Research Code UMC Utrecht (PDF) *07-02-2019*

- The Research Code of UMC Utrecht is available as a PDF in both Dutch and English. However, we want to prevent multiple versions of it from "roaming around" and recommend that you always consult the latest version of the website at http://researchcode.umcutrecht.nl –

Contents

SCIENTIFIC INTEGRITY

Guiding principles

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).*

Scientific misconduct and fraud

Unfortunately, scientific integrity violations do occur; they are referred to as scientific misconduct or scientific fraud.

Fabrication: making up results and presenting them as genuine;
Falsification: manipulating research processes, or changing or omitting data;
Plagiarism: making use of other people's work without properly recognising it or providing references.

Other examples are:

- Not (or not fully) meeting the inclusion and exclusion criteria set out in the protocol;
- Using improper statistical methods to generate wished-for conclusions;
- Not meeting the applicable ethical and statutory requirements, e.g. misrepresentation of interests, breach of trust/confidentiality, lack of informed consent, and abuse of research subjects or materials;
- Not dealing properly with misconduct or fraud, e.g. covering up misconduct and thwarting whistle-blowers.

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 Klokkenluiders*, Maliebaan 72, Utrecht), or
3. An advisor with a duty of confidentiality, like a lawyer.

What about anonymity?

It is possible to report suspicions of scientific misconduct anonymously. However, we have learned from experience that the best approach is to make an appointment with the Confidential Advisor for Integrity for a confidential, private conversation. In this case your identity will only be known to the Confidential Advisor for Integrity. Based on this conversation, you can personally decide whether, how and where you will report your suspicion.

RESEARCH

Sound scientific research

The standards listed below, from the Netherlands Code of Conduct for Research Integrity (VSNU), apply as minimum requirements that researchers must meet in the design and conduct of their research, whether acting as an individual or as part of a team. UMC Utrecht supports researchers in this, and creates a work environment where sound research practices are promoted and assured.

Design

1. Consider the interests of scientific research and/or society when determining the subject and structure of your research.
2. Conduct research that can be of scientific or social relevance.
3. Do not make unsubstantiated claims about results to be obtained.
4. Take the state of the art into account when developing new research.
5. Make sure your research design can provide an answer to the research question.
6. Ensure that the methods you employ are well justified.
7. If the research is conducted on commission and/or is funded by third parties, always make clear who the commissioning party and/or funding body is (see Collaborative arrangements).
8. Be open about the role of external stakeholders and possible conflicts of interest (see Conflicts of interest).
9. In research with external partners, make clear written agreements about research integrity and related matters such as intellectual property rights (see Ownership and valorisation).
10. As necessary, describe how the collected research data are organized and classified so that they can be verified and reused.
11. As far as possible, make research findings and research data public subsequent to completion of the research. If this is not possible, establish valid reasons for their non-disclosure.
12. a. In the event of an investigation into alleged research misconduct, make all relevant research and data available for verification subject to the confidentiality safeguards established by the board of the institution.

b. In highly exceptional cases, there may be compelling reasons for components of the research, including data, not to be disclosed to an investigation into alleged research misconduct. Such cases must be recorded and the consent of the board of the institution must be obtained prior to using the components and/or data in question in the scientific or scholarly research. They must also be mentioned in any results published.
13. Ensure that the required permissions are obtained and that, when necessary, an ethical review is conducted (see Respect for people and Respect for animals).
14. Accept only research assignments that can be executed in accordance with the standards in this Code.
15. Enter into joint research with a partner not affiliated with an institution which has adopted this or a comparable Code only if there is sufficient confidence that your own part of the research can be conducted in compliance with this Code and the joint research results meet generally accepted principles of integrity in research.

Conduct

1. Conduct your research accurately and with precision.
2. Employ research methods that are scientific and/or scholarly.
3. Make sure that the choice of research methods, data analysis, assessment of results and consideration of possible explanations is not determined by non-scientific or non-scholarly (e.g. commercial or political) interests, arguments or preferences.
4. Do not fabricate data or research results and do not report fabricated material as if it were fact.
5. Do justice to all research results obtained.
6. Do not remove or change results without explicit and proper justification. Do not add fabricated data during the data analysis.
7. Ensure that sources are verifiable.
8. Describe the data collected for and/or used in your research honestly, scrupulously and with as much transparency as possible (see Data management in research).
9. Manage the collected data carefully and store both the raw and processed versions for a period appropriate for the discipline and methodology at issue. (see Data management in research).
10. Contribute, where appropriate, towards making data findable, accessible, interoperable and re-usable in accordance with the FAIR principles (see Data management in research).
11. Take into consideration the interests of any humans and animals involved, as well as any risks to the researchers and the environment, while always observing the relevant statutory regulations and codes of conduct (see Respect for people and Respect for animals).
12. Keep your own level of expertise up to date.
13. Take on only those tasks that fall within your area of expertise.
14. If you are an experienced researcher, then act as a role model for inexperienced colleagues (see Good mentorship).

Support

UMC Utrecht imposes stringent quality requirements on scientific research. In line with the care for patients, it is essential that scientific research meets certain quality requirements. UMC Utrecht supports researchers in this. Training programmes, procedures and quality controls help improve the quality of scientific research. UMC Utrecht offers online research support from the start of a research project (WMO/non-WMO/biobank/animal/fundamental research) to its completion.

At UMC Utrecht, quality assurance of WMO and non-WMO research occurs in accordance with the NFU requirements:

Policy and SOPs: Policy and SOPs for research.

Monitoring: Monitoring is compulsory for all WMO research, with the monitoring intensity depending on the risk classification (SOP Monitoring).

Data and Safety Monitoring Board (DSMB): UMC Utrecht has an internal DSMB. (SOP DSMB)

Auditing: UMC Utrecht has a UMC-wide internal audit programme (SOP Auditing).

Archiving: All files of research involving human subjects (whether or not subject to the WMO) must be archived conform applicable laws and regulations (SOP Termination).

Training: Since 2006, all clinical investigators have been required to complete the BROK course ('Basic Course on Regulations & Organisation for Clinical Investigators'). Once every four years, every clinical investigator must obtain BROK re-certification, and they have to register for this re-certification themselves. For other scientific researchers, the WMO/GCP training course is compulsory (SOP Training Requirements).

Research Code: The present Research Code describes both the applicable laws and regulations and the policy of UMC Utrecht concerning scientific integrity.

Respect for people

It is the duty of researchers to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of people, who are involved in research (Declaration of Helsinki).

Respect for people cannot be laid down in rules or procedures. It is a state of mind. As a researcher, you feel responsible for your research subjects. You take their interests, and the impact the research project may have on them, into consideration. You ensure that they are aware of this as well.

Responsibility for the protection of research subjects must always lie with the researcher and never with the subject, not even after the subject has given his/her consent. Respect for people taking part in research is essential in order to guarantee the confidence and cooperation of future research subjects.

Research involving human subjects

Research involving human subjects may fall within the scope of the Dutch Medical Research Involving Human Subjects Act (*Wet medisch-wetenschappelijk onderzoek met mensen* or WMO), in which case it is referred to as WMO research, but some research involving human subjects does not (non-WMO research).

The Dutch national Central Committee on Research Involving Human Subjects (CCMO) describes the laws and regulations for research involving human subjects, for WMO research, for non-WMO research. The CCMO has drawn up a decision diagram which can help determine whether a research proposal falls within or outside the scope of the WMO.

UMC Utrecht has a Medical Research Ethics Committee (MREC), which is officially recognized by the CCMO. According to UMC Utrecht's current policy, all clinical research involving human subjects must be submitted to the MREC before the study starts. This applies regardless of whether the study is subject to the WMO. The MREC will issue a non-WMO statement if it concludes that the research is not subject to the WMO. WMO research needs to be positively reviewed by an MREC -or in specific kinds of research by the CCMO itself- before the research is allowed to start.

Non-WMO research does not have to be reviewed by an MREC or CCMO. In UMC Utrecht however, research that involves human biological materials needs to be positively reviewed by the Biobanks Review Committee (see Research involving human biological materials). New policies for non-WMO research are currently being developed in UMC Utrecht.

WMO research
The review of WMO research proposals by the MREC occurs on the basis of (inter)national laws and regulations. UMC Utrecht's policy with regard to WMO research can be found here. More information for UMC Utrecht researchers can be found at the website of the MREC.

Non-WMO research
Examples of non-WMO research are: prospective observational studies, retrospective status research, non-demanding questionnaires, case reports, non-WMO studies with a medicinal product or medical devices. For research involving human subjects that falls outside the scope of the WMO, national codes of conduct apply. Specific types of research are, moreover, subject to legislation, such as the Agreement on Medical Treatment Act (Wet op de geneeskundige behandelingsovereenkomst (WGBO), in Dutch) . More information can be found at the website of the CCMO and the website of the MREC.

In case of non-WMO research with a medicinal product, special rules apply, with extra attention being paid to drug advertising and to national and international safety studies with authorised drugs.

Healthy volunteers
To research involving healthy volunteers, the following applies at UMC Utrecht:
1. Healthy volunteers must also be registered in the Electronic Medical Record (EPD/HIx).
2. Employees of UMC Utrecht cannot take part in a study as a subject if the principal investigator works in the same department as the subject. For more information: Information on policy for medical scientific research.

Research involving human biological materials

Out of respect for people, researchers must ensure that the human biological materials they can use come from people who have expressly given their consent for this or who have not objected to it. Results of research involving human biological materials may benefit the subjects themselves and/or others. The Dutch national Good Practice Code (*Code Goed Gebruik*) applies

to research involving human biological materials. UMC Utrecht is responsible for all human biological materials stored here and for the dedicated policy, as described in the UMC Utrecht Biobank Regulations (*Kaderreglement Biobanking*).

Review of collection and use of human biological materials

At UMC Utrecht, the Biobanks Review Committee (*Toetsingscommissie Biobanken* or TCBio) assesses the scientific, legal and ethical aspects of both the collection of human biological materials and the use of collected human biological materials and the corresponding personal and other data. Information about the submission of proposals for the set-up of a sub-biobank and/or the issue of human biological materials can be found here. In some cases, supplementary human biological materials are collected from subjects in WMO studies for a sub-biobank. The MREC will then review this sub-biobank in combination with the WMO study.

Storage of human biological materials

UMC Utrecht has set up the Central Biobank (*Centrale Biobank*). In this biobank, researchers can store the human biological materials in a safe and approved manner (ISO 9001-certified).
In principle, the materials are available to all researchers; they can be used for research with permission from the party collecting them, and after obtaining approval from the Biobanks Review Committee.

The following applies specifically to the storage of human biological materials:

1. Safety & accuracy: When collecting, processing and storing human biological materials, pay express attention to health and safety aspects, infection risk, expiry, identification, encoding, confidentiality and registration. Biological materials collected as part of diagnostic processes or treatment must be processed and stored according to the specific applicable protocols (microbiology, clinical chemistry, pathology).
2. Traceability: The stored human biological materials must be encoded, meaning that the person from whom material originates can only be identified via an encrypted code.
3. Storage period: The storage period for human biological materials can be as long as has been agreed in the informed consent document. Guidelines for storage periods are agreed for each type of material within a specific medical field.

Research with data relating to humans

Out of respect for people, as a researcher you ensure that personal data is from people who have either expressly given their consent for this or have not objected to it. Naturally, as a researcher you will protect people's privacy at all times. Research that 'merely' involves data use can still affect people's interests or rights. For example, a study may yield information that can benefit the subjects themselves and/or other people. This is why you need to exercise caution.

Since 25 May 2018, research involving personal data is subject to the European General Data Protection Regulation (GDPR). For research, the GDPR includes specific exceptions to the general rules. As a researcher at UMC Utrecht you must adhere to the Dutch GDPR implementation law (*Uitwerking AVG*). In line with this, UMC Utrecht has drawn up several guidelines concerning privacy and information security. For researchers at UMC Utrecht, the regulations for processing of patient data (Privacy Regulations) apply in particular, especially Article 14: Medical scientific research with personal data. More information about privacy in scientific research can be found here.

To assure scientific integrity, proper data management is important as well (FAIR data management). See Data management in research.

UMCU Privacy Regulations, Article 14:
Medical scientific research with personal data

Article 14. Medical scientific research with personal data

1. Medical scientific research is preferably performed using anonymous data. If this is not possible, it can be done using pseudonymised data. Or, as a last resort, it can be done using identifiable data, but only with the patient's permission.

2. Data subjects are informed about the possible use of their data for medical scientific research, and of the fact that they can object to this use.

3. If data has been pseudonymised or is identifiable, the treating physician may decide to provide it or have it provided for the purpose of medical scientific research and for statistical purposes.

4. For the use of pseudonymised or identifiable data for the purpose of medical scientific research, the data subject is in principle asked for their consent (see Article 5).

5. Medical scientific research with personal data can be conducted without the data subject's consent if:
a. Asking the data subject for their consent is not reasonably possible and guarantees have been provided with regard to the performance of the research, to such an extent that the data subject's privacy will not be disproportionately undermined, or
b. In view of the nature and the purpose of the research, asking the data subject for their consent cannot be reasonably required, and the treating physician has ensured that the data is provided in a form that makes it impossible to identify the individual natural person concerned.

In the cases referred to above, data provision is only possible if:
a. The research is of a general public interest;
b. The research cannot be performed without the person concerned, and
c. The data subject has not objected to the data provision.

Research with medical devices

The term medical device is the legal term for medical equipment or instruments designated by the manufacturer for use in humans for the diagnosis, treatment or alleviation of diseases. When scientific research is started with a medical device, different legislation must be complied with. Think of the Medical Research Act with People (WMO), Law and Decree on Medical Devices or the European Medical Device Directive (EMDD). More information about **scientific research with medical devices**.

Respect for animals

While animals can be used for research or educational purposes, they must be protected and respected when doing so, owing to their intrinsic value.

The current laws and regulations governing animal testing have been described in detail by the Animal Welfare Body Utrecht (*Instantie voor Dierenwelzijn*).

In the Netherlands, the Experiments on Animals Act (*Wet op de dierproeven* or Wod) applies. The Dutch Association for Laboratory Animal Science (*Nederlandse Vereniging voor Proefdierkunde* or NVP) recommends using the 3 Rs (Russel and Burch). The 3Rs-Centre Utrecht Life Sciences (ULS) offers support in this. These principles promote the best possible use of animals, and at the same time can improve the value of scientific experiments:

- ***Replacement:*** *methods/techniques/strategies that avoid or replace the use of animals in research;*
- ***Reduction:*** *use of methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals;*
- ***Refinement:*** *use of methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used.*

Experiments with animals are not permitted if the same results can be obtained in a different way, or if the experiment can be performed with fewer animals or less suffering. Moreover, the scientific value of the experiment must be proportional to the animals' suffering. At Dutch UMCs, animal test subjects must be handled in a humane way and must be accommodated, cared for and treated in accordance with the European Directive of 22 September 2010 on the protection of animals used for scientific purposes.

Animal Experiments Committee Utrecht

Research performed on or with animals at UMC Utrecht must be reviewed and approved in advance by the Animal Experiments Committee Utrecht (*Dierexperimentencommissie Utrecht*)

Researchers performing animal experiments

All researchers intending to work with animals must first complete the Course on Laboratory Animal Science (*Cursus Proefdierkunde*). To realise responsible use of animal test subjects, all employees involved in animal testing at Utrecht University and UMC Utrecht must adhere to several codes of practice.

Reporting Desk for Professional Conduct and Animal Welfare

If, as a student or employee, you find yourself in a situation involving animal test subjects that violates the applicable ethical standards or statutory requirements, you can report this to the Reporting Desk for Professional Conduct and Animal Welfare (*Meldpunt Professioneel Handelen en Dierenwelzijn*). This reporting desk has been set up for employees and students of UMC Utrecht and Utrecht University in the faculties of Veterinary Medicine, Science, and Medicine, and the Central Animal Laboratory (*Gemeenschappelijk Dierenlaboratorium*).

Always discuss the situation with your lecturer, tutor or superior first. If their response is unsatisfactory, then contact the Animal Welfare Body Utrecht. If you still have concerns after that, you can file a report with the Reporting Desk for Professional Conduct and Animal Welfare. Your report will be handled confidentially.

Data management

Data management in science is essential to realise high-quality research and scientific integrity. Both UMC Utrecht and our researchers make sure that people's privacy is protected and that proper, responsible data management is carried out, both before, during and after the performance of a study.

UMC Utrecht plays a leading role in global movements such as Open Science (and Open Access). Like the other Dutch UMCs, UMC Utrecht adheres to the NFU guidelines for data stewardship, and this is reflected in the UMC Utrecht Data Management Policy (*Datamanagementbeleid*). We acknowledge data as legitimate and citable products of research, and we are transparent about how data can be accessed or used.

This means that as a researcher you ensure that your research data is in line with the FAIR principles (meaning that research data must be 'findable, accessible, interoperable and re-usable'), and is shared with other researchers as much as possible. To achieve this, a Data Management Plan (DMP) must be completed as an integrated part of the research protocol. The DMP describes the standardised way in which the data is collected, used and stored during the research, filed after the study, and made accessible to others after the research has been completed. Sometimes a Privacy Impact Assessment (PIA) is also required. UMC Utrecht offers support in this in several ways; see ICT in research for more information.

We ensure that contracts relating to research data are fair and acceptable as regards the use, ownership and/or protection of data based on intellectual property rights.

Privacy and information security

There are few institutions where ensuring proper information and communication is valued as highly as at our UMC. The quality of our care, our scientific research and our educational programmes depend on it. After all, we can only make the right decisions if the data on which we base ourselves is correct and available when we need it. In short: we must prevent loss or abuse of information at all times. However, technical measures alone will not be sufficient to cover all risks. Like any job, privacy protection and information security are done by people, which means they are your responsibility as well. Information must be available at the right moments, must be reliable, and must be protected against unauthorised access.

UMC Utrecht's policy (guidelines and normative frameworks) can be found here.

UMC Utrecht has drawn up several general rules for privacy and information security:

- Handle information carefully.
- Use ICT resources with great care.
- Be aware of the dangers of the internet and e-mail.
- Report security incidents (reporting data breaches!).
- Always be alert!

Specific information about privacy and scientific research can be found here.

POSITION AND PUBLICATION

Good mentorship

Inexperienced researchers conduct their research under the guidance of a more experienced researcher, such as a post-doctoral researcher, a university lecturer or a university professor. In practice, these people often act as role models for the young researcher when it comes to scientific integrity.

Proper mentorship for a young researcher consists of the following:

- Offering guidance and feedback on a daily basis;
- Encouraging the researcher and showing a genuine interest in their work;
- Supervising their work with an appropriate intensity and with respect;
- Supervising all relevant stages of the research project;
- Monitoring progress and critically reviewing the raw data together with the young researcher;
- Encouraging them to work in accordance with the quality requirements, and monitoring this through quality checks;
- Supervising the researcher's integrity relating to the design and performance of the study, data management and submission of publications;
- Checking whether the young researcher applies proper authorship principles.

PhD students

The purpose of the working relationship between the researcher and their superior must be clear, as must the researcher's tasks and the superior's responsibilities with regard to the research. These aspects are laid down in the compulsory Teaching and Supervision Agreement. By signing this agreement, a PhD student certifies that they will act with scientific integrity and they will adhere to the Netherlands Code of Conduct for Academic Practice.

Students

Scientific research and students' research traineeships fall within the normative frameworks of this Code. Failure to comply with the standards in this code can lead to a complaint procedure and the imposition of sanctions. If, in exceptional cases, only research has been conducted within an educational context that does not result in publications other than a published thesis, this can be dispensed with.

Combining roles properly

Researchers at a university hospital often perform additional roles or hold additional positions. For instance, they can be a medical specialist, a lecturer or an entrepreneur in addition to being a scientist. As a result, conflicts of interest may develop, and these may lead to dilemmas. It is not possible to offer definite advice for all these types of situations, but the present Research Code can serve as a guide. Moreover, at UMC Utrecht all employees are subject to the general code of conduct: Integrity at UMC Utrecht.

As these kinds of dilemmas are a regular occurrence at a university medical centre, it is important to be aware of them and to talk about them with colleagues on a regular basis. In addition, it is possible to practise situations where there may be a conflict of interest, and people can learn from experience how to deal with various situations in the best way possible.

Publications, authorship and references

Publications

Knowledge dissemination must be the main objective when publishing research information. Researchers are responsible for publishing data from their research. They recognise the publication of research as being essential for scientific progress and endeavour to have their research published, regardless of the outcome.

1. Present sources, data and arguments in a scrupulous way.
2. Be transparent about the method and working procedure followed and, where relevant, record them in research protocols, logs, lab journals or reports. The line of reasoning must be clear and the steps in the research process must be verifiable. This usually means that the research must be described in sufficient detail for it to be possible to replicate the data collection and its analysis.
3. Be explicit about any relevant unreported data that has been collected in accordance with the research design and could support conclusions different from those reported.
4. Be clear about results and conclusions, as well as their scope.
5. Be explicit about uncertainties and contra-indications and refrain from drawing unsubstantiated conclusions.

6. Be explicit about serious alternative insights that could be relevant to the interpretation of the data and the research results.
7. As far as possible, make research findings and research data public subsequent to completion of the research. If this is not possible, establish the valid reasons for this.
8. Be open and complete about the role of external stakeholders, commissioning parties, funding bodies, possible conflicts of interest and relevant ancillary activities (see Scientific integrity in collaborative arrangements).
9. When publishing research findings in journals, use a peer review procedure.
10. Be generous in cooperating with internal and external reviews of your own research.

Note: Interests of sponsors must not prevent or significantly delay knowledge dissemination. Sponsors can have the opportunity to comment, but the researcher must reserve the right to leave the publication unchanged.

Right to authorship

Authorship must be based on a substantial intellectual contribution to the research and the manuscript.

1. Do justice to everyone who contributed to the research and to obtaining and/or processing the data.
2. Ensure a fair allocation and ordering of authorship, in line with the standards applicable within the discipline(s) concerned.
3. All authors must have made a genuine intellectual contribution to at least one of the following elements: the design of the research, the acquisition of data, its analysis or the interpretation of findings.
4. All authors must have approved the final version of the research product.
5. All authors are fully responsible for the content of the research product, unless otherwise stated.

UMC Utrecht subscribes to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals as described by the International Committee of Medical Journal Editors. Anyone who is an author must meet the requirements for authorship. And anyone who meets the requirements for authorship must be offered authorship. Every author must have contributed to the project to a sufficient degree to be able to take responsibility for the contents of the entire article.

An author must take responsibility for at least one component of the work, must be able to indicate who is responsible for the other components, and should not have any reason to doubt the competence and integrity of their co-authors.

A person has a right to authorship if they meet each of the following three criteria:

1. They have contributed substantially to:

- The set-up and design, or
- Data collection, or
- Analyses and interpretation of the data.

2. They have collaborated by writing or critically reviewing the manuscript.
3. They have given their final approval of the version to be published.

For the sake of clarity it is important to state that:

- Obtaining a grant, collecting data and/or generally managing a research group is NOT sufficient to warrant authorship;
- Wrongly listing authors or co-authors (guest or honorary authorship) or wrongly leaving out qualified researchers (ghost authorship) is regarded as scientific misconduct.

Proper referencing

One aspect of scientific integrity is the correct use of references.

1. When making use of other people's ideas, procedures, results and text, do justice to the research involved and cite the source accurately.
2. Avoid unnecessary reuse of previously published texts of which you were the author or co-author.
   a. Be transparent about reuse by citing the original publication.
   b. Such self-citation is not necessary for reuse on a small scale or of introductory passages and descriptions of the method applied.
3. Always provide references when reusing research material that can be used for meta analysis or the analysis of pooled data.
4. Avoid unnecessary references and do not make the bibliography unnecessarily long.

Peer review

The reviewer's motivation must be based on the importance of sound science. For the researchers involved, serious consequences are attached to opinions given by external reviewers about articles and research proposals. Therefore, it is important to ensure that the review is excellent in terms of the quality of the contents, respect, and impartiality. In addition, peer reviewers must assure idea ownership and confidentiality.

1. Be honest and scrupulous as a peer reviewer or reviewer, and explain the assessment.
2. Do not use confidential information that was acquired in the context of an assessment, unless explicit consent was given.
3. Do not review a work if your independence can be called into question, for example because of possible business or financial interests (see Conflicts of interest).

4. Do not review works outside the area of your own expertise, unless in general terms only.

Public communication

Some research projects may be of a sensitive nature for certain groups in society. Think of the press, the general public, or interest groups. This sensitivity may be related to the subject of the research or to the method used. In such cases, more is often involved than just facts: perception frequently plays a role as well.

1. Be honest in public communication and be clear about the limitations of the research and your own expertise. Only communicate about the research results if there is sufficient certainty about the results.
2. Be open and honest about your role in the public debate and about the nature and status of your participation in that debate.
3. Be open and honest about possible conflicts of interest, also to external parties (see Conflicts of interest and Ancillary activities).

Dealing with the Media

Media attention has certain benefits. Researchers can show how public funds have been spent, and they can inform society about scientific developments (social duty and accountability). Moreover, if positive information is provided this can facilitate the acquisition of funding and build a reputation of solid expertise for UMC Utrecht.

Yet it is often difficult to convey the message researchers want to bring across including the subtler nuances. Commercial and political interests may result in undue influence. Therefore, careful, responsible conduct is required. The Marketing & Communications Department can offer assistance as well as advice on how and when to communicate with these groups.

For that reason, the Executive Board wants all contact with the press to run via the Projects & Advice Team of UMC Utrecht (Marketing & Communications Department).

The guidelines as described in the Media Protocol help achieve successful interaction with the press.

COLLABORATIONS

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.

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).

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.

NIH-funded research

Every Investigator at UMC Utrecht, 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 UMC Utrecht 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 2015-2017.

All researchers of the University Medical Centre Utrecht are asked to inform Research Support Office when applying for NIH research funding.

More information can be found here.