organisations, revising manuscripts and grant applications, *etc.* Such activities are deemed to be part of their "work" and as such are not seen to compromise the commitment to the Institute. The training activities within the programmes run by the European School of Molecular Medicine (SEMM) are not considered to be external activities, as indeed the IFOM training activities are managed and coordinated by SEMM, whose founders include IFOM. Teaching as part of the programmes run by the Università degli Studi di Milano (UNIMI) is not considered an external activity as there is a formal agreement in such respect in place between IFOM and said University. However, a significant undertaking to teach at another institute, albeit acceptable, must be approved in advance by the Conflict of Interest Committee.

Fee-paying work for companies and being party to managerial decisions in other legal entities are acceptable provided that the time and effort for any such undertaking does not compromise a researcher's duties to or performance for, the Institute.

Such activities should not exceed 20% of a researcher's time and commitments.

In addition, IFOM scientists should not hold executive positions (such as CEO, Chairman, Scientific Director) in commercial companies, save for exceptional circumstances and for limited periods of time, which must in any event be authorised in advance by the Conflict of Interest Committee. Holding such a

position could give rise to a significant conflict of commitment and priorities, even if the time required for holding the position is limited.

Conflict of Interest Committee

For the purpose of disciplining any potential conflicts of interest which are inconsistent with the institute's principles and values, IFOM has set up an internal Conflict of Interest Committee. The Committee comprises a changeable number of members who are selected by the Committee Director which also selects the Committee's Chairman. The Committee has an advisory role and reports back annually to the Committee Director on the results of its activities.

The Committee meets formally at least once a year in order to discuss any cases submitted or whenever is deemed necessary. Members of the committee may consult with one another via e-mail, telephone, *etc.*

Each member shall hold office for 3 years and may be re-elected.

Reporting

Periodic and full reporting on any potential conflicts is at the very centre of how Conflicts of Interest are regulated.

Upon joining the Institute, new members to IFOM are required to submit a declaration of any conflict of interest to the administration. IFOM members will then be required to submit annually a confidential declaration listing all external activities they carry out (whether remunerated or not) and the time dedicated to each, and moreover, whether such activities have significantly changed (and how) or will change (and how) (such as for example, an offer for a teaching contract, consultancy work, *etc.*). All such documentation shall be forwarded to IFOM's administration and if necessary, also subject to the review of the Conflict of Interest Committee.

Whenever a researcher is involved in negotiations with for-profit entities to exploit or support research activities (e.g., sponsored research agreements, patent licenses, collaboration agreements etc), such researcher shall be required to answer an appropriate questionnaire, which will be provided by TTFactor (the company charged with managing the contracts with profit-making bodies on behalf of IFOM), and that will examine whether the researcher has a potential conflict of interest or commitment that may affect such negotiations. The completed questionnaire will be transmitted by TTFactor to IFOM.