Financial Conflict of Interest Policy & Standard Procedures

1. Introduction

A conflict of interest occurs when an employee, or the department/section he or she works in, has financial or personal ties with other persons or organisations which could influence the research or other activities that are performed within Erasmus MC. The extent of this influence ranges from negligible to substantial. Financial interests (such as financial entitlements, paid consultancies, equity interests, gifts, royalties) are the easiest sources of conflicts of interest to identify but the most likely to undermine scientific independence. A conflict of interest can, however, also exist without the employee being aware of it. Conflicts of interest are often associated with the interests of (pharmaceutical and other types of) companies, but they can also stem from personal relationships. Research sponsored by the government or other funding agencies could also give rise to conflicts of interest.

The purpose of this policy is to outline processes for identifying, managing and preventing individual conflicts of interest for all those involved in scientific research and other activities at Erasmus MC.

This Standard Procedure sets out the procedures for dealing with the potential or existing conflicts of interest.

2. Potential conflict of interest situations

2.1 Collaboration with commercial parties

Erasmus MC encourages researchers to convert the results of academic research, if feasible, into new diagnostic, therapeutic or educational tools for the purpose of contributing to medical science and improving patient care. Any collaboration with third parties may not, however, in any way cast doubt on the independence of the research performed at Erasmus MC. Such doubt could damage the reputation of employees and the institution. Furthermore, conflicts of interest will have a significant impact on individual careers and affect the ability to attract external funding.

Nowadays, funding bodies frequently demand clear rules on conflicts of interest to determine eligibility for grants.

2.2. Other paid activities and external posts/activities (ancillary activities)

Clause 9.3 of the Collective Labour Agreement for University Medical Centres (CLA UMC of 2018-2020) includes rules on external activities that apply to all employees covered by the CLA. External posts, paid or otherwise, are not permitted if they are incompatible with the employee’s responsibilities at Erasmus MC or could harm the interests or reputation of Erasmus MC. The CLA therefore contains rules that require external activities to be reported to and approved by the employer. Within Erasmus MC, relevant external activities have to be reported to the employee’s direct manager, who, in turn, is accountable to the Executive Board. If the above mentioned approval is not granted, management may decide to instruct the employee to cease the external activities and/or transfer the income to Erasmus MC, if that income is above € 2,200 per annum (CLA UMC 2018-2020). Further information on the application of the rules on external activities can be obtained via the CLA UMC.
2.3 Significant financial interest

A financial conflict of interest may arise if a researcher/employee has a significant financial interest in a commercial entity or any other third party and such entity or third party is also involved in projects or other activities of Erasmus MC.

A “significant financial interest” as meant here, is defined as: anything of monetary value, including but not limited to, salary or other payments for services (e.g. consultancy fees or honoraria); intellectual property rights (e.g. patents, copyrights and royalties from such rights); equity interests (e.g. shares, option rights or other interests in third party equity).

Reports on all financial interests which have an effect on the research, including those which could possibly affect the research and/or whereby, in turn, the planned research could affect those interests, are mandatory; for example:

- Payments in excess of customary small business gifts (exceeding a value of €50) and all payments not meant as a reimbursement of any actually incurred costs, including salary, fees, royalties or other payments related to intellectual property rights and honoraria, including payments or benefits to family members such as spouses and/or dependent children.
- Any proprietary interest in a product or service tested in a study, such as intellectual property rights, royalties or other revenues from agreements the value of which may be affected by the outcome of the research;
- Any significant equity interest in a sponsor of the study, such as a position as director, project leader, partner, authorised representative, employee or any other position in the management; shares, option rights, or other financial interests the value of which cannot be readily determined through reference to public sources (e.g. shares in start-up companies) and which exceeds €2,200 per annum or represents more than a 5 % of the total equity (including interests of a spouse and/or dependent children).

The term significant financial interest does not include an interest of any amount in publicly traded diversified mutual funds.

2.4 Situations that may give rise to bias

This includes carrying out research when the researcher or his/her immediate family has a financial or other interest in the company that is funding research (in full or in part).

2.5 Situations that may give rise to the inappropriate use of Erasmus MC property or resources

Examples are for instance the free use of Erasmus MC facilities for personal purposes or to support the activities of a third party.

2.6 Situations that may give rise to inappropriate use of information

For example, providing access to information collected by Erasmus MC or with the use of Erasmus MC’s resources or which the researcher concerned has in his/her possession because of his/her position, to an entity or person in which the researcher has a financial interest. Such a situation is undesirable if Erasmus MC did not authorise the use.
2.7 Situations that may give rise to self-dealing

Such as purchasing supplies, instruments or equipment for research or education from a supplier in which the researcher/employee has a financial or other interest, or influencing the negotiations between Erasmus MC and external organisations in which the employee has a financial interest or other kind of relationship.

3. Policy

It is Erasmus MC’s policy to bring potential conflicts of interest out into the open in order to evaluate their potential impact on the research and the research subjects, and to take decisions on them so as to safeguard the scientific independence of Erasmus MC and its researchers. Based upon the guidelines of the Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra) NFU, Erasmus MC has established the following procedures for dealing with and preventing conflicts of interest.

Rules and procedures for preventing and reporting potential conflicts of interest

2. Policy on share ownership or other interests in the capital of third parties (companies) by Erasmus MC employees (Participatieregeling)
3. Transparency
   In order to safeguard the independent position of individual employees and the reputation of Erasmus MC as a whole, all employees must report every external activity/post that might lead to a (financial) conflict of interest to his/her manager. In most cases, this will be the head of the department or section where the employee works. If a head of department wants to make a report, he/she will report directly to the Executive Board. Employees should also report to the agencies/organisations that fund their research. Every 12 months, the Executive Board asks for an overview of the external activities/posts (including financial details) of professors (hoogleraren) and assistant professors (universitair hoofd docenten). The data are published on the Erasmus MC website. Department heads and other managers are responsible for providing these data promptly.
4. Healthcare employees may find it necessary, and in some cases are even obliged, to disclose financial relations in the Healthcare Transparency Register. These disclosures are the individual responsibility of the employee concerned, but are required by Erasmus MC and needed for adequate transparency.

Although transparency does not, in itself, eliminate bias or conflicts of interest, it does bring financial relationships out into the open and may be a starting point for any questions. Employees who participate in the scientific research must provide information about any relationships that could potentially give rise to a conflict of interest, as well as about situations that could create that impression.

4. Discuss the matter during the annual appraisal

Potential conflicts of interest must be a subject during the annual appraisal between the researcher/employee and his/her manager/department head.
5. Regular reports to the management

Researchers/employees are required to report immediately to their direct manager, usually the head of the department or section (or, if the employee is a department head, to the Executive Board) if they believe there might be a conflict of interest or exposure to potentially conflicting interests outside the Erasmus MC.

The report may be discussed (where necessary) in advance with the Legal Department or with the lawyers in the Technology Transfer Office (TTO). The Executive Board may decide to publish the report. Both the report and any approval granted by the Executive Board or department head will be recorded in the employee’s personnel file.

6. Resolution of conflicts of interest by an ad hoc FCOI Committee

A conflict of interest situation, which cannot be resolved by the involved employee concerned and his/her manager, is to be reported to the Dean. The Dean will appoint an ad hoc FCOI Committee based on a proposal from the Confidential Counsellor for Scientific Integrity (vertrouwenspersoon wetenschappelijke integriteit). This FCOI Committee will consist of:
- the head of an Erasmus MC scientific department (not being the direct manager of the employee concerned) and who is not involved in the matter at hand;
- the Director of TTO;
- an ad hoc external consultant; and
- a secretary (e.g. one of the lawyers from Erasmus MC's Legal Department or from TTO).

The FCOI Committee will evaluate the situation and has the authority to contact the researcher and those involved to discuss how to resolve the conflict of interest. If the situation cannot be resolved, the conflict of interest will be referred to the Executive Board to decide on actions to be taken and the final resolution.

7. Effective date

This FCOI becomes effective on the date of final adoption by the Executive Board of Erasmus MC as of 1 January 2020.

8. Power to deviate by the Executive Board

The Executive Board has the discretionary power to deviate from this FCOI at any time. In individual cases, the Executive Board may adopt a deviating decision. The Executive Board may seek the prior (written) advice of the Director of Technology Transfer Office (TTO), if necessary.

Adopted by the Executive Board of Erasmus MC 23-11-2020