Maastricht UMC+ Research code

Versie 2024

Maastricht UMC+ | Maastricht University


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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 this 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, productive and safe. 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 (date January 24) of the Research Code Maastricht UMC+ is only 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** and the website of the **Maastricht UMC+**.

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Leading principles of scientific research

The Research Code Maastricht UMC+ follows the five principles of good research as identified and defined in the **Netherlands Code of Conduct for Research Integrity.** These 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 counter arguments 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 favorably or unfavorably 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 practitioners 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.

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 subject 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 focuses on the definition of the principles of research integrity and the ensuing guidelines for good research practices, providing both. 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 downplaying 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.
- Selectively withholding research results.
- Allowing funders/sponsors to jeopardise the independence nature of research or reporting of results to introduce or spread bias.
- Expanding unnecessarily the bibliography of a study.
- Misrepresenting research achievements.
- Exaggerating the importance and practical applicability of findings.
- Delaying or inappropriately hampering the work of other researchers.
- 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 Maastricht employees).

In case of questions or complaints regarding scientific integrity, different routes can be followed depending on the situation. The roadmaps 'scientific integrity and social safety' will guide you through the different possible routes.

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- or partial compliance with one or more 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 extent 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 or falsify 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.
- 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(s) 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 reason(s) 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.
- 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 openness, a solid research data management plan and a publication policy that includes thorough, independent peer review.

Rules of conduct to prevent plagiarism

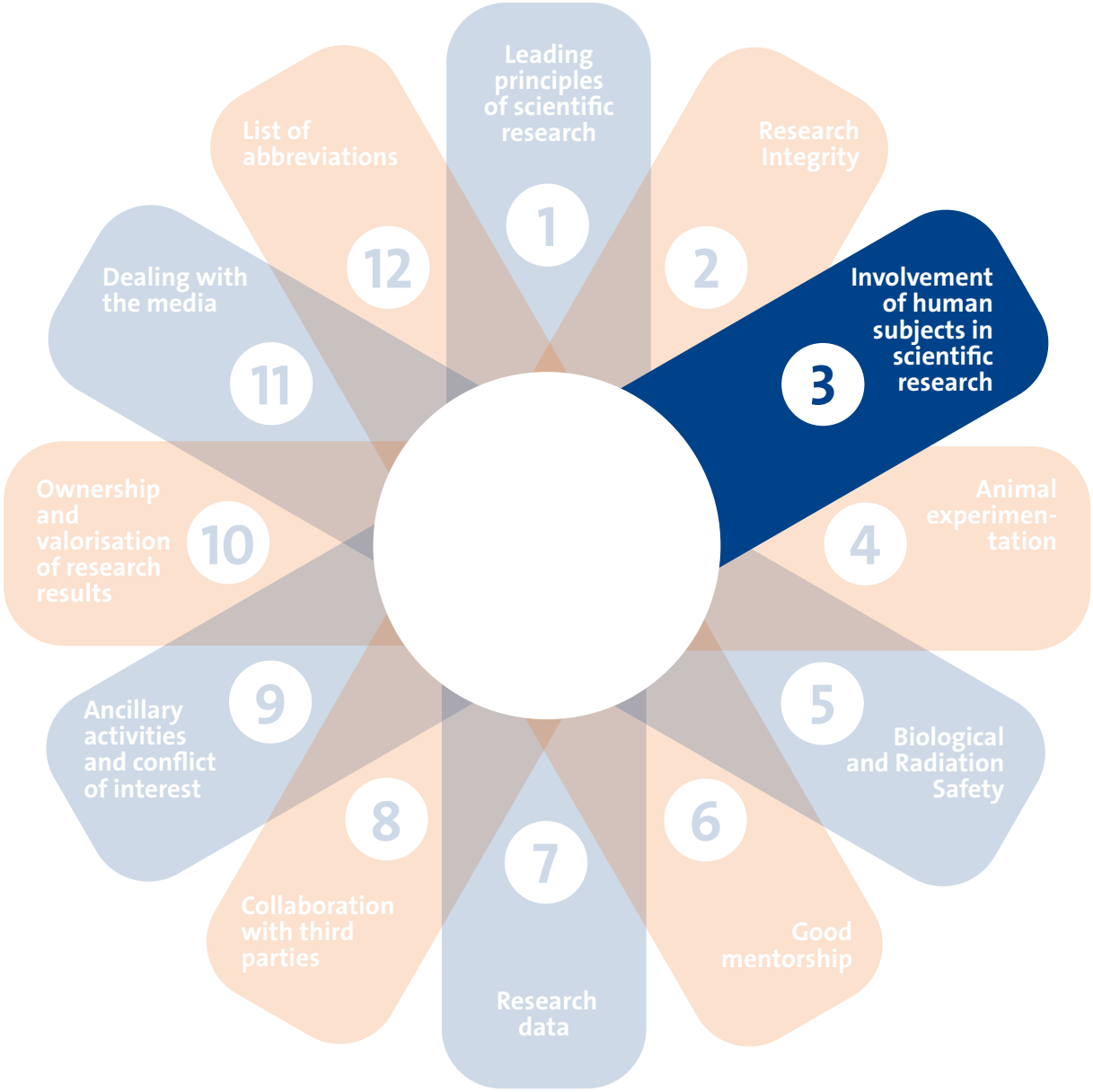
The practice of science continually builds upon the work of scientific predecessors. Therefore, it is customary to indicate how ideas (theories) and research (results) of others have been used.
The following rules of conduct could help to prevent plagiarism:

1. Give a reference when your text describes somebody else's theory, standpoint or research results;
2. Try to make your references as accurate and up-to-date 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 quotes clearly in the text, including where they begin and end.

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 or partial-compliance with them undermines professional responsibility, which harms research, the relationship between individual researchers, and possibly also the public 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

Several national and international laws specifically apply for scientific research involving human subjects, which are summarized below.

Medical Research Involving Human Subjects Act (WMO)

In The Netherlands, medical scientific research involving human subjects is covered by the Medical Research Involving Human Subjects Act (in Dutch: **Wet medisch-wetenschappelijk onderzoek met mensen**; WMO) if participants are being subjected to actions or if rules of behaviour are imposed on them.

EU Medical Device Regulation (MDR)

On May 26, 2021 the **EU Medical Device Regulation 2017/745 (MDR)** has come into effect with specific rules for the submission, review and conduct of clinical investigations with medical devices. The MDR has three different frames for clinical investigations, which can be found in articles 62, 74 and 82. Each frame has different requirements and procedures.

EU In Vitro Diagnostics Regulation (IVDR)

On May 26, 2022, the **EU In Vitro Diagnostics Regulation (EU no 2017/745; IVDR)** has come into effect with specific rules for the submission, assessment and conduct of in vitro diagnostic medical device (IVD) performance studies.

EU Clinical Trial Regulation (CTR)

On January 31,2022, the **EU Clinical Trial Regulation (CTR) 536/2014** has come into effect with new and identical rules for all clinical trials (national and multinational) with medicinal products in the European Union. In short, if the medicinal product(s) is/are being investigated and the trial participants are subjected to procedures or are required to follow certain rules of behaviour other than normal clinical practice, it is considered a clinical trial and the CTR is applicable. A main characteristic of the CTR is an application procedure via a single point – an EU portal and database: Clinical Trial Information System (CTIS).

Non-WMO research

This involves scientific research with human participants that is not subject to the WMO; for example retrospective studies using only existing data. In case of research with medicinal products or research with medical devices, this should additionally fall outside the scope of respectively the CTR or MDR in order to classify as non-WMO research.

On the **CCMO** website, more detailed information on these legislations can be found. On the Maastricht UMC+ Quality System Research **(QSR)** website, more information about Maastricht UMC+ specific policy and procedures during study preparation, execution or closure are available for (non-) WMO, MDR/IVDR and CTR research.

3.1 Requirements for 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, to assure participants' physical and mental integrity, safety and privacy, and the validity and reliability of data of all research conducted. This means that the Executive Board of Maastricht UMC+ needs to assure that Quality Assurance (QA) and Quality Control (QC) measures are in place and that research employees are facilitated.

For this purpose, the Executive Board of Maastricht UMC+ collaborates with the Clinical Trial Center Maastricht **(CTCM)** and FHML Research Institutes, and receives, if needed, input from the Medical Ethics Review Committee (METC azM/UM).

The Executive Board of Maastricht UMC+ adheres to the **NFU guideline regarding quality assurance of research involving human subjects** (in Dutch: NFU richtlijn Kwaliteitsborging mensgebonden onderzoek) to assure quality and safety of the research involving human participants. For this purpose, the Quality Assurance program (in Dutch: KwaliteitsBorgingsProgramma; link via **MUMC+ Intranet** or **FHML intranet**) has been implemented in the Maastricht UMC+.

For all WMO, MDR/IVDR or CTR studies, or non-WMO studies with patients (or patient data) from the academic hospital Maastricht performed at Maastricht UMC+, approval must be obtained from the Executive Board of Maastricht UMC+ before the start of the study.

Furthermore, all UMC's require that investigators conducting WMO, MDR/IVDR or CTR research own a valid **BROK© certificate** at the start of the study.

CTCM

The main goal of the CTCM is to enable research involving human participants to be carried out responsibly and professionally and according to laws and regulations. Under the responsibility of the Executive Board of Maastricht UMC+, several QA and QC measures are performed by the CTCM as part of the Quality Assurance Program:

- Coordination of the eBROK and Good Clinical Practice (GCP) certification obligation for the research employees;
- Maintaining the Quality System Research (QSR) and give advice on the content of the procedures (Helpdesk);
- Coordination of the approval for, and registration of all scientific research with human subjects (reviewed by the METC azM/UM) by the Executive Board of Maastricht UMC+;
- Performing general risk management for studies falling under WMO, MDR/IVDR or CTR;
- Managing the Clinical Trials Information System (CTIS) and CTIS helpdesk for submissions and notifications;
- Performing regular departmental audits to evaluate and monitor the conduct the conduct of scientific research with human participants;
- Serving as the contracting party for investigator-initiated scientific research with human participants conducted at or with academic hospital Maastricht (see also Chapter 8);
- Research Data Management advice, support and tooling: a.o. Data Management Plan support and electronic Case Report Form (eCRF) support (see als Chapter 7);
- Periodically performing Risk-Based Quality Control Monitoring visits at the sites to monitor compliance to laws and regulations.

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 (or patient data) from the academic hospital Maastricht, it is obliged by the Executive Board of Maastricht UMC+ to submit your research plan to the METC for judgement.

In parallel to METC submission, submit your research to CTCM for obtaining approval from the Executive Board of Maastricht UMC+.

Researchers undertaking work with human participants that falls outside the scope of the WMO, MDR/IVDR or CTR and does not include patients (or patient data) from the academic hospital Maastricht, 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

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, involving patients from the academic hospital Maastricht) 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 Maastricht , 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 Maastricht , the research proposal should be submitted to the FHML-REC.


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Animal experimentation

Maastricht UMC+ and Maastricht University (UM) are aware of the ethical objections regarding experimentation on animals and take therefore a lot of responsibility when it comes to this subject. Experiments with animals are only performed if a scientific biomedical question cannot be answered by other, alternative approaches (such as cell culture, organs on a chip, research in humans etc.) and the use of live animals is indispensable. Work with laboratory animals in biomedical science at UM follows the 3Rs concept, thriving to **reduce** the number of animals used, to **refine** the methods applied to minimise the burden animals might experience and to **replace** animals wherever possible by alternative approaches.

UM takes the position that biomedical research with animals is currently (2023) and also in the upcoming years, necessary to advance biomedical progress and to contribute to better medical and healthcare programs. Nevertheless, UM sees the potential of alternative, non-animal methods (NAMs) to contribute to the biomedical field and to provide alternatives to research using animals. For the time being, both approaches deserve funding and will be supported by UM.

Legal provisions

EExperiments involving animals are subjected to strict legal provisions that are based on and include the Experiments on Animals Act **(in Dutch: Wet Op de Dierproeven, WoD)**. The latest version of the WoD became active in 2014 and builds upon the **European Directive 2010/63** (link), which is the predominant legal document for Animal Experimentation in Europe.
Besides this, UM considers and follows relevant international and national guidelines (Codes of Practice on Laboratory Animal Science).

Permits to perform biomedical research with animals are strictly regulated and follow a multi-step workflow with several controls and decision-making processes:
Step 1: A proposal based on latest scientific knowledge is generated by the researcher and checked for compliance with animal wellbeing requirements by the local Animal Welfare Body (in Dutch: IvD – Instantie voor Dierenwelzijn).
Step 2: The proposal will be sent (via the Institutional License Holder) to the Central Commission Animal Testing (in Dutch: Centrals Commissie Dierproeven, CCD). The CCD requests a statement with focus on scientific validity and ethical appropriateness from an Expert Group, called Animal Experimental Commission (in Dutch: Dier Experimenten Commissie, DEC).
Step 3: CCD receives the report of the Expert Group (DEC) and decides, based on this recommendation and the CCD's own evaluation if the proposal fullfills all legal requirements to be performed/executed.
Step 4: Based on a positive vote of the CCD, the researcher generates so-called Working Protocols, describing details of the experiments. Working Protocols are supported and evaluated by the IvD.

Skills and competencies

UM assures that all legal provisions for persons performing animal experimentation (art.9 and art.13f2) will be fulfilled. For this a Laboratory Science (LAS) course, that is recognized by the Dutch authorities (NVWA, Nederlandse Voedsel en Warenautoriteit), and accredited by FELASA (Federation of Laboratory Animal Science Association) is offered. UM complies with the concept of Life Long Learning and offers its employees Continuous Professional Education in the field of Laboratory Animal Science.

Central Animal Facility

UM facilitates biomedical work with animals by running a Central Animal Facility (CPV, Centrale Proefdier Voorzieningen) that provides all services around housing, maintenance, purchasing etc. of animals used in experimentation. By centralizing in the CPV, UM ensures that all legally binding guidelines when dealing with laboratory animals can be met.

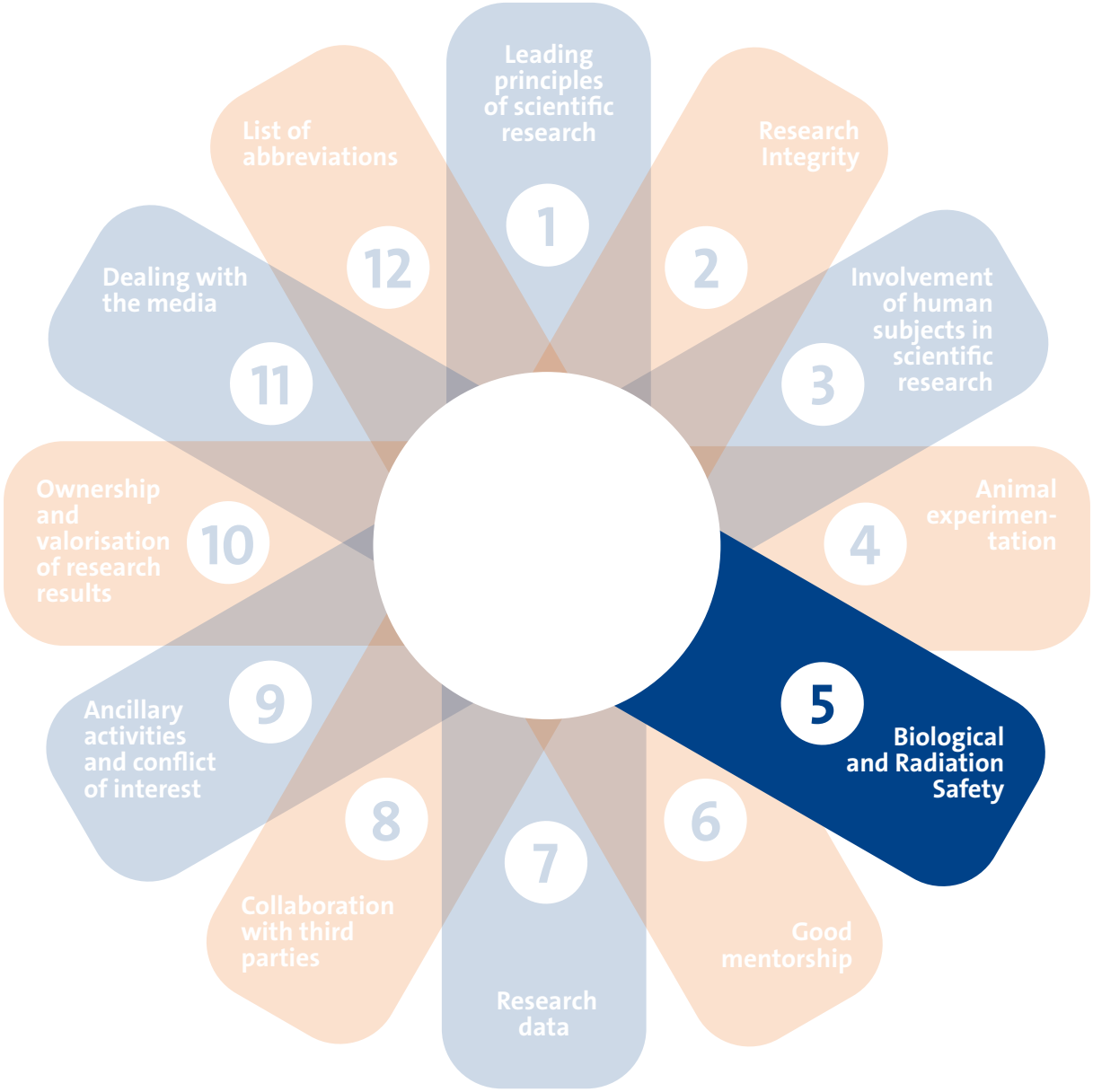
Animal Welfare Body

UM has installed an Animal Welfare Body (IvD) to accompany, support and survey all activities around the use of animals at UM.the animals.

Openness

UM is open about the biomedical work with animals performed at its facilities. On its website UM informs about the numbers of animals used in Biomedical Research per year and provides information around experimentation with animals. UM has signed the Dutch Transparency Agreement on the use of animals in Biomedical Research and informs the public proactively via different channels (e.g. EARA: Week of Openness, Articles in Newspapers). UM is member of EARA (European Animal Research Association) and ART (Animal Research Tomorrow, formerly Basel Declaration).

Permits to perform biomedical research with animals are strictly regulated and follow a multi-step workflow with several controls and decision-making processes. 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 SBE. 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 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 general coordinating Radiation Protection Expert (ACD) of the 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 of ionizing radiation. Specific conditions, requirements and information regarding biological and radiation safety as well as the required forms are published on the **SBE 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 Warenautoriteit in Dutch)** has the surveillance regarding the compliance to this protocol.

Before collecting or ordering 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 off: 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

Good mentorship is pivotal in the PhD journey, and forms the basis upon which a successful academic career is built. The quality of supervision and the relationship between supervisor and PhD candidate play a crucial role in optimizing the outcomes of a PhD trajectory, fostering personal development, but also in instilling a culture of ethical and responsible research. Frequent interactions with the supervisor help the PhD candidate to learn and develop, to stay motivated, to take the right decisions at the right time, to adhere to the project's timetable and to achieve the best results. Furthermore, the importance of strong mentorship goes beyond the individual's development as a researcher; it also enhances 'good science' in general and lays the foundation for a future generation of skilled and ethically sound researchers.

To enhance good mentorship the Maastricht UMC+/FHML Faculty PhD Committee (FPC) has developed the so-called 'Golden Rules', for supervisors as well as for PhD candidates (6.1 and 6.2). Furthermore, to safeguard the quality of supervision of PhD candidates, the Maastricht UMC+ offers twice a year, on a structural basis, a Competence Development Course for PhD supervisors, called the 'Basic Qualification Supervision' course. This course is aimed at Maastricht UMC+ supervisors, to develop their competences as a PhD supervisor, sensitize them with regard to coaching issues, and to provide them with tools to make their supervision more effective. After all, it is not easy to balance the effective monitoring of the progress and success of a research project with positive and personalized coaching of the PhD candidates. All participants of the course get to practice their supervising skills with actors and are made aware of different leadership styles. The training is highly appreciated by the participants and is being perceived as very useful and of high quality.

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.

Finally, it is important that a research culture is established and nurtured within our organization, in which it is good practice to look out for each other, and in which PhD candidates will feel safe. Regular meetings with the daily supervisor or the supervisory team, in which an open atmosphere makes it possible to discuss the overall wellbeing of the PhD candidate, should be standard practice. All (new) supervisors and PhD candidates should be informed about the support systems in place. Flow-charts such as the **PSI Roadmap Scientific Integrity and Social Safety** can be a good tool to point people in the right direction.

6.1 Maastricht UMC+ Golden Rules for PhD Supervisors

1. **Discuss and evaluate mutual expectations regarding research and supervision.**
   Clarify expectations and discuss the supervision needs with your PhD candidate. Make sure to develop clear agreements and accepted deadlines. To this end, use routine work meetings, as well as the annual interview.
2. **Develop a clear, scientifically sound and feasible research plan with your PhD candidate.**
   Use the **Personal Research Plan (PRP)** within the first three months of the research trajectory. Discuss it regularly — at least once a year — with your PhD candidate and, if needed, revise/update it.
3. **Make a clear plan with your PhD candidate to support personal growth and development.**
   Use the **Training and Supervision Plan (TSP)** within the first three months of the research trajectory and regularly update it. Identify training opportunities to support the acquisition of **competences** needed to develop into an independent researcher/scientist for future work, in and out of academia.
4. **Be aware that support needs may change.**
   Throughout the PhD trajectory, direct (give clear instructions and protocols), lead (guide towards achieving concrete goals), coach (give the necessary inputs to further develop), support and delegate (leave full independence in performing specific tasks).
5. **Provide constructive feedback on process and results.**
   Invest the time needed to motivate and develop the researcher, not just the research project. Provide regular feedback based on the development level and the project's tasks and goals. Your **feedback** should be compassionate, concrete, constructive, and critical.
6. **Be open to receive feedback from your PhD candidate.**
   Be approachable and regularly ask your PhD candidate for feedback in a respectful and encouraging way. Learn from your PhD candidate.
7. **Recognise, monitor and address work pressure.**
   Learn how to recognise early signs of work pressure and emotional strains. Regularly address well-being issues and reach out during challenging periods.
8. **Open up your network, discuss career perspectives and opportunities.**
   Throughout the PhD trajectory, discuss interests, ambitions, and future career options. Offer training and research opportunities from your network and resources to help the PhD candidate create a professional network.
9. **Work on your supervisory skills and regularly evaluate your own way of supervision.**
   Reflect on your own strengths, motivation and growth. Continuously develop your supervision and management skills through available training opportunities at FHML, Maastricht University, and externally.
10. **Assure scientific soundness and follow the scientific integrity code of conduct.**
    Maastricht University and Maastricht UMC+ have established a **Research Code** based on the codes of conduct of the Universities of The Netherlands (UNL). All your professional activities, including supervision, should comply with these codes. Expect the same from your PhD candidate.

6.2 Maastricht UMC+ Golden Rules for PhD Candidates

1. **You are the captain of the ship.**
   You're stakeholder #1 in your project, which means that you are responsible for your PhD progress and completion. Take initiative on planning, organisation and time management throughout your PhD. Communicate your wishes, needs and challenges to your supervisory team. Remember you're smart! Yes, You Can!
2. **Develop a clear, scientifically sound and feasible research plan.**
   Use the **Personal Research Plan (PRP)** within the first three months of the research trajectory. Discuss it regularly — at least once a year — with your supervisory team and, if needed, revise/update it.
3. **Make a clear plan to support your professional and personal growth.**
   Use the **Training and Supervision Plan (TSP)** within the first three months of the research trajectory and regularly update it. Identify training opportunities to support the acquisition of competences needed to develop into an independent researcher/scientist for future work, in and out of academia. Discuss your professional/personal development with your supervisory team at least once per year – and more often if your needs are not being met.
4. **Discuss and evaluate mutual expectations regarding the supervision.**
   Clarify expectations and discuss your supervision needs with the supervisory team early in the project. Make sure to develop clear mutual agreements on supervision, responsibilities and communication. Use routine (weekly/monthly) work meetings, as well as the annual interview appraisal. Remember that constructive, bidirectional feedback is key. Also, realise you are in a position to give feedback in turn.
5. **Manage your time well.**
   You have a limited, fixed time to finish your PhD project, so make sure to manage your time well. Develop time management skills and discuss timelines with your supervisory team to ensure you to obtain your PhD without delay.
6. **Discuss your personal support needs.**
   Throughout your trajectory, regularly discuss the support you need within your team and outside of it. Make use of all available support that is being offered. It is also important to acknowledge that support needs can shift throughout the project.
7. **Follow the scientific integrity code of conduct.**
   Maastricht University and Maastricht UMC+ have established a **Research Code** based on the codes of conduct of the Universities of The Netherlands (UNL). Familiarise yourself with the policies and expected behaviours. All your professional activities, whether they refer to education, research, patient care, or management, should comply with these codes. Know that you can expect the same from your supervisor.
8. **Organise your own peer support network.**
   Talk to your fellow students. It is easier to overcome difficulties together. Try to be attentive and recognise when someone is struggling and don't hesitate to offer your help. Take advantage of the available peer support.
9. **Plan your future post-PhD.**
   Throughout your PhD trajectory, discuss your interests, ambitions, and future career options with your supervisory team. Ask your supervisor for relevant contacts who may help you in your post-PhD career. Make active use of opportunities that help you to create a professional network. Don't be afraid to talk to people and take initiative.
10. **Recognise, monitor and address work pressure.**
    Learn how to recognise early signs of work pressure and emotional strains and know to monitor them. Should work pressure escalate, contact the appropriate persons and/or services to address the situation. Don't forget to put time into your personal life and things you enjoy.

6.3. Authorship & order of authors

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 **International 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. Substantial contribution to the concept or design of the research, or to the acquisition, analysis or interpretation of the research data;
2. Writing or critical editing the text;
3. Approval of the final version of the manuscript;
4. Responsibility for all parts of the manuscript, as shown by willingness to ensure that questions about the accuracy of any part are properly investigated and answered.

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.

The conditions above imply that:

- 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. 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.

The **COPE** provides helpful information and tools (flowcharts, checklists, and examples) for establishing authorship and resolving potential disputes.

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. Examples of this related to authorship are:

- Enforced authorships that do not meet the above criteria.
- Omitting someone who qualifies as an author or not giving someone who meets the first criterion the opportunity to qualify as an author, for example by not soliciting input during the writing and editing process.

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, contributed sufficiently, 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.

Acknowledgements

Acknowledgements may list those who have contributed substantially but do not meet the criteria for authorship, with their title, position, affiliation and specified contribution. They must agree to be named and in the manner in which they are named. Examples of those who might be acknowledged include people who provided purely technical help, writing assisstance including AI, see chapter 6.4., financial or material support or only general support.

Financial and other substantial material sources of support for the research should be listed in the Acknowledgements or in the Funding Statements.

Sources

The work of others should be respected by attributing their ideas and text to them through adequate citation and references. References should be cited completely and as accurately as possible. In references to books and reports, cite the relevant pages. If substantial use is made of quotations from a single source, it is wise to consult with the original author(s) because of possible copyright issues.

6.4. AI technologies

AI technologies such as generative pre-trained transformers (GPTs; e.g. ChatGPT) offer new possibilities, for example as a writing aid. However, these language models are trained on incomplete and sometimes incorrect data. It is therefore important to critically evaluate the generated output. Potential risks include biases, unfounded claims, and incomplete references. In extreme cases even racist and unethical expressions might be generated.

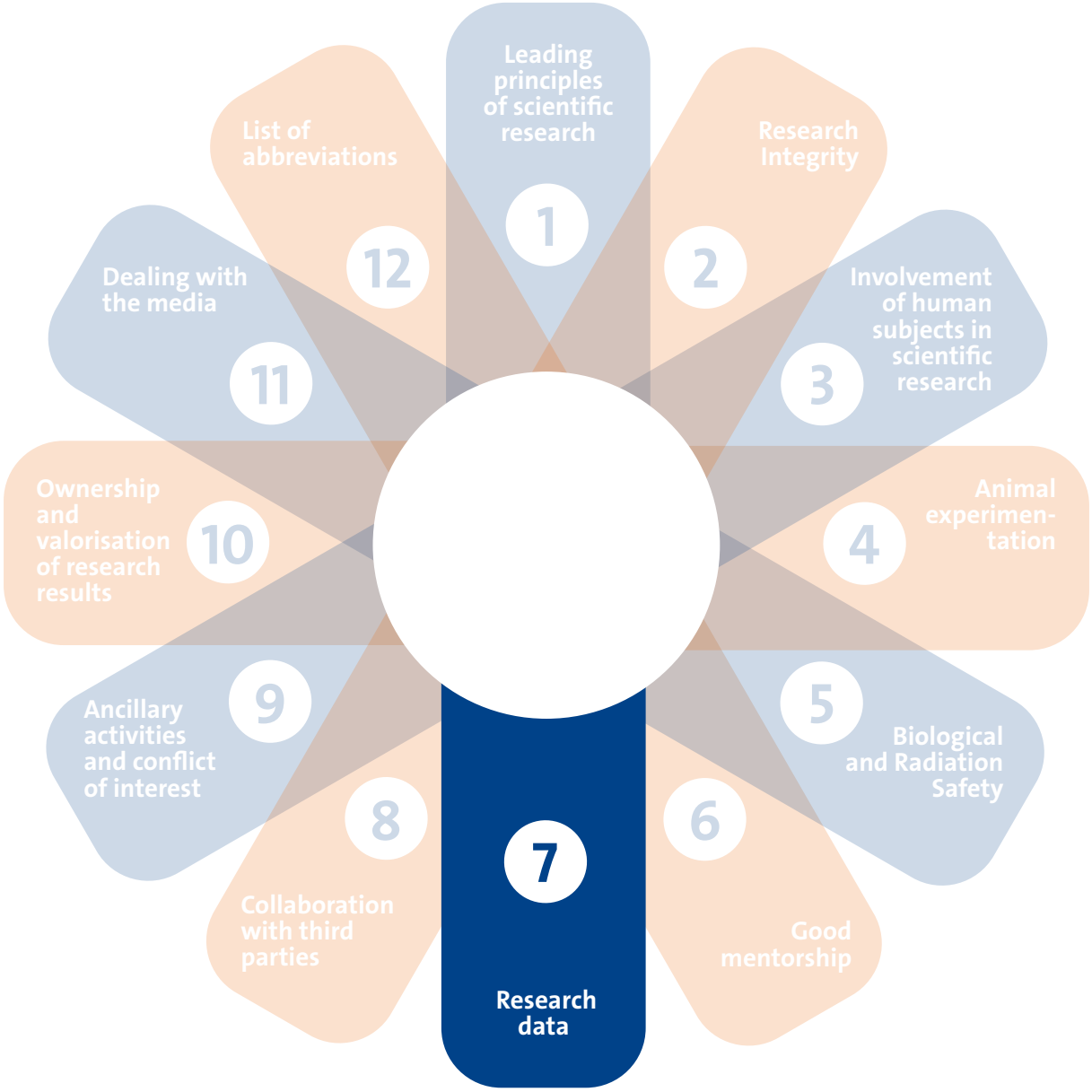
Researchers using AI technologies should be aware of these risks. It remains the responsibility of the researcher to verify the content, ensure accuracy and completeness, and add relevant source citations where needed. Transparency about the use is essential in publications and other expressions for instance b mentioning in acknowledgements that AI was used in the writing process. Many journals now have author guidelines on the use of these technologies and a language model cannot act as a 'non-human' author.
At the same time, it is a rapidly developing field. As the models improve, the risks decrease. Guidelines for use should therefore be updated regularly. Suggestions for responsible use include verifying output, adding references where relevant, and being transparent about the implementation.

Finally, you should keep in mind that data entered into GPTs is stored on external servers. Therefore users should never enter personal data or company-sensitive data such as patient data, innovative ideas, or (unpublished) scientific data/outcomes. As these technologies, their use, and ideas are developing rapidly, this section will be updated regularly.

SHE, the School of Health Profession Education, has set up guidelines for the use of generative AI.

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.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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 shareable, 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 during the whole data life cycle is part of good research practice. By establishing the management of research data at an early stage, chances of having to face unpleasant surprises 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 (Source: Research Data Management Kit (RDMkit).

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 and security compliance, legal aspects and ethics when Personal data is processed.

Note that a datamanagement plan is mandatory for WMO, MDR/IVDR or CTR research.

For medical scientific research involving human participants which is subject to the WMO, MDR/IVDR or CTR (see Chapter 3) with academic hospital Maastricht or UM (FHML) as study sponsor, CTCM provides essential datamanagement support from study preparation to study closure as part of the 'Quality Assurance Program' (in Dutch: KwaliteitsBorgingsProgramma; link via **MUMC+ Intranet** or **FHML intranet**). In the study preparation phase the **research data management plan** and a quality checked electronic Case Report Form (eCRF) in a validated Electronic Data Capture System (EDC), are mandatory for obtaining approval from the Executive Board of the Maastricht UMC+.

In order to facilitate reuse of prospectively collected research data following study closure, CTCM collaborates with DataHub and MEMIC in the MUMC+ Data Steward team.

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 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 and trains 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**, **Health-RI Limburg** and the **Grants Office** in order to make use of their expertise regarding for example (patient) privacy, information security, governance and laws and regulations.

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

- The **NFU HANDS Data Stewardship**;
- The **UNL Code of Conduct for the use of Personal Data in Scientific Research**;
- The **UM Research Data Management Code of Conduct**.
- The **Code of Conduct for Health Research** (Gedragscode Gezondheidsonderzoek) from COREON (in Dutch: Commissie Regelgeving Onderzoek)

If you need assistance please read **https://mumc.atlassian.net/wiki/spaces/RMS/overview** or contact our MUMC+ Data Steward team via **https://mumc.atlassian.net/servicedesk/customer/portals** or contact CTCM directly.

7.2 General Data Protection Regulation (GDPR)

The GDPR (Algemene Verordening Gegevensbescherrming, 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 ensure GDPR compliance of the research within Maastricht UMC+, a **GDPR registration tool** was designed for research involving UM (FHML). 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.

For research involving the academic hospital Maastricht, project information on processing is registered in **PaNaMa**, the research management system of Maastricht UMC+ which is managed by CTCM. Until further notice, no additional action by the researcher is needed in relation to the 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 or data processing, the data protection officer of the **UM** (**fg@maastrichtuniversity.nl**) and/or of the academic hospital Maastricht (**fg@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 Maastricht 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 impactful and transparent way of conducting research. To accelerate the transition to Open Science in the Netherlands, the National Platform Open Science (NPOS) was founded. NPOS is a collaboration of Dutch organizations of higher education and research who have drawn up a **National Plan Open Science** . This plan was first presented to the Dutch government in 2017 and received an update in 2022. The current plan concentrates on three programme lines that are meant to guide the Open Science transition:

1. Open Access
2. FAIR Data
3. Citizen Science

The Open Science movement involves becoming more open about how researchers work, collaborate, communicate, share resources and disseminate research results, thereby increasing the societal impact of their work. UM supports this movement and presented an updated **Open Science policy** in 2022, which is aligned with the program lines in the National Plan Open Science. The Maastricht UMC+ of course also 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 Access to publications from publicly funded research. The Maastricht UMC+ follows the ambition of the **National Plan Open Science**, which is 'making all scholarly output Open Access'. 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 'Gold 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. The UM Library has negotiated Read & Publish deals with hybrid journals which offer authors discounts up to 100% to publish their paper OA. There are also deals available with a limited number of Gold Open Access journals. The deals can be checked in the **Open Access Journal Browser**. If an article is published in a traditional, non-Open Access subscription-based journal, the author can still 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. For UM, this research database is called Pure and researchers can opt in to automatically have their non-Open Access papers taken up in **Pure**, thereby following the Green route. In order to enable this Green service, authors can simply sign up for Taverne (the copyright law amendment that enables this Green Open Access option). It should, however, be pointed out that Gold or hybrid Open Access is still the preferred route and also the route required for papers resulting from EU-funded and national funded research (e.g. NWO, ZonMw).

Proper data management is part of good research practice. Researchers are aware of open science, FAIR principles, 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 register before starting.


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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 conflict of interest and should thus be avoided.

It should be noted that the name Maastricht UMC+ is used to externally represent two legal entities, that is the academic hospital Maastricht and/or UM (FHML), 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 Maastricht 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.

Situations vary, interests may differ and specific conditions may apply to each research project. Therefore, it is important to always reach out for assistance when collaborating with an external partner.

In case of research conducted at or with the UM(FHML), contact the office support unit of the applicable FHML Institute (who will involve Legal Affairs for legal advice).

In case of human research concerning patients, patient data (i.e. data transfer/sharing), use of facilities of the academic hospital Maastricht, or in case of consultancies, contact a Project Administration Specialist of CTCM (**cbm.ctcm@mumc.nl**).

Legal Affairs or CTCM will help you with the topics that must be addressed in a written agreement. CTCM is the only mandated party to act as signatory regarding research with human participants (WMO (MDR/IVDR, CTR) and non-WMO) involving the academic hospital Maastricht. 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 the academic hospital Maastricht or UM (FHML).

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 Institutes, have to report this to the Grants Office.

8.1 Knowledge security

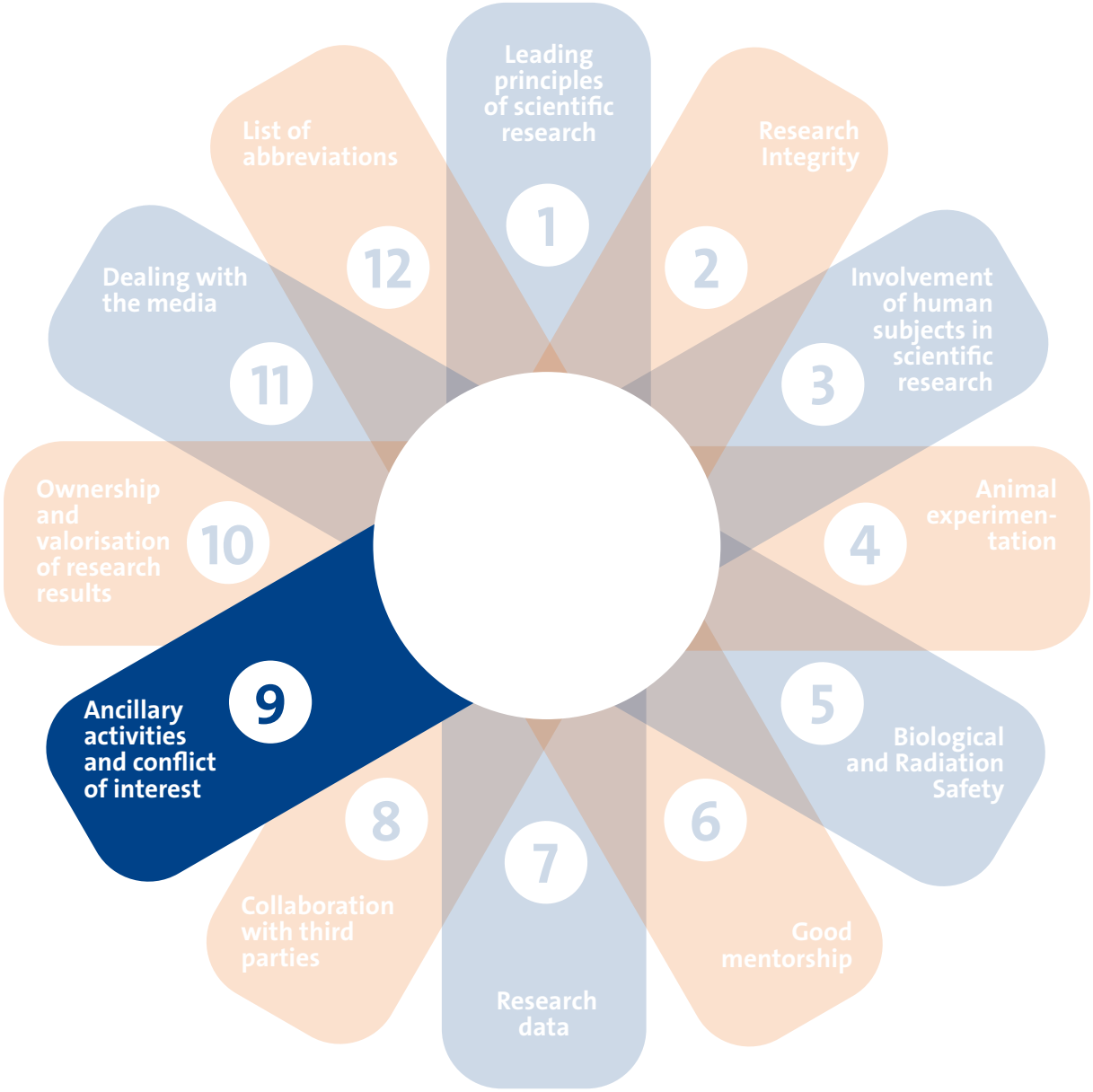
The **National Guideline on Knowledge Security** describes the dilemma that top-level science cannot exist without collaboration with other parties but that the threats around knowledge security are increasing, especially in international collaborations. The basic premise is that scientific organisations and their researchers must ensure that international collaborations can take place safely: open where possible, protected where necessary.

Knowledge security involves:

- Preventing unwanted transfer of sensitive knowledge and technology. Unwanted transfer occurs if our national security is at stake.
- Preventing covert influence on research by other states. Such interference endangers academic freedom and the security of a civil society.
- Ethical issues that may play a role in collaboration with countries that do not respect fundamental human rights.

For each study, the risks concerning knowledge security and the protective measures needed must be clear. For more information, see the national **Knowledge Security Office** and the **UM Knowledge Security Office**.

Before entering an agreement with an external partner contact the office support unit of the applicable FHML Research 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 Maastricht or consultancies). For each study, the risks concerning knowledge security and the protective measures needed must be clear.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Ancillary activities 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 ancillary activities 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 Ancillary activities

- **Academic hospital Maastricht employees:**
  The collective labour agreement for University Medical Centres **(CAO NFU)** contains a regulation for ancillary activities that applies to all employees whose contracts are subject to the CAO. The CAO (art. 9.3) contains a regulation stipulating that ancillary activities 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. More information can be found on the **MUMC+ Intranet.**

- **FHML/UM employees:**
  At UM, there are regulations regarding the ancillary activities of UM professors and other staff members. Article 1.14 of the **Collective labour agreement for Dutch Universities** stipulates that all university staff members are obliged to report their ancillary activities. Additionally, UM has its own **regulations regarding ancillary activities.**

  Employees who carry out ancillary activities or intend to do so must register this online in **UM SuccessFactors.** The administrative manager will automatically be notified of the registration by e-mail. If the work does not affect the employee's performance at UM 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. More information, including an instruction for registration of ancillary activities, can be found **here**.

  The Minister of Education has made agreements about the transparency of ancillary activities of professors. All of the ancillary activities of a professor can be found on their personal profile page. The professor is responsible for keeping this information up-to-date. The ancillary activities are discussed during the annual assessment interviews.

  In certain situations, the Knowledge Centre for International Staff (KCIS) also has to be informed about ancillary activities. Employees can directly contact KCIS: **info-kcis@maastrichtuniversity.nl**. This applies to employees who carry out ancillary activities abroad and for employees with a nationality from outside the EU/EEA or a Croatian nationality who carry out ancillary activities in the Netherlands. KCIS will check whether the employee's work permit and/or residence permit allows the ancillary activities.

9.2 Conflict of interest

There is a conflict of interest when an employee, or the department/institute for which he or she works for, has financial or personal ties with other persons or organizations which could influence the research or other activities within Maastricht UMC+. 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 for example personal relationships, academic competition and intellectual passion.

Certain guidelines apply when weighing up the pros and cons of favors offered by companies. 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, employees are not allowed to accept gifts, invitations and/or sponsoring in exchange for a favor. Moreover, employees must always consult their manager before accepting an offer. Any financial sponsorship is added to the departmental budget.

Employees 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. Employees 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 are:

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 to support a company in which the researcher holds an interest.

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.

Ancillary activities that may affect the interests of UM/FHML or Maastricht UMC+ must be reported. There are instructions available for registering and granting ancillary activities. 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 chapter 8. Collaboration with third parties).

Publications

Within an academic institution, researchers are conducting research. When publishing scientific work, the copyright is often 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 any agreement 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 is 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 chapter 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 publicly 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 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.

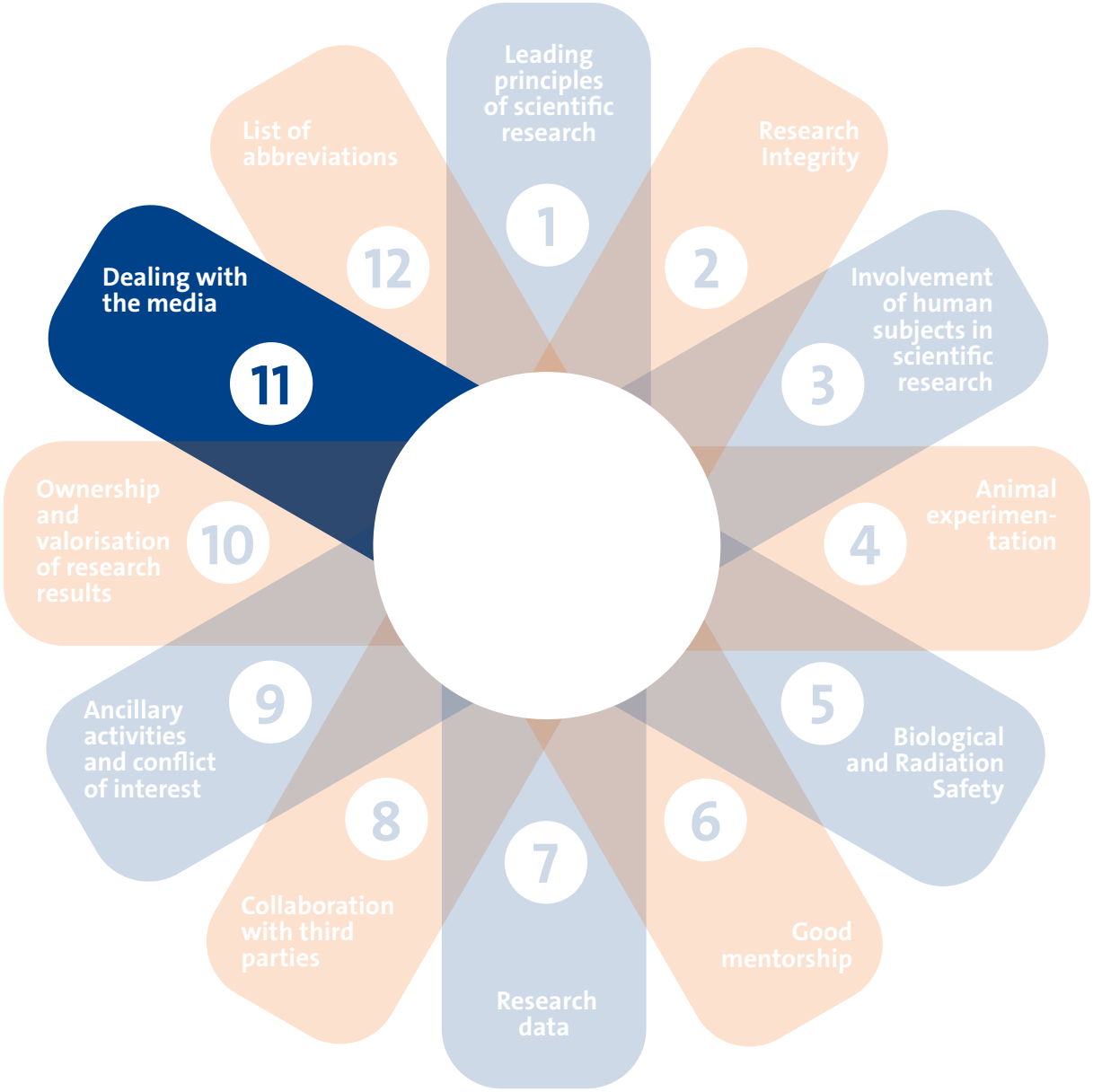
10.2 Valorisation of research results

Valorisation is the process of creating value from knowledge, by making knowledge available and suitable for economic and societal use, 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.


Leading principles of scientific research
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Research Integrity
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Involvement of human subjects in scientific research
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Animal experimen-tation
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Biological and Radiation Safety
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Good mentorship
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Dealing with the media

Science is not only relevant and interesting for the academic community but also captures the interest of the general public. Scientists are therefore encouraged to communicate about research findings. While engaging with the media can enhance the outreach and impact of scientific research, scientists must be careful to ensure the integrity of their message and conflicts of interest.

Seeking publicity and cooperating with the media can be beneficial: it provides a platform showing the relevance of research done, strengthens the academic reputation of institutions, and accounts for using public and private financial resources. Media coverage can also help researchers to make a bigger impact: creating awareness at a larger audience, contributing to the societal debate, making people enthusiastic about research, and positioning the researcher as an expert.

However, caution is necessary when approaching (or being contacted by) the media, as there are potential pitfalls to navigate. It is, for example, possible that the desired message does not remain intact. A complex and nuanced research result can easily change into a simplistic 'clickbait' message. Sometimes, publicity concerning scientific results affects 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. Finally, media can have commercial interest themselves.

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.
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. The presentation of clinical research requires the same degree of due care.
3) Caution should also be exercised when preliminary 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 the Maastricht University or the Maastricht UMC+ press office.

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 there is an 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 research institute.

Maastricht University press office

Before publishing research results in the media or before doing a radio/TV interview, contact the press office of Maastricht University. The Maastricht University press office provides advice, recommendations and guidelines to make the outcome of the cooperation with the media as successful as possible. They also offer coaching sessions, public speaking, and media trainings.
Involve the Maastricht University press office and/or the Marketing & Communication department of FHML during the process of your research and do not leave it until the latest moment. If you foresee interesting research results that you want to share with the media it is recommended to immediately get in touch. Early involvement of the press office and Marketing & Communications FHML generates time to prepare the media strategy and message.

Contact information Maastricht University press office and Marketing & Communication FHML:

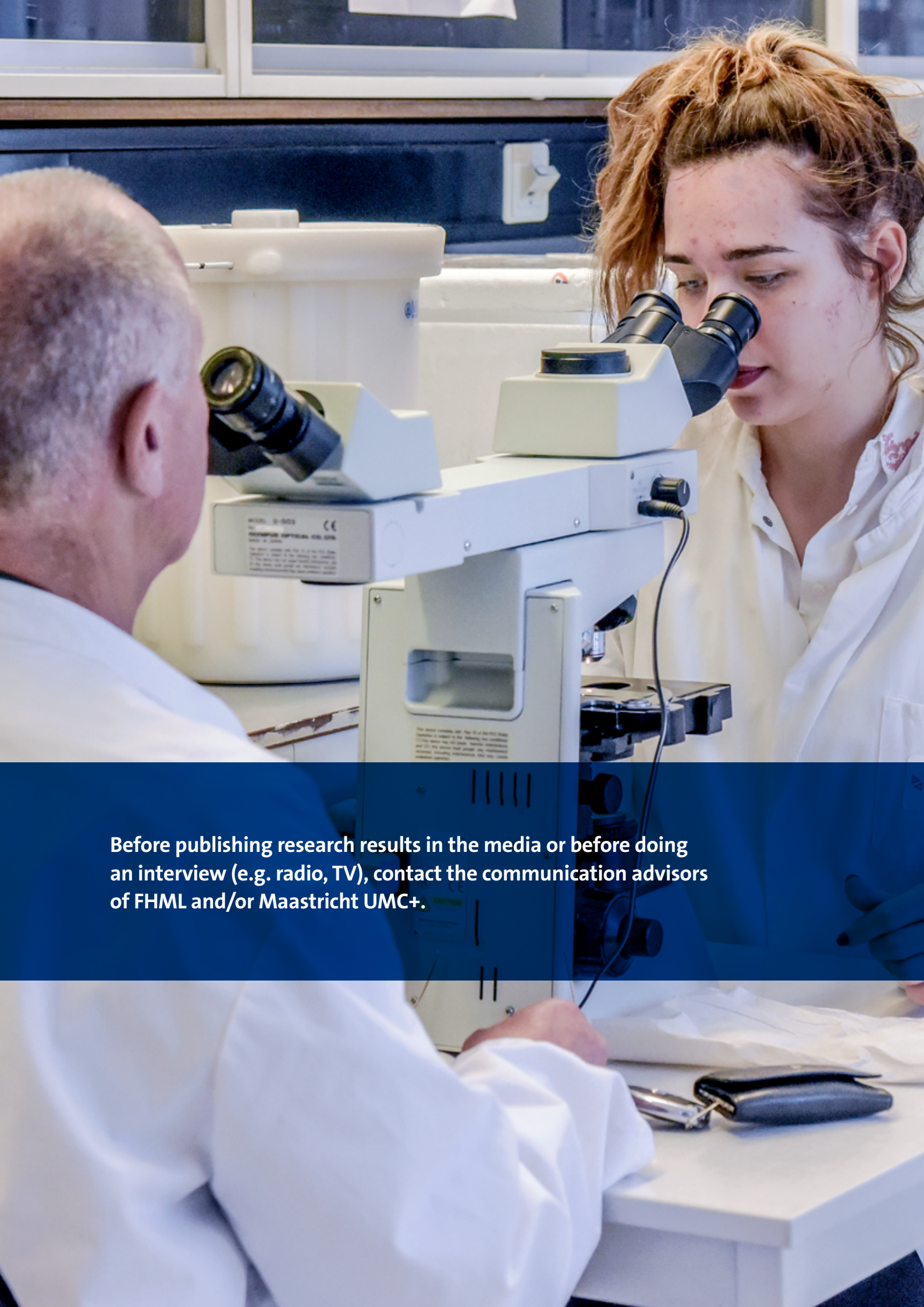
- Press office Maastricht University: **www.maastrichtuniversity.nl/news-events/press**
  Contact person research FHML: **Mark van der Linde**
  mark.vanderlinde@maastrichtuniversity.nl
- Marketing & Communication FHML: **communicatie-fhml@maastrichtuniversity.nl**

Maastricht UMC+ press office

Researchers who work for Maastricht University and Maastricht UMC+ can also follow the Maastricht UMC+ press protocol. 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 Maastricht UMC+ press office:

- 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+.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Biological and Radiation Safety
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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	e-learning 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 Gemodificeerd Organisme in Dutch)* Genetically Modified Organism
GPTs	*(Generative Pre-trained Transformers)*
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 Warenautoriteit 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
UNL	*(Universiteiten van Nederland)* Association of Universities in the Netherlands
WMO	*(Wet medisch-wetenschappelijk onderzoek met mensen in Dutch)* Medical Research Involving Human Subjects Act
WOD	*(Wet Op de Dierproeven in Dutch)* Animal Testing Act
QA	Quality Assurance
QC	Quality Control
QSR	Quality System Research

Maastricht UMC+

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