

Financial Conflict of Interest Policy related to NIH-funded research at the University Medical Centre Utrecht

All researchers of the University Medical Centre Utrecht are asked to inform the Signing officials at the [Research Support Office](#) when applying for NIH research funding.

By applying for or participating in NIH research funding activities, the University Medical Centre Utrecht (UMC Utrecht) , and on behalf of the institution each investigator involved, is subject to [Public Health Services \(PHS\) regulation 42 CFR 50 Subpart F “Promoting objectivity in research”](#).

In this document we bring all related UMC Utrecht policies together, which inform all relevant parties of the rules and procedures to be followed, in case of Financial conflict of interest.

Institutional policy on financial conflicts of interest (FCOI) related to NIH-funded research at the University Medical Centre Utrecht (UMC Utrecht)

In application of Regulation 42 CFR 50 Subpart F, the UMC Utrecht maintains a policy on Outside activities, as defined in the Article 9.3. of the [collective labor agreement for university medical centres \(CAO UMC\)](#) in the Netherlands.

The CAO UMC is formally a public-law employment status regulation.

The terms of the CAO apply for all employees of the UMC Utrecht to the extent that they are employed by virtue of a letter of appointment or a contract of employment, unless otherwise agreed between the governing board and the unions in the LOAZ (National Consultative Committee of University Hospitals and the Unions).

Article 9.3 Outside activities (Collective labour agreement for university medical centres in the Netherlands 2018-2020):

- Employees do not require the prior consent of the employer for the acceptance or performance of outside activities, unless those outside activities could affect the interests of the UMC and/or the proper performance of their job.
- The employer shall grant permission for outside activities if in its opinion the performance of those outside activities cannot damage the interests of the UMC and/or affect the proper performance of the job. If it is in the interests of the UMC, the employer may agree to allow employees to perform their outside activities wholly or partially during their working hours.
- The employer shall grant permission for a fixed period or for an indefinite period and may attach further conditions to its consent. The employer may stipulate the condition that the employee must pay all or part of the income that he earns from outside activities to the employer. This condition may be stipulated for income that exceeds €2,200 a year and is earned from activities that follow from the employee's job at the UMC.
- The employer may withdraw the permission that has been granted if it considers that circumstances under which the permission was granted have changed.
- In the case that the employee is performing or has performed outside activities without the permission required by virtue of the first paragraph, the employer shall still give

the employee the opportunity to request the necessary permission. If the permission is not granted, the employer may, without prejudice to the provisions of Article 11.1 (dereliction of duty) instruct the employee to cease the activities and/or pay the income earned to the employer.

- In consultation with the works council, the employer may lay down further rules for the administrative implementation of the provisions of this article.

In brief, every Investigator at UMCU, applying for or involved in NIH-funded research, is subject to the Public Health Service's (PHS) Financial Conflict of Interest (FCOI) regulation (42 CFR Part 50 Subpart F) and as an employee of UMCU abides to the regulations stated in the Article 9.3 on Outside activities, of the formally agreed collective labour agreement for the university medical centres (CAO UMC) in the Netherlands 2018-2020.

In addition, to foster scientific integrity the institution has a Research Code that applies to all investigators of UMCU. Chapter 11 on Conflicts of interests highlights the abovementioned framework and the procedures for reporting on outside activities.

Within the given framework, he/she is will disclose his/her financial interests related directly to the NIH-funded project. This should be done using the form [Register side jobs](#) (direct link to intranet site of UMC Utrecht), provided in the Personnel portal of the UMC Utrecht. With that form the investigator applies for supervisors consent on taking on a side job conform article 9.3 of the UMC- Collective Labor Agreement (CAO).

Next to this, investigators are required to take a web-based NIH tutorial on financial conflict of interest prior to beginning a project:

NIH tutorial

An electronic copy of the tutorial's certificate has to be sent to rso@umcutrecht.nl.

If a Financial Conflict of Interest is identified, proper measures will be taken to mitigate the conflict of interest, as described in the collective labor agreement for university medical centres in the Netherlands, Article 9.3.

Research Code for scientific integrity

Next to the Collective Labour Agreement the UMCU has a research code in place describing all aspects of research integrity including dependency of commercial or financial considerations: <http://researchcode.umcutrecht.nl/8105/research-code>

Guiding principles scientific Integrity

Research integrity plays a vital role in allowing scientific research to function properly. The reputation and the reliability of scientific research depend on the individual actions of every researcher. The 4 guiding principles for proper conduct at UMC Utrecht (see Integrity at UMC Utrecht) also apply to research. The content is in line with the Netherlands Code of Conduct for Research Integrity (VSNU).

HONEST – I refrain from making unfounded claims, I report on the research process accurately, I refrain from fabricating or falsifying data or sources, I take alternative opinions

and counter-arguments seriously, I am open about margins of uncertainty, and I refrain from presenting any results more favourably or unfavourably than they actually are. The way in which the research process is conducted and divided into phases must at least be evident to my peers. The line of reasoning must be clear. The steps in the empirical research process must be verifiable, so that my research can be replicated.

RELIABLE – I use methods that are seen as standard within the discipline, or that are at least defensible, and I exercise the best possible care in designing, conducting, reporting, disseminating and applying the research. It must be clear to others what data the research was based on, how this data was obtained, which results were achieved and how, and what role external stakeholders played. If parts of the research or the data cannot be made accessible, I substantiate properly why this is not possible.

ENGAGED – I conduct research that is scientifically or socially relevant. I take account of the fact that researchers do not operate in isolation. I take into consideration the legitimate interests of human and animal test subjects involved in the research, any commissioning parties, the environment, culture, science and society

INDEPENDENT – I allow neither the choice of method, the assessment of data and the weight attributed to alternative statements nor the assessment of other people's research or research proposals to be influenced by non-scientific considerations (e.g. considerations of a commercial or political nature).

In case of scientific misconduct (or suspicions thereof)

Do you think you have come across a situation involving scientific misconduct or an integrity violation (scientific or otherwise)? Then talk about it with others (see below), and/or discuss it with the Confidential Advisor for Integrity (VPI) (UMCU).

Do you want to report the scientific misconduct or integrity violation (scientific or otherwise), or your suspicion thereof?

1. Discuss it with the person concerned first.
2. If this is not possible, or if that person does not take action after being called to account for their misconduct, then contact one of the following people:
 - a. Your direct superior, or
 - b. Another senior manager, or
 - c. The Confidential Advisor for Integrity (VPI) (UMCU), or
 - d. The Executive Board of UMC Utrecht, or
 - e. The Supervisory Board (if the situation to be reported concerns actions of the Executive Board).
3. ALTERNATIVE 1: Contact the Academic Integrity Counsellor (UU).
4. ALTERNATIVE 2: Write a formal report to the Committee for Academic Integrity (UU), which works according to the Utrecht University Academic Integrity Complaints

Procedure.

Do you need more information, help or advice?

1. Contact the Confidential Advisor for Integrity (VPI) (UMCU)* (UMC Utrecht), or
2. The advisors of the Dutch Whistleblowers Authority (Huis voor Klokkenuiders, Maliebaan 72, Utrecht), or
3. An advisor with a duty of confidentiality, like a lawyer.

Collaborative agreements

If scientific research is funded from a different source than UMC Utrecht, it is vital to conclude a proper contract with the external sponsor. Contract management must be in accordance with the assignment of powers of UMC Utrecht. A clear grant agreement must be concluded with the sponsor, to avoid misunderstandings or manipulation of the research. The contracts must be signed in accordance with the assignment of powers of UMC Utrecht. The Research Contracts Team has developed several model contracts that can be used as a basis (also refer to the Explanation on Model Contracts).

For research contracts, division management is authorised to sign contracts on behalf of UMC Utrecht. It is important, however, that if one or more members of the division management concerned is an interested party, another member of this division management must sign the contract in their place. For contracts involving risks or commitments of over EUR 1 million, a signature from a member of the Executive Board is also required.

For contracts concerning a transfer of or an exclusive license for existing intellectual property rights (also referred to as ‘background IP’), written permission from the director of UMC Utrecht Holding BV is required.

Ancillary activities

UMC Utrecht welcomes the performance of ancillary activities by its employees, as in most cases it is a sign of social engagement. UMC Utrecht promotes active participation of scientists in national and international committees, partnerships, research projects, networks and conferences.

Conflicts of interest must be prevented at all times. In principle, accepting ancillary activities is permitted, provided that the employee adheres to the rules for ancillary activities and that the activities are not contrary to UMC Utrecht’s interests.

Ancillary activities also include:

- Providing guest lectures or giving other talks;
- Fulfilling administrative memberships;
- Fulfilling positions on advisory boards or research committees;
- Performing volunteer work using the researcher’s expertise;
- Fulfilling a role within a corporation that is connected with the researcher’s scientific
- work (e.g. product or advice development).

Ancillary activities must be reported in the staff portal. Moreover, all scientists, researchers and professors at UMC Utrecht must disclose their ancillary activities by registering them in PURE.

Via the corporate website of UMC Utrecht, an up-to-date record of current ancillary activities is published. This is in accordance with the Netherlands Code of Conduct for Academic Practice of VSNU:

“Every academic practitioner affiliated with a university provides an up-to-date and complete list of their relevant ancillary activities on the university website.”

More information can be found in the Memorandum on Ancillary Activities of the UMCU.

Ownership and valorisation

Knowledge ownership

Under Dutch law and internal regulations, all results, including (without limitation) data, computer software, apps, computer databases, prototypes and biological materials (cell lines, plasmids, etc.) developed by an employee of UMC Utrecht during their term of employment remain the property of UMC Utrecht. In addition, UMC Utrecht holds all intellectual property (IP) rights to the above. It is important to agree proper arrangements in a timely manner with third parties or, for instance, temporary researchers or students (academic visitors) with regard to IP rights (and their transfer, if applicable).

Patentable inventions

UMC Utrecht has an ‘inventors’ scheme’. This scheme includes two types of arrangements: an arrangement about the internal division of costs and benefits of intellectual property rights and an arrangement about ‘fair remuneration for intellectual property rights at UMC Utrecht’. The latter arrangement includes guidelines about fair remuneration to be offered to inventors in case of commercialisation. This arrangement is in line with the framework regulation on valorisation of the Dutch Federation of Academic Medical Centres (NFU), which UMC Utrecht has committed to.

Valorisation of research results

Research results may lead to the development of new products or processes that may subsequently be marketed. The IP rights to those new products or processes may be licensed to a business or institution. Another possibility is that the new product is further developed by a spin-off business.

UMC Utrecht Holding BV is the central point of contact for potential commercialisation of patents and inventions. The Set of Guidelines Dealing with Intellectual Property Rights (IPR) for academic start-ups (Richtsnoer omgang met intellectuele eigendomsrechten (IER) richting academische start-ups) sets out the principles based on which start-ups can gain access to the IP rights of UMC Utrecht.

Academic entrepreneurship

‘Academic entrepreneurship’ means that an employee starts a business, wholly or partly for their own risk and account, and does so based on, or making use of, knowledge, materials, research results and/or intellectual property rights generated or developed in UMC Utrecht’s

name. In this context, the employee may also obtain shares or an option to acquire shares in the business, become employed by the business to a certain degree, or be engaged as an external advisor. UMC Utrecht welcomes academic entrepreneurship by its employees. After all, in most cases it is a sign that they are engaged with society. However, we do want to be able to be transparent within and outside our organisation, and prevent conflicts of interest, damage to the reputation of the employee and/or UMC Utrecht itself, and unequal treatment.

The Policy Framework on Academic Entrepreneurship (Beleidskader Academisch Ondernemerschap) describes the preconditions for academic entrepreneurship and explains what constitutes a significant personal financial interest. This document sets out in what situations permission and/or advice must be obtained. The Executive Board of Utrecht Holdings can offer advice in this matter. Legal Affairs can perform a legal assessment in accordance with the Assignment of Powers of UMCU Utrecht 2016 (Bevoegdhedenregeling UMCU Utrecht 2016).

Employees must:

1. Be absolutely transparent about the mutual interests of the parties involved. The direct superior of the employee concerned must have given their formal approval in writing;
2. Record ancillary activities and significant personal financial interests every year during the annual appraisal interview. In all situations where the employee concerned has a potential conflict of interest, the employee must report this.

Fundraising and sponsoring

Fundraising is the acquisition of funds, such as donations, bequests, legacies, private gifts, government grants and sponsor funds (see Research Support Office & Fundraising Team). Sponsoring concerns a reciprocal agreement whereby one party, the sponsor, delivers a performance with monetary value and the other party, the sponsored party, provides communication opportunities and/or other facilities for the sponsor in return, which directly or indirectly result from the activities of the sponsored party.

The following guidelines apply to sponsoring at UMC Utrecht:

1. In principle, any business that wants to sponsor the organisation while respecting the interests and the role of the institution will be eligible. However, to protect the good name of the organisation and the industry, businesses that manufacture and/or sell products which according to generally accepted views are deemed to be, or may possibly be, harmful, may be excluded as sponsors.
2. Associations with products which according to the government or generally accepted views are harmful to people's health will be avoided.
3. The performance delivered in return consists of communication or other facilities. In principle, whatever is done in return must be in proportion to the financial contribution offered. Almost any performance done in return or communication opportunity has monetary value, which reflects not only the direct costs of the communication but also its associative value. Especially in case of doubt, it makes sense to have the performance delivered in return assessed by people who are not involved in the negotiations (contact the Research Support Office for this purpose).

4. A special arrangement applies to initiatives to name buildings or building sections (rooms, halls and auditoriums) after sponsors and contributors. Permission must be obtained from the Executive Board for this.
5. Assigning care priority to certain categories of people in connection with sponsoring is not permitted.
6. The sponsored party respects and protects the privacy of its consumers (patients). Consumer data is not provided to the sponsor.
7. The sponsor and the sponsored party each have their own domain. The sponsor cannot influence the determination or implementation of the sponsored party's policy.
8. It is important to aim for transparency and to be able to account for how money, goods and time are managed.

As regards pharmaceuticals and medical devices, association with a single pharmaceutical manufacturer or drug must be avoided. When pharmaceutical companies are approached, UMC Utrecht therefore always approaches several of these companies. This is communicated to them clearly when they are approached. In the end, the result can only be sponsoring by a single business, however.

You can contact the Marketing & Communications Department if you have any questions about fundraising and sponsoring.

Inducements offered by businesses

The term 'inducement' refers to money, services or goods with monetary value being promised, offered or provided with the apparent aim of promoting the prescription, dispensing or use of a drug.

Receiving gifts

The acceptance of compensation, rewards, gifts or free use of third-party services can have unexpected and unwanted consequences. This can even lead to undesirable preferential treatment of certain businesses and persons, and to employees becoming susceptible to blackmail. To prevent employees from ending up in a situation of this kind, and to avoid giving the impression that the acceptance of business gifts may influence the provision of services, the Executive Board has laid down a Code of Conduct.

Acceptance of invitations for and offering of hospitality during meetings

Acceptance of hospitality during meetings means acceptance of compensation or acceptance of payment of travel, accommodation and registration costs, meals, etc., by businesses during meetings. Hospitality can only be accepted after approval has been obtained from the direct superior of the person concerned, and if at least the following requirements are met:

1. The hospitality remains within reasonable limits, is offered at an appropriate location, and is of secondary importance to the meeting's main objective;
2. Attendance of the substantive part of the meeting is functional, meaning that it is significant for the UMC Utrecht employee and in line with their current or future professional activities.

Acceptance of sponsoring of activities

When financial support or support that has monetary value in another way offered by businesses, i.e. sponsoring, is accepted, the reliability, independence, impartiality and scrupulousness of UMC Utrecht and its employees cannot be compromised.

Service provision to businesses

The following requirements apply to the performance of work at the request of businesses that is in line with tasks in the area of scientific research or knowledge transfer and for which the businesses offer remuneration:

1. In case of remuneration as part of scientific research or knowledge transfer, this financial information must be available publicly so that UMC Utrecht can be transparent about the risk of conflicts of interest.
2. When weighing up interests, it is essential to assure the reliability, scrupulousness and impartiality of UMC Utrecht. Even an appearance of unreliability, carelessness or partiality must be avoided.

Awarding contracts to businesses

Employees of UMC Utrecht cannot be involved in the awarding of contracts to businesses in which they themselves have an interest.

Inducements and academic education and training tasks

If inducements could lead to activities with and by students, interns, residents and PhD students, the following points of departure apply to prevent conflicts of interest:

- Contracts awarded to students, interns, residents, researchers and PhD students must be primarily aimed at and be secondary to the academic development needs of the person concerned.
- The lecturer, supervisor and/or educator must be transparent towards the student, intern, resident, researcher or PhD student about their personal interests.
- The student, intern, resident, researcher or PhD student must publish the results of the work as part of their training or research.

Conflicts of interest

Avoiding conflicts of interest or the appearance thereof is absolutely essential. Employees bear primary responsibility for preventing potential conflicts of interest or keeping them under control, and for reporting them to their superior. Every researcher is responsible for ensuring that their own financial interests or those of the research sponsor can never have a negative effect on patients' treatment. Unjustified inclusion of subjects must be avoided. Any appearance of a conflict of interest may harm subjects' confidence in the integrity of scientists. Researchers must be aware of the importance of gaining the confidence of potential and existing subjects. If a researcher has personal financial interests in a study with human subjects, this is regarded as an unacceptable conflict of interest.

MREC review of financial arrangements

The MREC offers its opinion on the remuneration offered to researchers and subjects, and the corresponding amounts, as well as on the relevant parts of every contract between the sponsor and the site (EU Directive 2001/20/EC Article 6-j). Any type of reward or possible conflict of

interest must be reported to the MREC. This is in accordance with the International Ethical Guidelines for Health-related Research involving Humans from the Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO)(2016).
26 In its review of sponsored research, the MREC assesses the financial interests in conjunction with other aspects of the research. Certain circumstances can increase the pressure exerted by financial interests. In particular, the MREC pays attention to:

- Studies involving patients from a small population. The importance of inclusion of an individual is greater if only a limited number of people meet the inclusion criteria for the study;
- Studies involving patients who are unable to exercise their free will;
- Studies involving patients who find themselves in circumstances where their capacity to form an opinion is under pressure (think of patients whose treatment options have been exhausted);
- Studies associated with a significant burden or a high risk for subjects;
- Studies where considerable amounts of money are paid to patients.
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NIH-funded research

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More information can be found here.

Further information

- [NIH Grants and Funding: Financial Conflict of Interest](#)
- [NIH Grants and Funding: Financial Conflict of Interest: Frequently Asked Questions](#)
- [Training \(for research administrators\)](#)
- [CAO UMC 2015-2017](#) (English)
- [UMC Utrecht information on Outside activities](#) (available through Intranet)