Maastricht UMC+ Research code

Maastricht UMC+ | Maastricht University


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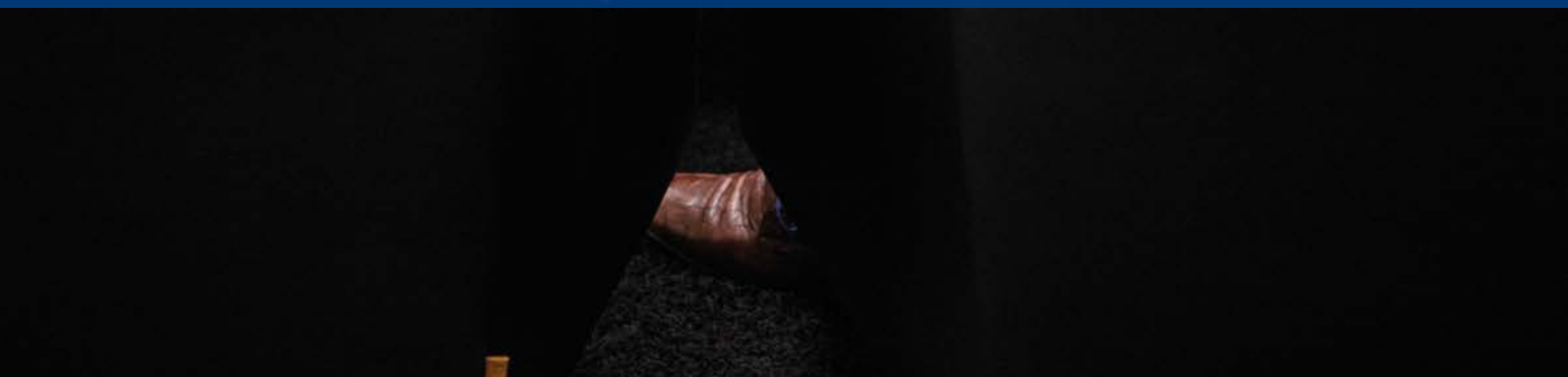
Prof. dr. M. van Dieijen, CEO
Prof. dr. A. Scherpbier, Dean FHML/Vice Chairman



Preface

Scientific and clinical research in particular, take place in an arena of competing interests. It is the task of the Executive Board of Maastricht University Medical Center+ (Maastricht UMC+) and the researchers to protect the integrity of scientific research in such an arena. Scientific integrity means following the principles and guidelines for ethically and socially responsible research.
The Executive Board of Maastricht UMC+ considers it essential that all researchers employed by the Faculty of Health, Medicine and Life Sciences (FHML) or the academic hospital Maastricht work in accordance with the current laws and regulations as defined in the Netherlands Code of Conduct for Research Integrity. The Research Code Maastricht UMC+ defines and refers to the rules for ethically and socially responsible conduct in scientific research within the academic hospital Maastricht and the FHML of Maastricht University (UM) who work together under the name Maastricht UMC+.

The Research Code Maastricht UMC+ provides those involved in research with the principles and framework to guide researchers in living up to values of ethically and socially responsible conduct in scientific research. Moreover, this code contributes to an atmosphere of openness and a culture in which doing research is enjoyable and productive. All scientific staff, from principal investigators to junior researchers, as well as research support staff should know of the code and be familiar with its content. For stakeholders, the Research Code offers a description of the principles applied by Maastricht UMC+ when preparing, performing and publishing scientific research.
Because the scientific world is very dynamic, the most recent version of the Research Code Maastricht UMC+ is available digitally. This allows for quick incorporation of new developments and, if applicable, changes in laws and regulations. Thus, researchers at Maastricht UMC+ are always assured of the most current information. The Research Code is available for download via the website of the FHML **(www.maastrichtuniversity.nl/researchcodeMUMC)** and the website of the Maastricht UMC+ **(www.mumc.nl/research/research-code)**.

The Executive Board of Maastricht UMC+ is confident that the Research Code Maastricht UMC+ will ensure scientific research with honesty, scrupulousness, transparency, independency and responsibility as leading principles.

On behalf of the Executive Board of Maastricht UMC+,
Prof. dr. M. van Dieijen, CEO
Prof. dr. A. Scherpbier, Dean FHML/Vice Chairman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1

Leading principles of scientific research

The Research Code Maastricht UMC+ follows the five principles of good academic teaching and research as identified and defined in the **Netherlands Code of Conduct for Research Integrity.** The five principles are:

1. **Honesty:** Academic practitioners are honest and open about their research and its applications. This means that they report the research process accurately, take alternative opinions and counterarguments seriously, are open about margins of uncertainty, refrain from making unfounded claims, refrain from fabricating or falsifying data or sources and refrain from presenting results more favourably or unfavourably than they actually are.

2. **Scrupulousness:** Academic practitioners use methods that are scientific or scholarly and exercise the best possible care in designing, undertaking, reporting and disseminating research.

3. **Transparency:** Academic practitioners ensure that it is clear to others what data the research was based on, how the data were obtained, what and how results were achieved and what role was played by external stakeholders. If parts of the research or data are not to be made public, the researcher must provide a good account of why this is not possible. It must be evident, at least to peers, how the research was conducted and what the various phases of the research process were. At the very least, this means that the line of reasoning must be clear and that the steps in the research process must be verifiable.

4. **Independence:** Academic practioners operate in a context of academic freedom and independence. They will not allow the choice of method, the assessment of data, the weight attributed to alternative statements or the assessment of others' research or research proposals to be guided by non-scientific or non-scholarly considerations (e.g. those of commercial or political nature). In this sense, independence also includes impartiality. Independence is required at all times in the design, conduct and reporting of research, although not necessarily in the choice of research topic and research question.

5. **Responsibility:** Academic practitioners acknowledge the fact that a researcher does not operate in isolation and hence take into consideration – within reasonable limits – the legitimate interests of human and animal test subjects, as well as those of commissioning parties, funding bodies and the environment. Responsibility also means conducting research, that is scientifically and/or societally relevant.

When a researcher is appointed at any university in the Netherlands, the researcher has to declare to be aware of and to adhere to the **Netherlands Code of Conduct for Research Integrity.**

Respect for people and test animals involved in scientific research
In addition to the aforementioned principles, respect for each individual and for the rights of each participant, regardless of his or her level of involvement in the study, is an absolute requirement in any kind of scientific research. This applies particularly to the right to protect the physical and mental integrity of individuals involved in research and their right to protection of privacy. Research with human participants can only take place based on voluntary cooperation and after these participants are fully informed about the implications and procedures involved.

In addition to humans, animals can also be the subjects of scientific research. Animal testing for research purposes is only allowed if there are no suitable alternatives available.

The Research Code Maastricht UMC+ endorses the five principles of the Netherlands Code of Conduct for Research Integrity: honesty, scrupulousness, transparency, independence and responsibility.


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Research Integrity

The Netherlands Code of Conduct for Research Integrity and the UM Code of Conduct on Integrity form the guiding principles for Maastricht UMC+'s integrity policy. The Netherlands Code of Conduct for Research Integrity focusses on the definition of the principles of research integrity and the ensuing guidelines for good research practices. The Code provides both methodological standards (as to what a good researcher does) and ethical standards (as to what a researcher with integrity does).

According to the Netherlands Code of Conduct for Research Integrity, there is a distinction between 'research misconduct', 'questionable research practices' and 'minor shortcomings'. 'Research misconduct' is the most serious violation. The clearest examples of research misconduct are fabrication, falsification and plagiarism.

- Fabrication means the invention of data or research results and reporting them as if they are fact.
- Falsification means the manipulation of data or research material, equipment or processes to change, withhold or remove data or research results without justification.
- Plagiarism means the use of another person's ideas, work methods, results or texts without appropriate acknowledgement.

Some examples of questionable research practices are (source: The European Code of Conduct for Research Integrity):

- Manipulating authorship or denigrating the role of other researchers in publications.
- Re-publishing substantive parts of one's own earlier publications, including translations, without duly acknowledging or citing the original ('self-plagiarism').
- Citing selectively to enhance own findings or to please editors, reviewers or colleagues.
- Withholding research results.
- Allowing funders/sponsors to jeopardise independence in the research process or reporting of results to introduce or spread bias.
- Expanding unnecessarily the bibliography of a study.
- Accusing a researcher of misconduct or other violations in a malicious way.
- Misrepresenting research achievements.
- Exaggerating the importance and practical applicability of findings.
- Delaying or inappropriately hampering the work of other researchers.
- Misusing seniority to encourage violations of research integrity.
- Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.
- Establishing or supporting journals that undermine the quality control of research ('predatory journals').

Possibility to report violations of scientific integrity

One way to monitor scientific integrity is to exercise the right of complaint when employees of Maastricht UMC+ have violated or are suspected of having violated scientific integrity. To implement this right of complaint, the UM has established the **Maastricht University Complaints Regulations on Scientific Integrity.** This regulation applies also to Maastricht UMC+ employees (FHML or academic hospital employees).

In case of questions or complaints regarding scientific integrity, different routes can be followed depending on the situation:

1. Contact your manager, promotor, PhD coordinator or confidential counsellor within the School/Institute.
2. Contact the **UM Counsellors on Scientific Integrity**.
3. Contact the **UM Committee on Scientific Integrity** (Commissie Wetenschappelijke Integriteit, CWI, in Dutch).

The cousellors on scientific integrity are the primary contact persons for questions or complaints concerning scientific integrity. The counsellor will try to mediate in the complaint in order to reach a resolution. If a solution cannot be found, the counsellor will guide the complainant in filing the complaint with the UM Committee on Scientific Integrity.
The Committee for Scientific Integrity advises the Executive Board on complaints regarding scientific integrity.
If the claimant or defendant disagrees with the recommendation of the UM Committee for Scientific Integrity and the initial or final decision of the Executive Board, the claimant or defendant may submit the case to the Netherlands Board on Research Integrity **(Landelijk Orgaan Wetenschappelijke Integriteit, LOWI)**. The LOWI will then issue an independent recommendation to the Executive Board.

Standards for good research practices

The **Netherlands Code of Conduct for Research Integrity** lists 61 specific standards for good research practices. Most are presented separately for each individual phase of the research process: design, conduct, reporting, assessment and peer review and communication. Some standards are applicable to all phases. Not all of the 61 standards have the same ‘weight’, and non-compliance with the standards does not necessarily mean that the researcher has committed ‘research misconduct’. It depends on which of the standards were not met, and to what extend a standard was not followed. In serious cases, non-compliance with one or more standards constitutes ‘research misconduct’ on the part of the researcher involved as well as, where applicable, the supervisor, principal investigator, research director or manager who incited that non-compliance.

In the list below, only the more serious standards are mentioned. The complete list of standards can be found in Chapter 3 of the Netherlands Code of Conduct for Research Integrity.

Design

- If the research is conducted on commission and/or funded by third parties, always specify the commissioning party and/or funding body.
- Be open about the role of external stakeholders and possible conflicts of interest.
- Accept only research assignments that can be undertaken in accordance with the standards in this Code.

Conduct

- 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.
- Do not fabricate data or research results and do not report fabricated material as if it were fact.
- Do not remove or change results without explicit and proper justification. Do not add fabricated data during the data analysis.
- Ensure that sources are verifiable.
- Describe the data collected for and/or used in your research honestly, scrupulously and as transparently as possible.

Reporting results

- Ensure a fair allocation and ordering of authorship(s), in line with the standards applicable within the discipline(s) concerned (see 6.3).
- Present sources, data and arguments in a scrupulous way.
- 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.
- Be explicit about uncertainties and contraindications, and do not draw unsubstantiated conclusions.
- When making use of other people's ideas, procedures, results and text, do justice to the research involved and cite the source accurately.
- Always provide references when reusing research material that can be used for meta-analysis or the analysis of pooled data.
- Be open and complete about the role of external stakeholders, commissioning parties, funding bodies, possible conflicts of interest and relevant ancillary activities.
- As far as possible, make research findings and research data public subsequent to research completion. Alternatively, provide the reasons why this is not possible.

Assessment and peer review

- Do not use information acquired during an assessment without explicit consent.
- Refrain from making an assessment if any doubts could arise regarding your independence (for example, because of possible commercial or financial interests).

Communication

- Be honest and transparent regarding limitations of the research and your own expertise in public communications.
- Only communicate sufficiently certain research results to the public.
- Be open and honest about potential conflicts of interest.

Standards that are applicable to all phases of research

- As a supervisor, principal investigator, research director or manager, refrain from any action which might encourage a researcher to disregard any of the standards in this chapter.
- Do not delay or hinder the work of other researchers inappropriately.
- In addressing research misconduct, make no accusation that you know or should have known to be incorrect.

Rules of conduct to prevent fraud

When it comes to integrity in the practice of science, the best safeguards against fraud are cooperation between colleagues, a solid research data management plan and a publication policy that includes thorough, independent peer review.

Rules of conduct to prevent plagiarism

The practice of science continually builds upon the work of scientific predecessors. Therefore, it is customary to indicate how ideas (theories) and research (results) of others have been used.
The following rules of conduct could help to prevent plagiarism:

1. Give a reference when your text describes somebody else's theory, standpoint or research results;
2. Try to make your references as accurate as possible;
3. Try to refer to an article or book in which a particular theory or standpoint was first published and check all the references yourself;
4. Indicate clearly in the text when you are quoting and where each citation begins and ends.

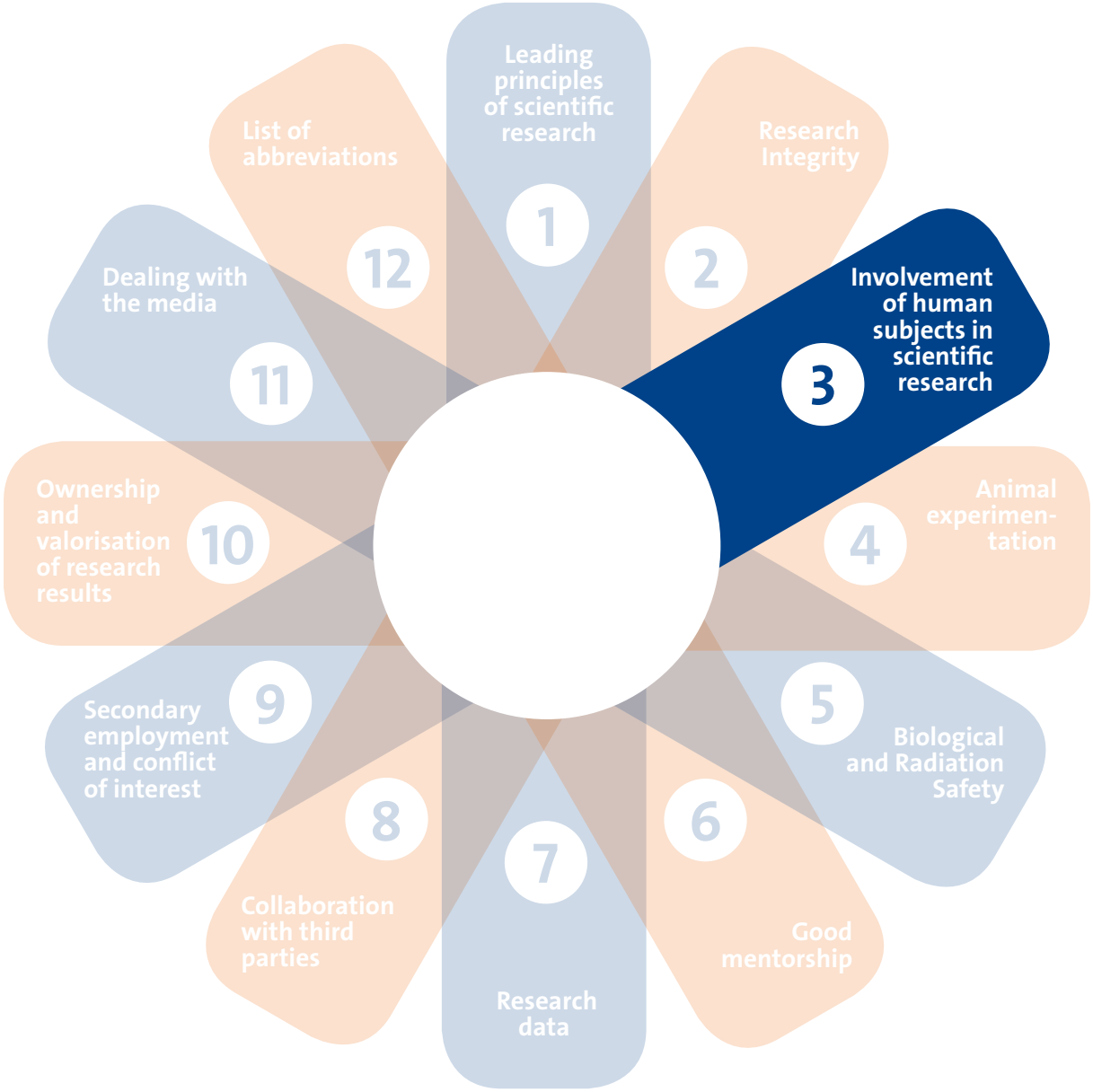
The University Library has a Similarity Check Service in their Research support portal. The similarity Check Service is a tool to authenticate your own writing, that by your co-author, or by your PhD candidate. **The University Library's Similarity Check Service** can help all researchers to prevent sloppy referencing or plagiarism.

There is a **comprehensive list of issues related to scientific integrity** available. It includes information on what to do and links to available websites/tools. The overview can be used for all involved in research (staff, technicians, post-docs, PhD students, bachelor/master students).

Researchers must always strive to ensure that the standards for good research practice are fulfilled scrupulously. Non-compliance with them undermines professional responsibility, which harms research, the relationship between individual researchers, and possibly also the trust in and the credibility of research. Consult the comprehensive list of issues related to scientific integrity for information on what to do and links to available websites/tools.

In case of questions or complaints regarding scientific integrity, depending on the situation, different routes can be followed.

To prevent sloppy referencing or plagiarism use the Similarity Check Service of the University Library.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Involvement of human subjects in scientific research

Two types of research involving human subjects can be distinguised:

1. Scientific research **subjected** to the Medical Research Involving Human Subjects Act **(Wet medisch-wetenschappelijk onderzoek met mensen**, WMO in Dutch). A study is subject to the WMO if the following criteria are met:
   - It concerns medical/scientific research and
   - participants are subject to procedures or are required to follow rules of behaviour.
2. Scientific research with human participants that is **not subject** to the WMO. This type of scientific research, for example retrospective research using existing patient files, does not comply with one or both of the above-mentioned criteria.

The **CCMO website** describes when this is the case.

The Maastricht UMC+ adheres to the NFU guidelines regarding quality assurance of research involving human subjects **(Kwaliteitsborging mensgebonden onderzoek in Dutch)** to assure quality and safety of the research involving human subjects.

All UMC's require that investigators conducting WMO research own a valid **BROK© certificate** , or obtain it within six months after the initial start of the study. For more information about the e-BROK course or possibilities for GCP-WMO courses contact **CTCM**.

3.1 Facilitation or review of scientific research with human participants

The Executive Board of Maastricht UMC+

The Executive Board of Maastricht UMC+ is ultimately responsible for proper conduct of scientific research with human participants. In this role, Quality Assurance (QA), Quality Control (QC) and facilitation of research employees is the particular focus of the Executive Board of Maastricht UMC+ to assure participants' physical and mental integrity, safety and privacy, and the validity and reliability of data throughout all research conducted.
In order to supervise scientific research with human participants, the Executive Board of Maastricht UMC+ collaborates with the Clinical Trial Center Maastricht (CTCM) and/or FHML Schools/Institutes, and receives, if needed, input from the Maastricht UMC+/UM Medical Ethics Review Committee (METC). For all studies (WMO and non-WMO) performed at Maastricht UMC+, approval must be obtained from the Executive Board of Maastricht UMC+.

CTCM

The main goal of the **CTCM** is to enable research involving human participants to be carried out responsibly and professionally. Several QA and QC measures are performed by the CTCM under the responsibility of the Executive Board of Maastricht UMC+:

1. Coordination and registration of the approval for all scientific research with human subjects by the Executive Board of Maastricht UMC+;

2. Serving as the contracting party for scientific research with human participants conducted at Maastricht UMC+;
3. Performing regular departmental audits to evaluate the conduct of scientific research with human subjects;
4. Periodically performing Risk-Based Quality Control Monitoring visits at the sites to monitor compliance to law and regulation;
5. Research Data Management advice and support: a.o. Data Management Plan support and electronic Case Report Form (eCRF) support;
6. Coordination of the eBROK and Good Clinical Practice (GCP) certification obligation for the research employees;
7. Implementing a Quality System Research (QSR) and give advice on the content of the procedures (Helpdesk) (see section 3.2).

Medical Ethics Review Committee (METC)

Ethical review is obligatory by law for all research that is subject to the WMO. The **METC** acts as an accredited independent Ethics Committee for review and approval of all scientific research with human participants subject to the WMO. Prior to the start of each WMO complicit research project performed at Maastricht UMC+, the Executive Board of Maastricht UMC+ requires the METC to review and approve the project.
For more information on the involvement and tasks of the METC during the preparation, execution and closure of scientific research with human participants, please consult the website of the **METC**.
In parallel to METC submission, submit your research to CTCM for obtaining approval from the Executive Board of Maastricht UMC+.

Non-WMO research

For non-WMO research with patients from the academic hospital, it is obliged by the Executive Board of Maastricht UMC+ to submit your research plan to the METC for judgement.
From the First of March 2019, researchers undertaking work with human participants that falls outside the scope of the WMO and does not include patients from the academic hospital, are able to submit their research proposal to the 'FHML-REC' - the FHML Research Ethics Committee for ethics review.
For questions concerning non-WMO research, the **METC** or **FHML-REC** can be contacted.

3.2 QSR Maastricht UMC+

At the Maastricht UMC+, a QSR, developed by CTCM, is implemented to provide an overview of all procedures regarding preparation, execution and closure of all scientific research with human participants.
The QSR consists of a website available to all employees where specific Standard Operating Procedures (SOPs) and Work Instructions (WIs) can be consulted to assure compliance to applicable legislation and Maastricht UMC+ specific guidelines. In addition, a CTCM helpdesk **(helpdesk.ctcm@mumc.nl)** was established for research employees with specific questions.

The Executive Board of Maastricht UMC+ is ultimately responsible for proper conduct of scientific research with human participants. Therefore, for all studies (WMO and non-WMO) performed at Maastricht UMC+, approval must be obtained from the Executive Board of Maastricht UMC+. Therefore, all WMO-research and non-WMO research, involving patients from the academic hospital, must be submitted to CTCM in parallel to METC. For non-WMO research, involving human participants that fall outside the scope of WMO and does not include patients form the academic hospital, the research proposal should be submitted to the FHML-REC.


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Animal experimentation

Maastricht UMC+ and UM are aware of the ethical objections regarding experimentation on animals and only conducts animal experiments when the scientific necessity for this research has been established by an independent animal experiments committee (Dier Experiment Commissie, DEC, in Dutch). Respectful treatment of animals, reduction of the number of animals used and refinement of the applied methods to minimize animal suffering (collectively known as the 3Rs – replacement, reduction and refinement) serve as points of departure in all the research.

The Experiments on Animals Act

Experiments involving animals are subjected to law-making. In the Netherlands, the applicable legislation is the Experiments on Animals Act **(Wet Op de Dierenproeven, WOD, in Dutch)**, which was amended on 18 December 2014. The act stipulates that animal experiments should not be conducted unless there are good reasons to and only if there are no alternatives available. Moreover, only licensed institutions like the UM, may conduct animal experiments. UM complies with the WOD and works according to the **Code of Conduct of the Central Animal Experiments Committee**, as well as the Animal Experiments Openness Code **(Code Openheid Dierproeven, COD, in Dutch)**. The COD aims to provide openness concerning all scientific research conducted using animals.

The trajectory from project idea to animal experiment

There are strict directives regarding animal experiments that ensure that the research is conducted carefully and responsibly. Specifically, each study requires a permit. Applying for such a permit involves multiple parties, ensuring a thorough decision making process. Initially, for each research proposal that involves animal experiments, researchers have to submit a proposal complying to a number of strict prerequisits to the institution's Animal Welfare Body (AWB)(Instantie voor Dierenwelzijn, IvD, in Dutch). The AWB then checks the proposal and further assists researchers who would like to request a project permit with the submission process. The mandated licensee of the institution submits the request to the Central Animal Experiments Committee **(Centrale Commissie Dierproeven, CCD, in Dutch)**. The CCD subsequently sends the permit request to the DEC. The DEC reviews the application on its scientific and ethical merits, and provides an advice to the CCD. Subsequently, the CCD can issue the permit, issue an amended permit, or decline the permit request. The CCD is the only body in the Netherlands that can provide licenses and permits for animal experiments. Once a permit is issued, detailed workplans based on the project permit are generated, which are evaluated by the IvD prior to the start of the experiments.

Additional conditions

Additional conditions apply to research with transgenic animals or animals 'treated' with genetically modified organisms (GMOs) (Genetisch Gemodificeerd Organisme, GGO in Dutch). Activities concerning this type of research are subject to the licensing Decree and Regulations GMO **(Besluit en Regeling GGO, in Dutch**). Implementation and execution of this decision is mandated to the directors of the administrative units and to the biosafety officers. Therefore, the **biological safety officer** will also review the workplans that are based on an approved application and must approve the workplans before the experiments can start.
The use of sources of ionizing radiation in animal experimentation is reviewed and must be approved by the **radiation protection expert of CRISP/Radiation Protection Unit (SBE)**, who is authorized to issue permits for working with ionizing radiation.

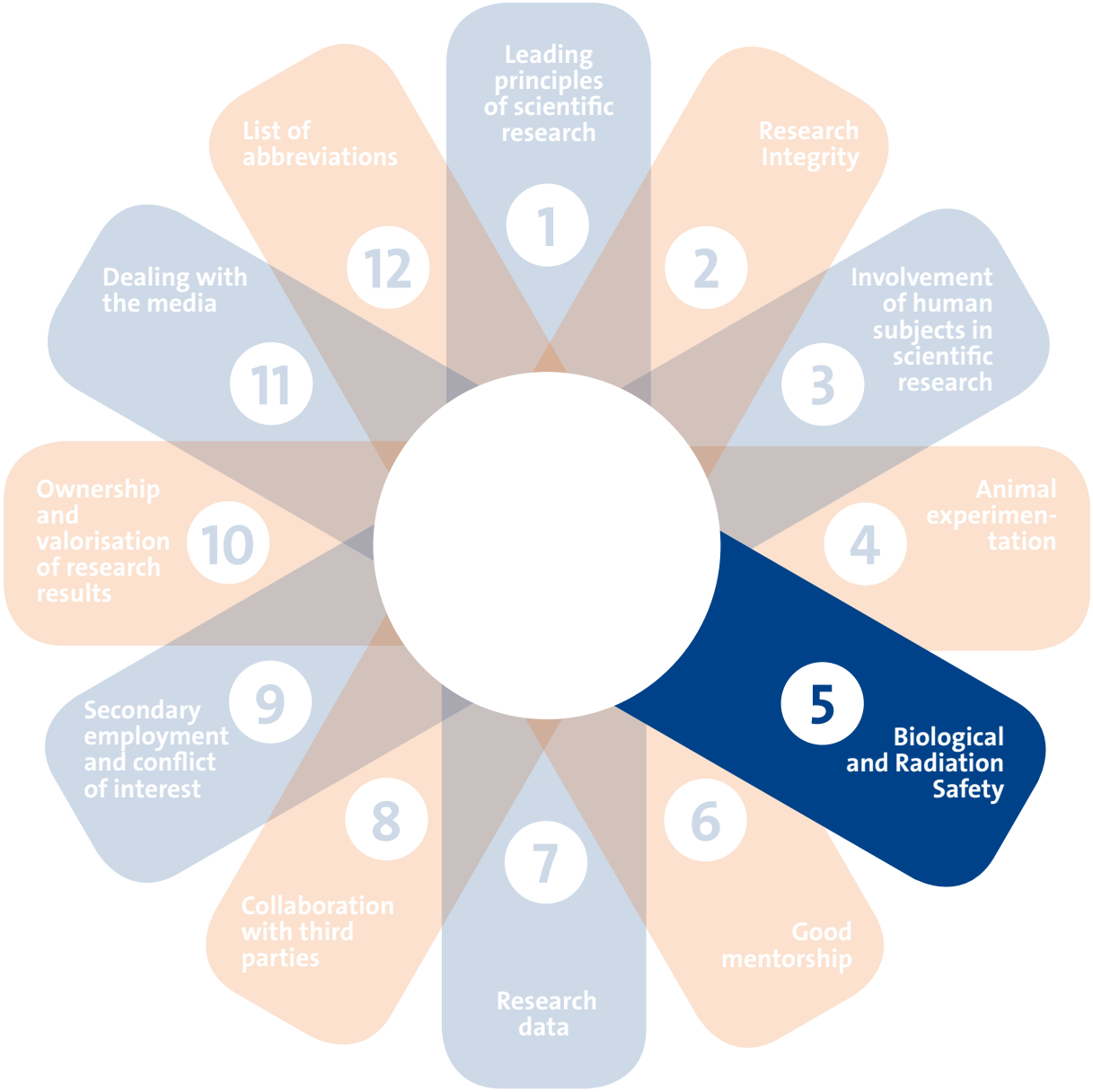
Requirements for people involved in animal experiments: Article 9 and 13f2b officials

In order to apply for a project permit, and design animal experimentation, a researcher must meet the requirements stated in article 9 of the WOD. In short, this means that the researcher must have successfully completed a course in laboratory animal science. This course focusses on experimental design, responsible care and use of test animals in biomedical research, as well as on the associated legislation, and earns participants the title of 'Article 9 official'. The course (in English) is offered three times per year by the Central Animal Service (Centrale Proefdier Voorzieningen, CPV, in Dutch, the website for the central animal facility is available for registered users via intranet). After completion, Article 9 officials are required to keep their theoretical knowledge as well as their practical competences when participating in the conduction of the experiments up-to-date. In addition to Article 9 officials, animal experiments can be conducted by 'Article 13f2b officials' (biotechnicians) who have completed a specialized training. Similar to the Article 9 Officials, the Article 13f2b Officials have to keep their theory and competences up to date.

Central animal facility

The CPV manages, in accordance with legal requirements, the facilities used for animal research. In addition to support by 'Art 13f2b officials in animal experiments', Article 13f2a officials (caretakers) in the CPV team are responsible for the housing and care of the animals.

The research plan concerning animal experiments has to be reviewed and approved by the IvD, CCD and DEC. Additional conditions apply when transgenic animals or ionizing radiation are involved. Researchers conducting animal testing need to meet the requirements stated in article 9 of the WOD.



Research involving GMOs is monitored by the biological safety officer at CRISP. Research involving ionizing radiation is monitored by the radiation protection expert at CRISP. Consider the regulation described in the Nagoya protocol before collecting or ordening genetic resources from other countries.

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Biological and Radiation Safety

The biological safety unit is part of the Centre for Research Innovation, Support and Policy (CRISP) and the biological safety officer monitors any work that involves Genetically Modified Organism (GMOs), biological agents and (genetically modified) animals in combination with biological agents or genetic modified organisms. Work involving GMOs and potential pathogenic microorganisms is subject to a number of different regulations. Activities that involve GMOs are subject to the Decree and Regulations GMO ('Besluit en Regeling GGO'), while activities involving pathogens (human as well as animal materials) are subject to the **Working Conditions Decree (ARBO-besluit)**.

The **radiation protection expert of CRISP/Radiation Protection Unit (SBE)** independently monitors activities involving ionizing radiation and is responsible for radiation protection in accordance with the legal requirements stipulated in the nuclear energy legislation. He gives permission/approval for application. Specific conditions, requirements and information regarding biological and radiation safety as well as the required forms are published on the **CRISP website**.

The **Nagoya Protocol** concerns regulations regarding the access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity. Since April 16, 2016 the Netherlands adopted the legislations regarding the **Nagoya protocol**. In the Netherlands, the Dutch Food and Consumer Authority **(NVWA, Nederlandse Voedsel-en Warenauthoriteit in Dutch)** has the surveillance regarding the compliance to this protocol.
Before collecting or ordening genetic resources from another country, a Maastricht UMC+ researcher needs to receive permission from the providing country; this is known as a prior informed consent (PIC). In order to receive PIC you need to agree with the providing country on the benefit-sharing conditions. This is referred to as mutually agreed terms (MAT). All the information regarding this needs to be documented properly by the researcher. Think of: date and place of access of resources or traditional knowledge, description of the genetic resources or of traditional knowledge, source from which the genetic resources or traditional knowledge associated with genetic resources were obtained and rights and obligations relating to access and benefit-sharing including for subsequent applications and commercialization.
For questions regarding the Nagoya protocol, you can contact CRISP at **info-crisp@maastrichtuniversity.nl**.


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Good mentorship

In many cases, research is conducted by junior researchers, supervised by a more experienced researcher (postdoc or staff member) and ultimately under the responsibility of a principal investigator. Junior researchers may be Bachelor or Master Students conducting research as part of their thesis or during internships, PhD candidates working on a dissertation or employed postgraduates.

6.1 Responsibilities of the supervisor

Good mentorship is an important aspect of good and responsible scientific scholarship and conduct. The duties (that constitute good mentorship) of an individual who supervises a junior researcher can be summarized as follows:

- Encouraging the junior researcher and showing a keen interest in the researcher's work;
- Providing adequate and substantive guidance and feedback, in a respectful way and within an acceptable timeframe, and adjusted to the level of the junior researcher and suited to the approach and phases of the research;
- Monitoring progress and critically reviewing the raw research data together with the junior researcher;
- Monitoring the junior researcher's integrity in relation to the studies, data handling and submission of publications;
- Checking whether claims to authorship are justified;
- Supporting the development of the junior researcher into an independent all-round researcher.

Points to remember

In order to fulfill these duties a supervisor should observe the following points:

1. There must be a clear and explicit agreement regarding the goal of the collaboration between the junior researcher and the supervisor and the expectations must be in the agreement. The goal can be to produce a thesis, but also an article, report or lecture.
2. The supervisor must ensure there is a clear work plan defining the activities expected from the junior researcher and the research to be performed. In case of a PhD candidate this has been regulated in a **Personal Research Plan (PRP)** that should be completed within the first three months of employment. In addition, PhD candidates will draw up a **Training and Supervision Plan (TSP)** at the start of the project in which agreements about the development of the researcher are laid down. The PRP and TSP are kept in a PhD tracking system **(PhD TRACK)** for the purpose of systematic evaluation of the progress of the project and supervision quality.
3. Each FHML School/Institute has a **PhD coordinator** and a **confidential advisor** to whom the supervisor as well as the researcher can turn in case of questions or problems.
4. The supervisor is required to make sure that there is sufficient access to research infrastructure and facilities and that appropriate support is available for the junior researcher to make the work possible.

5. The supervisor should inform the junior research about the standards for good research practice. As a guideline, the **comprehensive list of issues related to scientific integrity** can be consulted. This overview has been designed for use by supervisors and PhD students at the start of a PhD trajectory, for discussion throughout the project and during the annual assessments.
6. In the regular consultations, at least the progress and any problems the junior researcher has encountered should be covered. The supervisor should guide the researcher in a way to ensure that the final data are produced in a fashion that is in accordance with all aspects of the Research Code. The supervisor(s) and the researcher should reach agreement upon the publication of the research findings and appropriate authorships (see 6.3).
7. Irrespective of the hierarchical relationship between the supervisor and junior researcher, both of them should maintain an open and critical attitude towards the academic goals as originally formulated by the supervisor.
8. The supervisor(s) should set aside time to provide and receive – respectful and constructive – feedback. Feedback benefits from open, clear and structured communication, and from a discussion of both positive and negative elements of the way the research and the supervision are performed.
9. The supervisor should provide the junior researcher with regular and timely guidance with regard to the research and personal development – albeit within reasonable limits. In case of a PhD candidate, **the Regulation Governing the attainment of doctoral degrees of Maastricht University** states that the candidate must have at least two supervisors. One member of the supervision team should act as daily supervisor.
10. In order to provide adequate supervision and monitoring to junior researchers, there is a progress monitoring procedure that is in accordance with the Dutch Collective Labour Agreement (CAO), which stipulates that every junior researcher has an annual appraisal and personal development interview.

Within the Maastricht UMC+, a Competence Development Course for PhD supervisors was implemented in 2017, called the 'Basic Qualification Supervision' course. This course is aimed at junior and medior supervisors with several PhD candidates, to sensitize them with regard to coaching issues, provide them with tools to make supervision more effective, practice skills with actors during the course and make them aware of different leadership styles. Contact person: **h.vanderboom@maastrichtuniversity.nl**.

6.2 Responsibilities of the junior researcher

All junior researchers have duties and primary responsibilities with regards to good scholarschip and the relationship with his/her supervisor, namely:

- To act professionally and assume responsibility for one's scientific work;
- To function as team member and to be accountable towards the supervisor(s);
- To be critical of one's own work and that of other team members;
- To follow mutual arrangements regarding the design and execution of the work;
- To accept guidance related to the PRP and TSP (in case of a PhD candidate);
- To follow mutual arrangements related to the organization of the work, including work hours and presence;
- To submit or deliver agreed work in progress on time;

- To conduct the research with care and integrity (consult the **comprehensive list of issues related to scientific integrity**);
- To handle data properly (e.g. not to omit or falsify data);
- To take great care when dealing with data, patients and laboratory animals, and to obey the rules such as those stipulated in this Research Code;
- To ensure that reporting is complete, transparent and scientifically sound.

PhD candidates with an employment contract as PhD candidate at FHML are assessed every year of their PhD research. The first assessment interview will determine whether the appointment will be extended for the duration of the contract, in order to finalise the PhD trajectory (go/no-go decision). This **information leaflet** will help to prepare this interview. PhD candidates who have a contract as researcher or health professional at Maastricht UMC+ or are non-employed (external) are advised to request an annual evaluation meeting with their supervisors as well.

All PhD candidates within Maastricht UMC+/FHML have to sign the **UM declaration of scientific integrity** at the start of their PhD project, stating that the candidate is familiar with the codes described in Chapter 2 and will comply to them.

6.3. Authorship & order of authors

Authorship is the most important instrument for a researcher to publish research results and to have an indication of the quality of his or her research. Every author must have participated sufficiently in the research project in order to be able to accept responsibility for the content of the article.
At the start of the research, all researchers, including the supervisor and the junior researcher, must make clear arrangements regarding publication and/or presentation of the research outcomes. If necessary, they can modify these arrangements during the course of the project. The qualification as author and the subsequent author order allocation are part of these arrangements.

Authorship

Various institutes, academic societies and journals have developed guidelines for authorship. The Maastricht UMC+ endorses the guidelines of the **Committee of Medical Journal Editors (ICMJE)** as a basis for authorship. Staff members of Maastricht UMC+ are obliged to follow these guidelines.

Authorship implies that the following four criteria are met (Source: **ICMJE**):

1. A substantial contribution to the intellectual concept and design of the research, or to the acquisition, analysis or interpretation of data;
2. Original writing or critical editing of written text;
3. Approval of the definitive version of the manuscript;
4. Agreement to be accountable for all aspects of the manuscript in ensuring that questions about the correctness of any part will be accurately examined and resolved.

In addition, the following best practices are adopted:

- The individuals who, on the basis of the above criteria, qualify as author are named as such;
- Each author should have participated sufficiently in the research to take (public) responsibility for all the relevant parts of the work. It is common practice to make at least one author (e.g. the senior or corresponding author) responsible for the legal and ethical aspects of the manuscript as a whole;
- The mere fact that someone contributes to attracting funds, collecting data, or general supervision of the research group or a (sub) department (gift authorship) does not justify a claim to authorship. Any claim to authorship that does not meet the above criteria can be reported to the managers and – if there is reason to do so – to the confidential advisor scientific integrity.

The conditions above imply thay:

- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship. Only if the original ideas for the research, as stated in the grant application, are the brainchild of the applicant AND the applicant will carry out proposed research (in part), the applicant qualifies for authorship. Right of authorship is not linked to certain job positions or professions and does not depend on paid or voluntary contributions to the research;
- All individuals designated as authors should qualify for authorship, and all those who qualify should be listed. This not only means that authorship should be justified, but also that it should not be deliberately withheld when a person is entitled to it;
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Order of authors

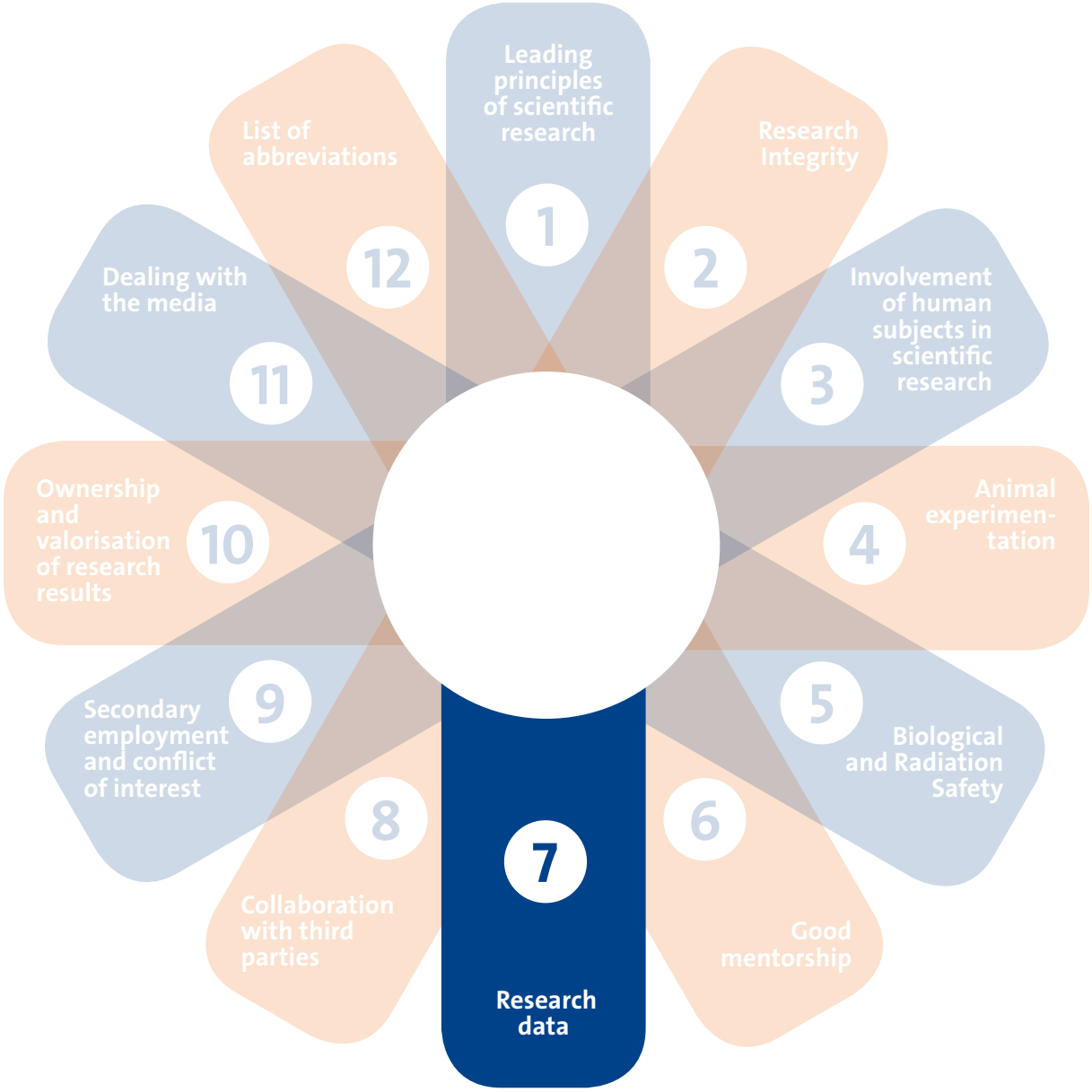
The first, second, last and penultimate authors generally make a more significant contribution to the article than the other authors. As a rule, the first author did the majority of the work on which the publication is based. The last (senior) author normally laid the foundation for the study and supervised it.

The order of authors must be jointly determined by all authors. All authors must declare themselves willing to explain the choice for the particular order. The researcher who has done the most important part of the work and who prepared the first draft of the manuscript is usually mentioned first in the order of authors. If the first and second authors have each made equal contributions, this must be mentioned in a footnote. The researcher who carries final responsibility for the project and who meets the criteria above, is mentioned last. All other authors are mentioned in order of contribution. If a dispute cannot be solved, it will initially be referred to the dean, and then to Rector Magnificus, who may ask a confidential counsellor for scientific integrity UM to deal with the matter.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include people who provided purely technical help, writing assistance, financial or material support or only general support. Thus the right to be acknowledged is also linked to the duty to accept the acknowledgement, as is the case with authorship.

Adequate supervision and training of a junior researcher by a supervisor is an important part of good academic practice. In addition, the junior researcher has the responsibilities to act professionally and accept guidance by supervisor(s).

The supervisor(s) and the researcher should reach agreement upon the publication of the research findings and appropriate authorships. Ensure a fair allocation and ordering of authorship(s), in line with the criteria for authorship.



Proper data management is part of good research practice. Researchers are aware of open science, GDPR and know how to handle in case of a (suspected) data breach or loss. Research processing personal data must be entered in the GDPR-online register before starting.

7

Research data

Maastricht UMC+ considers it very important to manage data with care and integrity, and to ensure the verification, reproducibility and possible reuse of research data. Accurate management of research data is essential in terms of accountability and scientific integrity, but also in terms of better retrieval, sharing, and storage of research data. Subsequent to the completion of their research project, researchers should make research findings and research data public, and if this is not possible, valid reasons for their non-disclosure should be given. Maastricht UMC+ follows the principles as defined in the **UM Research Data Management Code of Conduct**.

7.1 Data management

Proper data management is part of good research practice. Funding agencies such as NWO and ZonMw more and more expect applicants to integrate general information about data management in research proposals. According to the **Netherlands Code of Conduct for Research Integrity**, every researcher has the responsibility to describe how collected research data are organized and classified so that they can be verified and reused. Thus, prior to the start of the actual research, it is important to make a research data management plan regarding:

- Types of data that will be generated and collected;
- Collection and storage of data during the research project;
- Methods of collection and standards used;
- Sustainability and access to data after the research project;
- Feasibility of sharing data (Open Data) during and/or after the research project;
- Privacy compliance and ethics when Personal data is processed.

By elaborating the management of research data at an early stage, chances of having to face unpleasant suprises later in research are reduced. Moreover, it makes data understandable and reusable by others, and it also allows transparency and verification of research. The different phases of proper research data management are shown in the Research Data Lifecycle below (figure 1). More information can also be found on the **UM Research Data Management portal**.

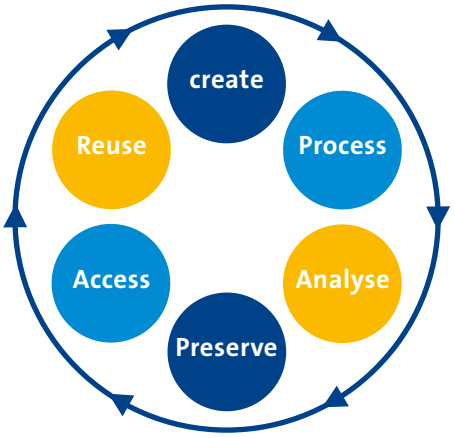


Figure 1: Research Data Lifecycle.

Maastricht UMC+ DataHub provides data management services for (non-)clinical studies. DataHub is a cross-organisational initiative within Maastricht UMC+. The DataHub team members are actively involved in developing knowledge, guidance and capacity building in managing and sharing data in accordance with the **FAIR data principles**, which specify that data and metadata should be Findable, Accessible, Interoperable and Reusable. They provide a modern, innovative infrastructure that is more than just a data archive and guides researchers who want to do more with their data through various aspects of research data management. Besides their own knowledge on technology and innovative data management, The DataHub team closely collaborates with partners like **MEMIC**, **CTCM** and the **Grants Office** in order to make use of their expertise regarding for example patient privacy, governance and regulations. The added value of the DataHub infrastructure during your Research Data Lifecycle can be found **here**.

Besides the **FAIR data principles**, Maastricht UMC+ also follows the principles and legal requirements as defined in:

- **The NFU HANDS Data Stewardship**;
- **The VSNU Code of Conduct for the use of Personal Data in Scientific Research**;
- **The UM Research Data Management Code of Conduct.**

7.2 General Data Protection Regulation (GDPR)

The GDPR (Algemene Verordening Gegevensbeschermng, AVG in Dutch) regulates the processing of personal data. Therefore, the Maastricht UMC+ has to keep records of every occurrence of personal data processing in a GDPR register. To asure GDPR compliance of the research withing Maastricht UMC+, a **GDPR registration tool** was designed. Researchers are asked to register their data processing activities in the online GDPR registration tool after the study is approved by the ethics committee/ assignment of a SAP number. Processing of personal data is not allowed before the GDPR registration.
Also, a Data Processing Agreement (DPA) with a third party has to be signed when the external partner processes personal data on behalf of the Maastricht UMC+ (see also chapter 8). For more information about GDPR, the data protection officer of the UM **(fg@maastrichtuniversity.nl)** and the Maastricht UMC+ **(functionaris.gegevensbescherming@mumc.nl)** can be contacted.

7.3 Data breach

Research data must be protected against unwanted or unauthorised publication, theft, distortion or loss. As the researcher is responsible for the research data, it is also the researcher's responsibility to protect these data properly.

During a data breach personal data may be accessed or modified by unauthorized parties. As a consequence, the data subjects may experience (serious) damage. In case of a (presumed) data breach, Maastricht UMC+ must report this to the Dutch Data Protection Authority (Autoriteit Persoonsgegevens, AP in Dutch) within 72 hours.

In case of a suspected data breach or loss of data, this must be reported as soon as possible:

- For FHML employees, report this as soon as possible to Servicedesk ICTS via **Servicedesk-ICTS@maastrichtuniversity.nl** or call 043-3885555.
- For academic hospital employees, report the data breach in IRIS (Incidenten Registratie Informatie Systeem In Dutch). In case of doubt send a message to **privacy@mumc.nl**. After office hours, the MIT costumerservice is available (call 74711).

7.4 Open Science

Open Science is a worldwide movement towards a more open way of conducting research. The **National Plan Open Science** concentrates on three key areas:

1. Promoting open access to scientific publications (open access),
2. Promoting optimal use and reuse of research data, and
3. Adapting evaluation and award systems to bring them into line with the objectives of open science (reward systems).

The Open Science movement involves becoming more transparent and open about how researchers work, collaborate, communicate, share resources and disseminate research results. The Maastricht UMC+ actively stimulates the implementation and practice of Open Science in academia.

7.5 Open Access

The Maastricht UMC+ supports the principle of Open Access with regard to publications: full and immediate Open Accces to publications from publicly funded research. The Maastricht UMC+ follows the ambition of the **National Plan Open Science**, which is to achieve 100% Open Access in 2020. The leading principle in this regard is that publicly funded research results should also be freely accessible to the public. There are several types of Open Access publishing. The preferred type is what is known as 'Golden Open Access', which means publishing in journals that are fully Open Access. Within this road, there are also 'hybrid' journals, which only make articles available as Open Access after payment by the author. If an article is published in a traditional, non-Open Access subscription-based journal, the author can take the 'green road', which means that the author's final version of a peer-reviewed journal article is placed in a public research database managed by an academic institution. Within the Maastricht UMC+ there is a library committee that negotiates contracts with publishers (Golden Open Access, Hybrid en Green Open Access). Furthermore, since 2017, publications of Maastricht UMC+ researchers are posted in the public UM research database PURE.

Before entering an agreement with an external partner contact the office support unit of the applicable FHML School/Institute (for research conducted at the FHML) who will involve Legal Affairs for legal advice or CTCM (for legal advice concerning human research conducted at the academic hospital or consultancies).

8

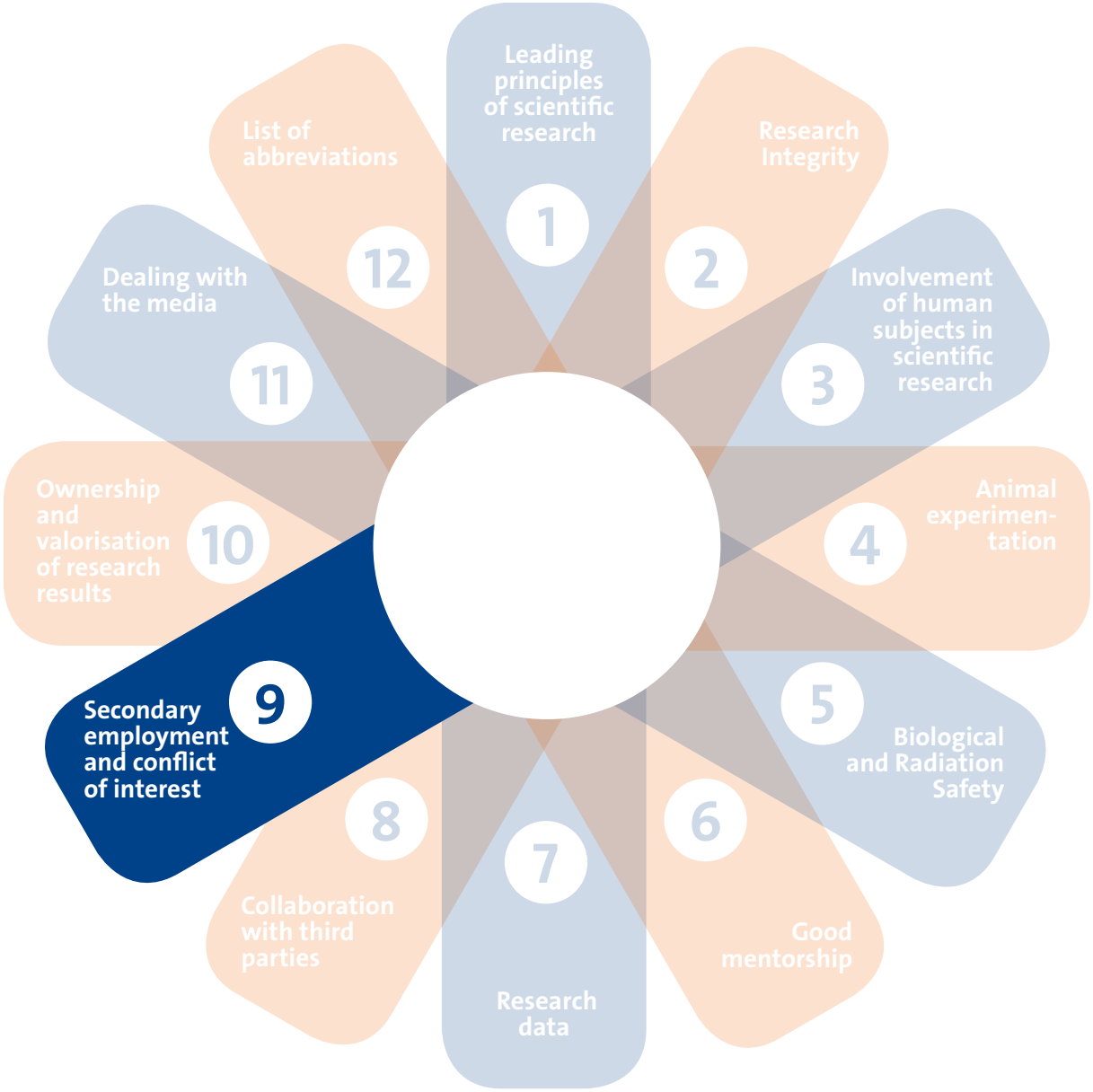
Collaboration with third parties

Researchers within the Maastricht UMC+ collect funding from and collaborate with a broad spectrum of third parties such as, but not limited to, academic parties, industries, national governmental agencies, charities and the European Commission. Inadequate agreements between a researcher and a third party concerning for example study design, implementation and disclosure of research results, processing of personal data, intellectual property, responsibilities and publications can lead to conflicts and should thus be avoided.

Situations vary, interests may differ and specific conditions may apply to each research project. Therefore, it is important to always contact the office support unit of the applicable FHML School/Institute (for research conducted at the FHML) who will involve **Legal Affairs** for legal advice or **CTCM** (for human research conducted at the academic hospital Maastricht or consultancies) before entering an agreement with an external partner. Legal Affairs or CTCM will help you with the topics that must be addressed in a written agreement and, in case of CTCM, act as signatory and contract and budget manager with regard to such research agreements. CTCM is the only mandated party to act as signatory regarding research with human subjects (WMO/non-WMO) involving academic hospital patients and/or doctors in case an agreement is desired/obligatory. For Maastricht UMC+ researchers it is important to know that the researcher is not authorized to sign any contracts; neither on behalf of oneself nor on behalf of Maastricht UMC+ or UM.

Moreover, researchers who intend to submit a proposal to Euroregional, Provincial and/or National programs, in which it is stated that the application has to be submitted via the FHML Schools/Institutes, have to report this to the **Grants Office**.

It should be noted that the name Maastricht UMC+ is used to externally represent two legal entities (academic hospital Maastricht and/or UM) when carrying out a joint policy as described in a joint policy document. Maastricht UMC+ itself can independently not enter into (legal) obligations: this is done via the two legal entities behind the name: academic hospital Maastricht and/or UM. So, when only UM is involved, UM is stated in the contract; when only the academic hospital is involved, academic hospital Maastricht is stated in the contract. When it involves a joint project of UM and the academic hospital, Maastricht UMC+ can be mentioned in the contract under the condition that the specific rights and legal obligations for the two legal entities (academic hospital Maastricht and UM) are clearly mentioned in the contract.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Secondary employment and conflict of interest

It is reasonable to expect that scientific staff will apply their knowledge and expertise for which they were appointed in the interests of Maastricht UMC+. The regulations concerning secondary employment are stipulated in the collective labour agreement (CAO). For Maastricht UMC+ employees, it depends on their individual contract whether the CAO-NU or the CAO-UMC applies.

9.1 Secondary employment (work for third parties)

- **Academic hospital Maastricht employees:**
  The collective labour agreement for University Medical Centres **(CAO NFU)** contains a regulation for the secondary employment that applies to all employees whose contracts are subject to the CAO. The CAO (art. 9.3) contains a regulation stipulating that secondary employment that may affect the interests of Maastricht UMC+ must be reported, and in specific cases, explicit permission of the Executive Board of Maastricht UMC+ may be required.

- **FHML/UM employees:**
  The latest **Collective labour agreement for Dutch Universities** contains a regulation for the secondary employment that applies to all employees whose contracts are subject to the CAO.
  Employees who carry out work for third parties or intend to do so must register this online using the Employee Self Service via MyUM. The administrative manager will automatically be notified of the registration by e-mail. If the work does not affect the employee's performance at Maastricht University and if there is no conflict with UM's interests, permission shall usually be granted. You will be notified by email whether permission for the registered work for third parties is granted.

  In addition to the Collective Labor Agreement (art. 1.14) Maastricht University has its own **Regulation concerning work for third parties (Regeling Nevenwerkzaamheden Universiteit Maastricht, in Dutch)**. An instruction for registering and granting work for third parties can be found on intranet.

  As a result of additional agreements with the Minister of Education, Culture and Science regarding the transparency of the work for third parties of professors, this sort of activity can be found on their personal profile page. The professor is responsible for keeping this information up to date. Moreover, the subject of work for third parties activities forms an integral part of the annual performance and development evaluations.

In certain situations, the Knowledge Centre for International Staff (KCIS) also has to be informed about the work on third parties. Employees can directly contact KCIS: **info-kcis@maastrichtuniversity.nl**. This applies to employees who carry out work for third parties abroad and for employees with a nationality from outside the EU/EEA or a Croatian nationality who carry out work for third parties in the Netherlands. KCIS checks if the work permit and/or residence permit allow the employee to carry out this work.

9.2 Conflict of interest

Until recently, academic researchers in (medical) science operated relatively independently. Guided by scientific principles, they independently determined the shape, content and timing of the research question, data acquisition and publication of the results. However, due to increasing pressure to acquire external funding and to sponsor's considerable interests in the outcome of clinical research, the independence of researchers can be threatened. A lack of independence can lead to science of inferior quality, undermine the reputation of science, impact negatively on patient care, create a lack of transparency, and damage the reputation of an institute.

There is a conflict of interest if a researcher, or the institute for which the researcher works, has financial and/or personal ties with other individuals or organizations that influence the researcher's conduct. When pharmaceutical industries, the government, non-governmental organizations or other interest groups are financing research, there is a danger of a conflict of interest. Such a conflict of interest can result from personal relationships, academic competition and intellectual passion.
Certain guidelines apply when weighing up the pros and cons of favors offered by companies. Central to the **NFU-guideline Gunstbetoon door bedrijven (in Dutch)** is the notion that employees themselves are always responsible for weighing up the interests, keeping in mind that reliability, due care and impartiality of Maastricht UMC+ are the absolute norm.

Generally, researchers are not allowed to accept gifts, invitations and/or sponsoring in exchange for a favor. Moreover, researchers must always consult their manager before accepting an offer. Any financial sponsorship is added to the departmental budget.

Researchers are expected to inform their manager directly whether they are facing a possible conflict of interest, or whether they have potentially conflicting interests outside the department. Researchers are required to disclose significant financial interests related to responsibilities to Maastricht UMC+ through their manager.

Examples of situations that may lead to a conflict of interest (Source: **Association of American Medical Colleges)**:

Situations that may involve research bias

- Research funded by third parties if the researcher or his family has financial interests with the funding party.
- Accepting favors from parties funding the research.
- Working as a consultant for research sponsors.

Situations that involve the use of facilities of the institute

- Allowing (PhD) students and staff to work for a company in which the researcher holds an interest.
- Improper use of facilities for personal gain or to support a company in which the researcher holds an interest.
- Associating one's name or work with the institute to take benefit from the goodwill of the institute.

Situations that involve the use of information

- Improper use of confidential information.
- Accepting support for research under conditions that require the results to remain confidential or unpublished, or which lead to a serious delay of publication.
- Providing an organization in which the researcher holds a financial interest with access to the institute's confidential information.

Situations in which the researcher negotiates with him/herself

- Purchasing materials, instruments or supplies from a company in which the researcher holds a financial interest.
- Influencing the negotiation of agreements between institute and the company in which the researcher holds a financial interest.

Secondary employment that may affect the interests of UM/FHML or Maastricht UMC+ must be reported. There are instructions available for registering and granting work for third parties.

As a general rule, researchers are not allowed to accept gifts, invitations and/or sponsoring in exchange for a favor. Researchers are expected to inform their manager directly whether they are facing a possible conflict of interest, or whether they have potentially conflicting interests outside the department.


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Ownership and valorisation of research results

10.1 Ownership of research data

Researchers will encounter different types of property rights regarding research data, materials, lab journals and publications when conducting research. Several laws determine the rightful owner of these materials: the 1912 Copyright Act (Auteurswet in Dutch) for publications and software and the 1995 Patent Act (Rijksoctrooiwet in Dutch) for a patent on, for example, a drug, a device or a production method.

The following paragraphs describe, per type of research result, important principles and points to consider for determining which law applies and who will own the results. When entering a contract, parties may come to a different agreement about who will own the generated research results (see also 8. Collaboration with third parties).

Publications

Within an academic institution, many researchers are conducting research. Therefore, the employer often demands (co-)ownership; by stipulation in the collective employment agreement (CAO), for example. When publishing scientific work, the copyright is usually transferred to the publisher of the journal concerned. This means that whenever the work is multiplied, the publisher must be asked for permission and/or paid a fee. However, an increasing number of sponsors demand to publish data in 'open access' journals.
In the agreement to be concluded with a third party, a procedure regarding publication will be added.

Inventions

Conform the 1995 Patent Act, Maastricht UMC+ is, as an employer, the owner of all patentable inventions: products, methods and devices, for example. If the patent is exploited, the inventor is entitled to reasonable financial compensation. Patenting knowledge does not stand in the way of publishing. The day after a patent application has been submitted, information about an invention can be published or discussed. Internet increases the speed with which information can disseminated, including scientific publications and lecture titles. Before sending out a publication or a title, it is advisable to enquire when information will be made public. Except when one wants to keep the possibility open to retract the patent before the Patent Coorperation Treaty (PCT) stage in order to buy extra time for a new and/or better patent. In that case it is best to postpone publication. The **Brightlands Maastricht Health Campus** (see 10.2) should be consulted concerning which strategy to follow.

Data and lab journal

According to the 1995 Patent Act, as soon as there is a patentable invention, the underlying data, results and lab journals are the property of the employer. The owner of a patent needs the lab journals to show how the invention came about.
Also, in view of Quality Assurance, Maastricht UMC+ must be able to have its research audited. Therefore, all data need to be accessible to an auditor. For this, Maastricht UMC+ DataHub which provides an institutional repository for research data (see 7. Research Data) can be contacted. When an employee leaves the organization, all lab journals and files on research, or research- or trial subjects must be handed over to the head of department. In case of an externally funded project, it is advisable to enter a contractual agreement regarding transfer of a copy of the data and results. An increasing number of sponsors demand to make data public available ('open access').

Human biological materials

Through donation, ownership is transferred from the person donating his bodily material to the Maastricht UMC+. The primary use of human material at the Maastricht UMC+ is scientific research. However, the hospital providing treatment may allow a third party to use the materials for a specifically defined research purpose. This purpose must be in line with the reason why the human biological materials were collected, such as research on diseases. To make sure this is the case, the original research purposes for which the human biological materials were collected need to be determined. This information is then included in a Material Transfer Agreement (MTA), which is drawn up next. This contract also specifies ownership of the results generated from the study of the human biological materials. For support regarding MTAs **Legal Affairs** can be consulted.
For further details on the use of human material in research and the specific rules and regulations that apply, **CTCM** can be contacted. For details on rules and regulations regarding the storage of human materials, the central **BioBank Maastricht UMC+** can be contacted.

Software

Ownership of software is subject to the 1912 Copyright Act. However, it is subject to the 1995 Patent Act if a patent application has been submitted. Patented software is, just like the invention described above, property of Maastricht UMC+. In most cases, there are no patent applications for software, and therefore the aforementioned system for publications applies.

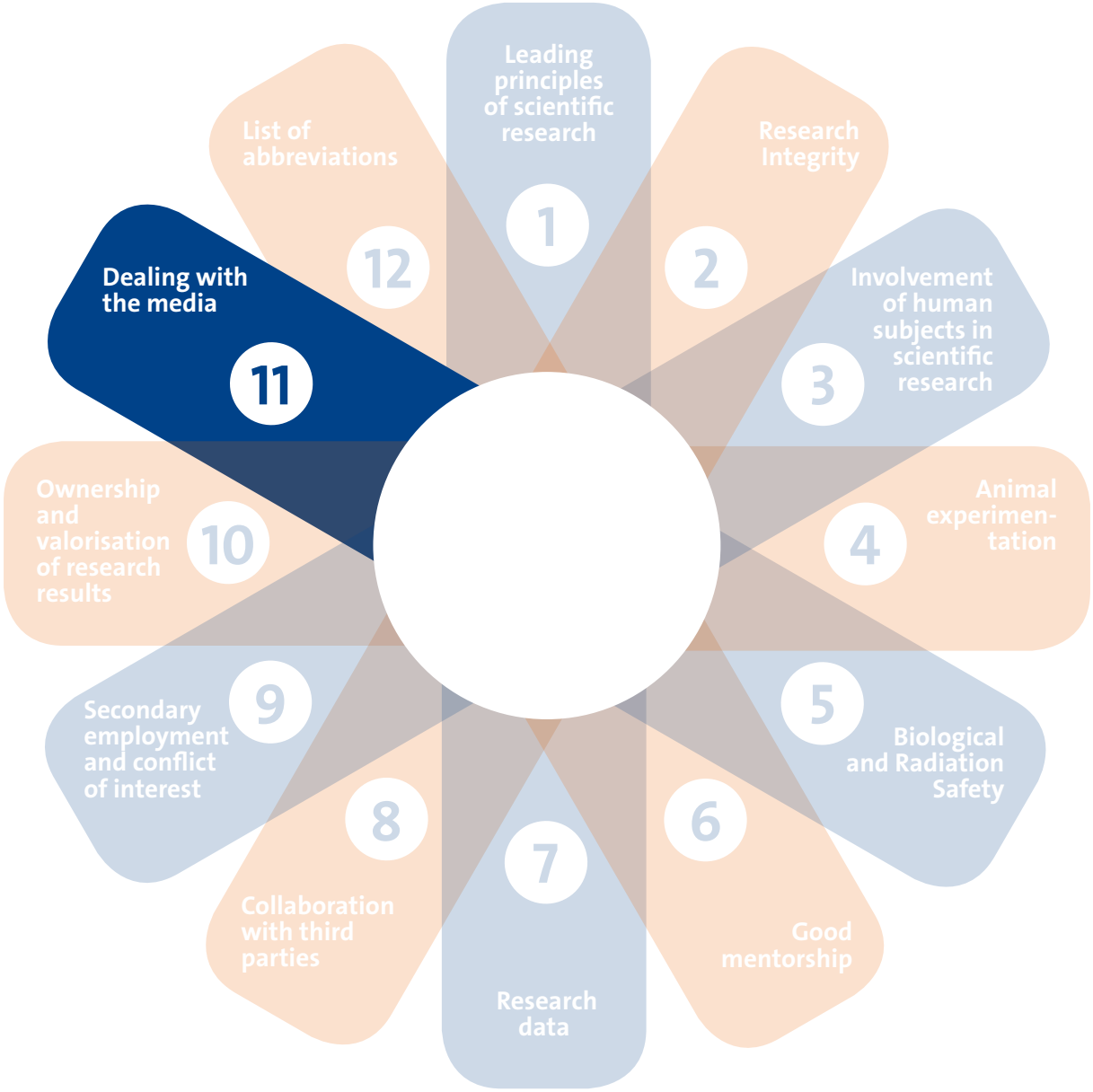
10.2 Valorisation of research results

Valorisation is the process of creating value from knowledge, by making knowledge available and suitable for economic and societal exploitation, for example by translating this knowledge into products, services, processes and new business.

Sometimes there is an opportunity to convert the results of scientific research into a new product via a patent, license or spin-off company. In such cases, the **Valorisation & Business Development team** of the Brightlands Maastricht Health Campus (BMHC) team should be contacted to make sure the right actions are taken and intellectual property rights for Maastricht UMC+ are addressed. The BMHC is the one-stop-shop for valorisation and hosts a wide range of expertises and capabilities. It has the knowledge and expertise to choose and put into place the right form of knowledge transfer and it can help authors and departments taking the necessary, formal steps. The BMHC examines whether the discovery or development could be patented or exploited and supports the researchers throughout the process. For instance, the BMHC can assist in negotiating intellectual property rights, establishing a limited liability company (BV, in Dutch) or releasing the knowledge under licence. For further information, see the **Valorisation Guideline of the BMHC**.

As of 1 January 2014, UM and the academic hospital Maastricht have a joint **Knowledge Rights Regulation**, which was developed to promote knowledge valorisation. This regulation sets out, for both employees and employer, a uniform set of rules regarding the rights and duties of both parties in relation to knowledge and research results. The regulation includes a reporting obligation. This means that employees who are approached by a company with a view to exploiting knowledge, or who have discovered or developed something that may be commercially exploited, must report this to their line manager, supervisor or the BMHC before publishing their finding or making it known in any other way.

Dependent on the type of research result, please consider important principles and points for determining which law applies and who will own the results. In case of a discovery or development that could be patented or exploited, contact the Valorisation & Business Development team well before publishing or presentation of the results.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Dealing with the media

Of all scientific disciplines, biomedical research generates most media attention. Next to the benefits of the generated interest, certain disadvantages can occur. It is for example possible that the desired message does not remain intact. Sometimes, publicity concerning scientific results impacts directly on commercial goals of e.g. pharmaceutical companies and/or suppliers of biomedical technology. In the public sector – on local, national and international level – publicity regarding the results of scientific research is often 'spun' to better suit political goals that are not always explicitly mentioned. At last, media can have commercial interest themselves.

To make science relevant and interesting to non-academics, scientists and journalists need to collaborate. Collaboration between both parties works best when both recognize it as a partnership with sharing knowledge as a common goal. When talking to the media, researchers must be aware of the above-mentioned pitfalls. More importantly, however, the researcher must be aware that in almost all cases, the commercial or political proprietors dependent on the researchers' cooperation. It is indeed this dependence that offers many possibilities for conveying information about the research findings independently and with integrity.

To share results of scientific research within and outside Maastricht UMC+ it is recommended to first contact the communication advisors (see contact information below). Advice from communication advisors can also be gathered in case of received questions or interview requests. They can help preparing the main message of the research and provide information on external communication.

Due care

The following points and recommendations should be considered when dealing with the media:

1) There must be transparency about the research funding if primary funding (one's own research budget) is not the only financial source. Transparency can prevent possible allegations or accusations. It is important to inform your contact in the Communications Department about these matters (see contact details below).
2) Responsible popularization of expectations regarding research projects or research findings can be difficult. In the media, the importance of fundamental research is usually measured by its potential for clinical application. A typical wrong example is the scientist or journalist who almost indiscriminately applies the positive results of in vitro or animal research to humans. The presentation of clinical research requires the same degree of due care.

3) Caution should also be exercised when interim research results point toward success. In such instances, it is tempting to publicize the results prematurely.
4) It can be advisable to inform the media pro-actively when media interest is expected and the research can easily lead to misunderstandings or touches on a subject that is the focus of a (fierce) public debate. In such circumstances it is often effective to send out a press release to set the right tone drawn up in collaboration with one of the communications advisors or, alternatively, to present the news to the media via an article on the UM or Maastricht UMC+ website or the Maastricht University magazine.
5) Premature publicity about research that has been submitted to a scientific journal for publication is inappropriate. Articles under submission, e.g. as part of a dissertation, should be treated with caution, to prevent rejection by the journal. Hence the obligation that all dissertations are included in the UM Repository, accompanied by a form signed by the promotor indicating whether there are any items that may not be published. If parts are not yet available to the outside world, they are automatically placed under embargo for one year.
6) When recruiting trial subjects via a press release or advertisement, pay close attention to correctly describing the conditions. Information about potential (side) effects and onerous research may not be vague, while the chance of being placed in a placebo group must also be clearly pointed out and explained. Publicity about these aspects must be exactly in line with the research protocol. If research is conducted as part of a multicenter-trial that is coordinated by an institute that is not the researcher's own, the researcher nevertheless remains responsible – even in the eyes of researcher's own institute.

Practice your skills

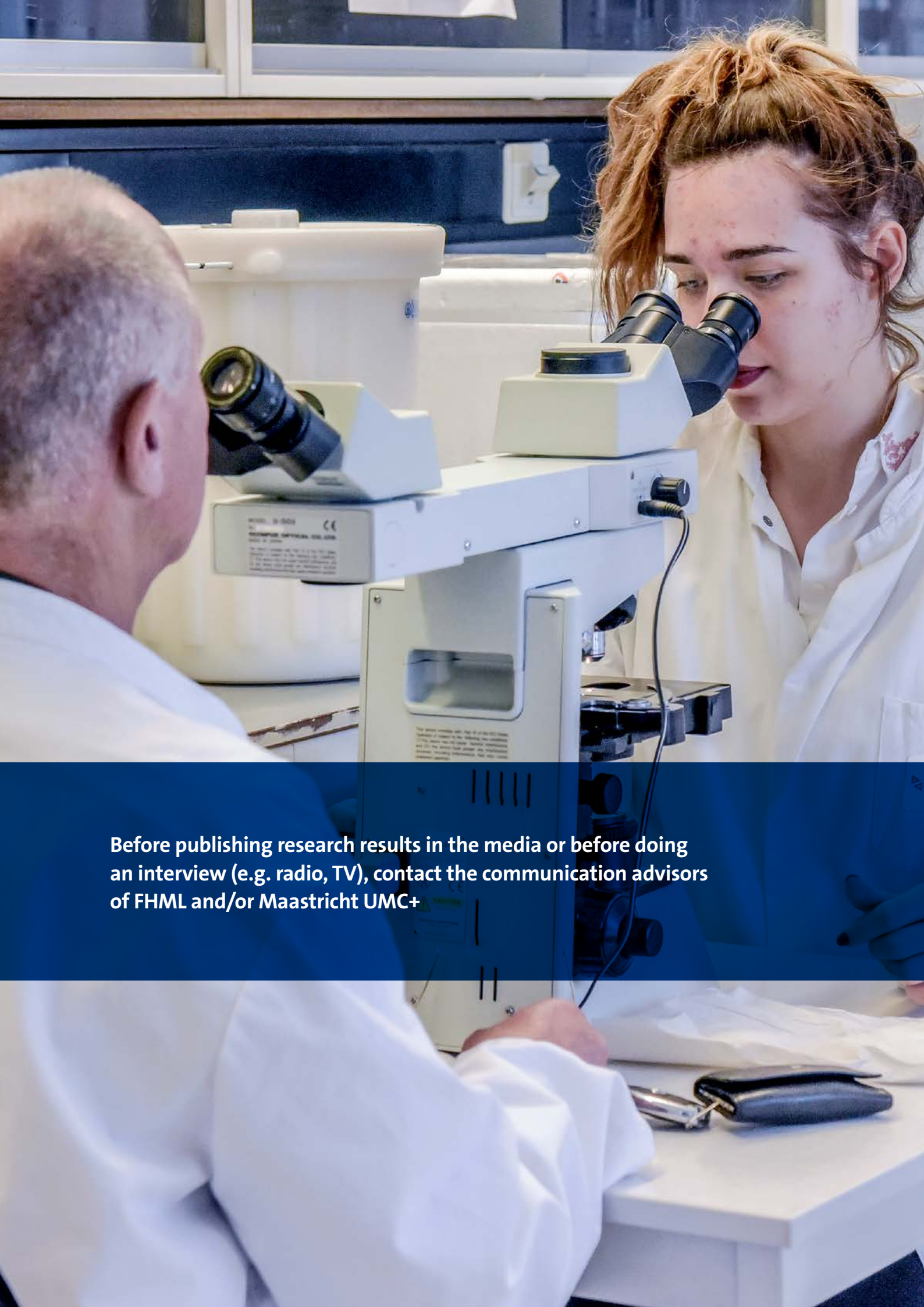
To practice public speaking or media skills, the UM offers **media training and coaching**.

Communication advisors/press officers

If questions arise that have not been addressed in this chapter, please contact the communication advisors. The communication advisors can help preparing written press releases in order to proactively communicate your message.
Please note that the press protocol of Maastricht UMC+ states that the press officers of the Communication Department Maastricht UMC+ should always be the first point of contact for the media. The press protocol (in Dutch) can be obtained by contacting the press officers of Maastricht UMC+.

Contact information communication advisors/press officers:

- Marketing & Communication FHML: **communicatie-fhml@maastrichtuniversity.nl**
- Press office Maastricht University: **www.maastrichtuniversity.nl/news-events/press**
- Press officers Maastricht UMC+: **www.mumc.nl/actueel/media/perscontact**



Before publishing research results in the media or before doing an interview (e.g. radio, TV), contact the communication advisors of FHML and/or Maastricht UMC+


Leading principles of scientific research
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Research Integrity
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Involvement of human subjects in scientific research
3
Animal experimen-tation
4
Biological and Radiation Safety
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Good mentorship
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Research data
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Collaboration with third parties
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Secondary employment and conflict of interest
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Ownership and valorisation of research results
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List of abbreviations

AP	*(Autoriteit Persoonsgegevens in Dutch)* Data Protection Authority
AVG	*(Algemene Verordening Gegevensbescherming in Dutch)* General Data Protection Regulation
BMHC	Brightlands Maastricht Health Campus
CAO	*(Collectieve Arbeids Overeenskomst in Dutch)* Collective Labour Agreement
CCD	*(Centrale Commissie Dierproeven in Dutch)* Central Animal Experiments Committee
COD	*(Code Openheid Dierproeven in Dutch)* Animal Experiments Openness Code
CMJE	Committee of Medical Journal Editors
CPV	*(Centrale Proefdier Voorzieningen in Dutch)* Central Animal Services
CRISP	Centre for Research Innovation, Support and Policy
CTCM	Clinical Trial Center Maastricht
CWI	*(Commissie Wetenschappelijke Integriteit in Dutch)* Committee Scientific Integrity
DEC	*(Dier Experiment Commissie in Dutch)* Animal Experiments Committee
EBROK	Electronical Basic course Rules and Organisation Clinical investigators
eCRF	Electronic Case Report Form
FHML	Faculty of Health, Medicine and Life Sciences
FHML-REC	FHML-Research Ethics Committee
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GRVP	*(Gemeenschappelijke Regeling Verwerking Persoongegevens Maastricht UMC+ in Dutch)* joint regulation processing personal data Maastricht UMC+
GMO	*(GGO, Genetisch Gemodificieerd Organisme in Dutch)* Genetically Modified Organism
IvD	*(Instantie voor Dierenwelzijn in Dutch)* Animal Welfare Body
KCIS	Knowledge Centre for International Staff
LOWI	*(Landelijk orgaan Wetenschappelijke Integriteit in Dutch)* Netherlands Board on Research Integrity
Maastricht UMC+	Maastricht University Medical Center+
MAT	Mutually Agreed Terms
MEMIC	Center for data and information management
METC	*(Medisch-Ethische Toetsingscommissie in Dutch)* Medical Ethics Review Committee
MVC	Maastricht Valorisation Centre
MTA	Material Transfer Agreement
NVWA	*(Nederlandse Voedsel-en Warenauthoriteit in Dutch)* Dutch Food and Consumer Authority
NWO	*(Nederlandse organisatie voor Wetenschappelijk Onderzoek in Dutch)* The Dutch Organisation for Scientific Research
PCT	Patent Coorperation Treaty
PIC	Prior Informed Consent
PRP	Personal Research Plan
SBE	*(Stralingsbeschermingseenheid in Dutch)* Radiation Protection Unit
SOPs	Standard Operating Procedures
TSP	Training and Supervision Plan
UM	*(Universiteit Maastricht in Dutch)* Maastricht University
VSNU	*(Vereniging van Samenwerkende Nederlandse Universiteiten in Dutch)* Association of Universities in the Netherlands
WIs	Work Instructions
WMO	*(Wet medisch-wetenschappelijk onderzoek met mensen in Dutch)* Medical Research Involving Human Subjects Act
WOD	*(Wet Op de Dierenproeven in Dutch)* Animal Testing Act
QA	Quality Assurance
QC	Quality Control
QSR	Quality System Research

Maastricht UMC+

Maastricht UMC+
P. Debyelaan 25
6229 HX Maastricht

For more information or questions regarding
the Research Code Maastricht UMC+
contact dr. E. Swennen
els.swennen@maastrichtuniversity.nl
T. 043 - 387 28 69

www.mumc.nl

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