

Research Code

Principles and guidelines for research integrity, independence and quality



Foreword

Good research flourishes in an academic climate characterized by honesty, scrupulousness, transparency, independence and responsibility—five principles that form the basis of this Amsterdam UMC Research Code. To create and maintain such a climate requires awareness, support, and ongoing dialogues among all people who need to understand what these principles mean and how they should be lived in day-to-day practice. These dialogues are important because scientific research does not take place in splendid isolation: we are part and parcel of a dynamic world that both influences the way in which we perform research and, in turn, is influenced by our work.

Three important trends may illustrate this. First, the digital transformation has prominently impacted the technological possibilities for doing science, as well as our ways of collaborating and communicating about science. This urges us to rethink, for example, the dilemma between protecting individuals' privacy when handling datasets and the societal call for reuse of data. Another new challenge is how to use social media responsibly, without over-simplifying complex messages. Second, the Open Science movement has raised a multitude of new questions, such as those relating to research collaborations. What information should we share with whom, when and under what conditions? Third, the scientific world has become increasingly competitive: many highly motivated and skilled researchers compete for a very limited number of grants and tenured positions. This may lead to undue pressure on both junior and senior researchers to produce and publish—preferably positive—study results. The unsustainable stress in the current science system has prompted a national and European discussion about redefining the existing framework for recognizing and rewarding performance of researchers, beyond merely counting publications.

This Research Code—applicable to all people performing research at Amsterdam UMC, as well as Amsterdam UMC employees involved in research elsewhere—can provide guidance and stimulate an ongoing dialogue about what good research entails.

The Amsterdam UMC executive board is grateful to the editorial board of this new edition of the Amsterdam UMC Research Code and to all other contributors. We trust that this document will help researchers to work collectively to preserve their independence and integrity, and to deliver high quality scientific research. We call upon all Amsterdam UMC researchers to bring the Research Code to life on a day-to-day basis in their research practices. Therefore, we kindly ask you to put topics addressed in this Code on the agenda of your regular team meetings, to discuss research integrity at research symposia, and most of all: to make it a habit to share your dilemmas and best practices with colleagues ¹.

Prof. Chris Polman and Prof. Hans Romijn
Deans and Chairs of the executive board

¹ **Examples of tools** that serve this purpose are the **'Dilemma game'**, an online serious game developed by the Erasmus University Rotterdam Taskforce Scientific Integrity; and the science theater production 'ConScience App', which was developed based on ideas from members of The Young Academy of the Royal Netherlands Academy of Arts and Sciences (KNAW) and produced by *het Acteursgenootschap*.



Introduction

“Research is the quest for knowledge obtained through systematic study, thinking, observation and experimentation”, according to the **European Code of Conduct for Research Integrity**. Biomedical research, more specifically, is crucial for gaining knowledge about the health and health promotion of populations and patients. Such research should therefore be trustworthy: its quality and reliability should be beyond doubt. Trust can only be guaranteed if scientists scrupulously respect the principles of research integrity. It is the responsibility and wish of Amsterdam UMC to provide a culture in which researchers are stimulated and supported to perform research to the highest ethical standards. In this Code, we outline the relevant requirements, regulations and considerations to support our scientists in doing research of high quality and integrity.

Basic principles To promote virtuous research, the federation of European universities (All European Academies; ALLEA) and the Association of Universities of the Netherlands (UNL, former *Vereniging Samenwerkende Nederlandse Universiteiten*; VSNU) have both issued a Code of Conduct for Research Integrity. Their basic principles form the starting point for thinking about and determining what good research entails. The following five principles underlie the **Dutch Code of Conduct for Research Integrity**. We cite the description of those principles here extensively, as they form the basis for this Amsterdam UMC Research Code. Specific chapters of the Amsterdam UMC Research Code that relate to these principles are referred to below.

1. Honesty “Honesty means, among other things, reporting the research process accurately, taking alternative opinions and counterarguments seriously, being open about margins of uncertainty, refraining from making unfounded claims, refraining from fabricating or falsifying data or sources and refraining

from presenting results more favourably or unfavourably than they actually are.” [see e.g. [Chapter 10 Dealing with the media](#), and [Chapter 12 Research misconduct: bad practices, prevention and dealing with suspected violations](#)].

2. Scrupulousness “Scrupulousness means, among other things, using methods that are scientific or scholarly and exercising the best possible care in designing, undertaking, reporting and disseminating research.” [see e.g. [Chapter 5 Research data management](#)].

3. Transparency “Transparency means, among other things, ensuring that it is clear to others what data the research was based on, how the data were obtained, how the 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.” [see e.g. [Chapter 5 Research data management](#) and [Chapter 11 Conflicts of interest](#)].

4. Independence “Independence means, among other things, not allowing 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 a 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.” [see e.g. [Chapter 8 Research collaboration agreements](#) and [Chapter 7 Peer review of research proposals and manuscripts](#)].

5. Responsibility “Responsibility means, among other things, acknowledging the fact that a researcher does not operate in isolation and hence taking 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 includes contributing to a safe research environment where colleagues, employees and subordinates are stimulated to perform research which adheres to the virtues described here. Responsibility also means conducting research that is scientifically and/or societally relevant.” [see e.g. [Chapters 3 Dealing with laboratory animals](#) and [Chapter 4 Dealing with human subjects involved in research](#)].

Research relevance The fifth principle, responsibility, is of primary importance. If research is the quest for knowledge, the first question is what knowledge we want to acquire. Biomedical research and data are meant to generate basic and applied knowledge on biology, health and healthcare. Some research is considered unacceptable. For example, a recent study concerning tobacco use, which was sponsored by the tobacco industry, was seen as unethical because its independence was compromised and it had a high potential to cause harm to society. Similarly, in the [EU Horizon 2020 programme](#), research activities directed at human cloning for reproductive purposes are not considered ethical and are therefore not eligible for funding.

While it may not always be evident what the impact of a specific study will be, researchers should always ask themselves whether their proposed studies are: 1) relevant, i.e. how they will contribute to the advancement of knowledge; 2) beneficent, i.e. how they are likely to contribute to society in the short and long term; 3) non maleficent, i.e. whether or not and to what extent they may harm human subjects or animals: do possible harms outweigh the benefits expected?; 4) independent, i.e. how they serve societal rather than personal, commercial or ideological interests ². Although outcomes may be difficult to predict, individual researchers must consider these issues and research groups should develop a shared strategy after weighing up these considerations.

² See University of Amsterdam advisory report: 'Integrity policy and research culture' (*Integriteitsbeleid en onderzoekscultuur, adviezen ter bevordering van integere wetenschapsbeoefening*), 2017, p.21 (internal document). Summary available via [this link](#).

Scope of applicability This Research Code coexists with the **Code of Conduct of Amsterdam UMC** and applies to all individual employees performing research at Amsterdam UMC as well as Amsterdam UMC employees involved in biomedical research elsewhere. It also applies to researchers from other institutions who collaborate in research projects under the responsibility of Amsterdam UMC. The Code applies to students working on research projects at Amsterdam UMC. Furthermore, it applies to Amsterdam UMC management and support staff, as they need to contribute to a research environment in which this Code is valued. External parties such as funding bodies, auditors, and societal or patient organizations can also refer to this Code.

Individual scientists are responsible for the quality and the integrity of the research they are involved in. They also have the responsibility to safeguard research integrity when collaborating in studies with others. Higher levels of seniority bring increased responsibility. This Code is an elaboration—specifically created for Amsterdam UMC—of relevant national and international legislation. As such, it primarily aims to enable and assist researchers at Amsterdam UMC to safeguard the quality and integrity of their work. Violations have to be dealt with as described in the final chapter of this code.

Continuous improvement This Code will be a living document. As research practices, guidelines, and legal or other regulations often change, the Amsterdam UMC Research Code will be updated on a yearly basis. Moreover, the editors welcome comments from users of the Code, which they will consider for future versions.

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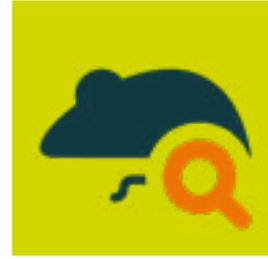
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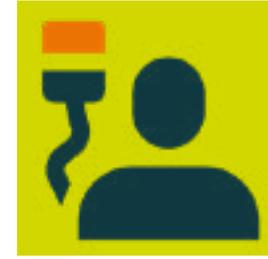
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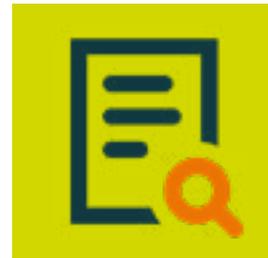
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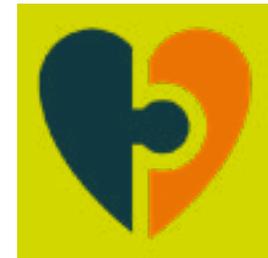
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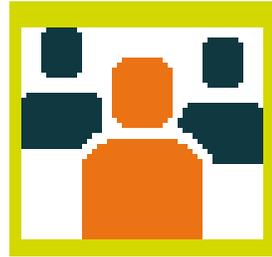
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1 Expectations regarding supervisors and early-career researchers

Scientific research is a team effort. Scientists at different career levels (and from different disciplines) cooperate in research. Mutual trust and respect are vital for responsible research conduct. Supervisors have the overriding responsibility for coaching early-career researchers. They are expected to create the necessary conditions for good research and to lead by example rather than referring to the power they represent. They should be committed to supporting and mentoring less experienced researchers through good scholarship and research integrity. Cooperation and dedication to this process are obviously needed from the early-career researchers as well. An interesting [study amongst PhD candidates and supervisors in the Netherlands](#) showed that both supervisors and early-career researchers regard personality, knowledge, skills and communication as important for a successful PhD trajectory. The expectations regarding supervisors and early-career researchers are described separately below.

1.1 What is expected of research supervisors

Good supervision is required for PhD candidates, and also for early-career researchers, MDs, postdocs, master's and bachelor's degree candidates. Supervisors may be PhD students, postdocs, or (assistant, associate or full) professors. Some supervisory responsibilities may be divided among members of the supervisory team. If so, this must be made explicit to the early-career researcher. The guidelines given here apply to all forms of supervision of research activities. We focus on three elements of the working environment that lead to an optimal research and learning experience for the early-career researcher.



1.1.1 Research climate

Good research thrives in a positive research and learning climate. Building and maintaining such a climate is a group effort, but the weight of responsibility for this lies with the senior researchers in the group.

A stimulating and productive research climate is characterized by:

- Striving to answer relevant research questions through work of high theoretical and methodological quality.
- Awareness of, respect for and adherence to research integrity.
- Creating room for open communication, including discussing uncertainties, dilemmas and errors.
- Constructive feedback (see also section 1.1.2).
- Room for original thinking and innovation.
- Having a good understanding of the current literature within the field.
- Enthusiasm.
- Having a genuine interest in the supervised person.

1.1.2 Motivating leadership

Effective mentorship is reflected in a good professional relationship. Both performing research and supervising it should be a pleasant and valuable experience. A good supervisor also acts as a mentor, a confidant, an advisor, a voice of reason and compassion. Early-career researchers want and need supervisors they can believe in and trust, and whose work they find genuinely interesting. **A motivating supervisor:**

- Is enthusiastic about the research.
- Strives for high quality.
- Shows interest in the work performed by the early-career researcher.
- Shows interest in the early-career researcher's personal circumstances.
- Gives the early-career researcher room to develop his/her own ideas and plans within the constraints of the research project.
- Supports the early-career researcher in designing and conducting experiments, but takes the lead when



the work exceeds the early-career researcher's capabilities.

- Does not ask for results that are too ambitious to achieve.
- Stimulates the development of academic skills.
- Stimulates networking.
- Provides constructive feedback, which entails both positive and critical comments. The latter should be formulated respectfully: address the work rather than the person, be specific, and provide suggestions for improvement that are manageable. Room should be given for the early-career researcher's response to this feedback.
- Sees a mistake or error as an opportunity for improvement.
- Is open to and asks for constructive feedback from the early-career researcher.

1.1.3 Research project organization

The goal of the research project and the procedures to be followed in the supervisory process should be clear and explicitly agreed upon from the start. This is essential to ensure timely completion of the research.

A good supervisor is committed to successful organization of the research project, and therefore:

- Ensures that the project is based on a well-defined, realistic plan.
- Provides alternative plans, if needed.
- Schedules regular meetings, taking into account the early-career researcher's preferences, level of experience and ability to work independently.
- Plans education and training.
- Is available for unplanned consultation when needed, within a reasonable time-frame.
- Reviews manuscripts, reports etc. within a reasonable and agreed time
- Provides the early-career researcher with adequate working conditions, including infrastructure.
- At the start of the project, reaches agreement with the early-career researcher on publication of the research findings, including authorship (see [Chapter 6 Authorship](#)).
- Has a performance appraisal interview with the early-career researcher at least once a year.



1.1.4 The PhD trajectory

The supervisor has overall responsibility for the PhD trajectory and has specific duties pertaining to this role. Regulations related to completion of a PhD trajectory are given for Amsterdam UMC locations **AMC** and **VUmc** by the **University of Amsterdam** and the **Vrije Universiteit Amsterdam**, respectively. Supervisors should be aware of the prevailing regulations at each location.

1.2 What is expected of early-career researchers

While good mentorship helps j early-career researchers to fully benefit from their research work, they also have responsibilities regarding the relationship with their supervisor, their team members, research participants and their work.

1.2.1 Attitude and communication

To achieve optimal scientific results and work in a stimulating environment, the early-career researcher also needs to show a positive attitude and communicate in a constructive way.

The early-career researcher:

- Treats his/her supervisor and colleagues respectfully.
- Is transparent about the work in every respect.
- Is open about his/her uncertainties, dilemmas and possible errors.
- Is open for feedback.
- Is accountable towards his/her supervisor.
- Is open to further learning and development of research skills.
- Gives feedback to his/her supervisor in a constructive manner.
- Can (critically) reflect on his/her behavior and work as a researcher.
- Participates in scientific discussions and the public debate.



1.2.2 Organizing the work

Early-career researchers should work effectively in the process of planning, implementing and evaluating the different aspects of the research. They organize their research adequately within the applicable financial and qualitative frameworks.

The early-career researcher:

- Takes responsibility and follows instructions regarding the design and execution of the research.
- Follows instructions regarding work organization, including working hours and presence on site (as long as these are within the boundaries of the work contract, legal restrictions and personal safety).
- Seeks and utilizes best practice information and expertise.
- Plans the research adequately.
- Carefully performs and documents all aspects of the research project.
- Promptly tells the supervisor if the planning or other aspects of the work are proving difficult to realize.
- Adheres to agreements and appointments.
- Ensures that his/her knowledge of theory and methodology are up to date.
- Is aware of research integrity standards and other regulations pertaining to the research project.
- Is a constructive research team member, i.e. supports colleagues when needed and communicates respectfully.
- Shows proper behavior and respect when interacting with research participants or handling animals.

1.2.3 The PhD trajectory

While the supervisor has overall responsibility for a PhD trajectory and specific duties relating to this role, the PhD candidate also has specific responsibilities regarding the PhD program. Regulations for obtaining a PhD are given for Amsterdam UMC locations **AMC** and **VUmc** and in the doctorate regulations of the **University of Amsterdam** and the **Vrije Universiteit Amsterdam**.



2 General research and laboratory practice

Amsterdam UMC aims to carry out biomedical research of the highest possible standard. Most research is performed within research groups or networks of research groups working on various aspects of the same research theme. The working environment of researchers should be organized in such a way that high standards of research quality, integrity, reliability and reproducibility of procedures can be met. Reproducibility can refer either to instances in which the original research data and methodology are used to reproduce the results, or to instances in which independent researchers obtain consistent results using their own data and methodology. Several factors can contribute to non-reproducibility, such as unknown variation or effects, inadequate documentation, technology limitations, potential biases, lack of training, institutional barriers, or even misconduct. The following general principles apply to good research and laboratory practice and promote reproducibility:

- The principal investigator (PI) is responsible for all aspects of the research.
- The PI works in close collaboration with the central (financial) administration to maintain a proper record of all current and past projects, including at least:
 - An identification tag (e.g. a project number), and expected start and end dates of each project.
 - The names and functions of all persons involved in the project.
 - Information about data and materials to be stored, including storage location and access rights.
 - All relevant documentation and correspondence regarding project agreements, such as reports to the financing party or consortia and agreements about authorship of publications, intellectual property (IP) and patent filing.
- For each project, the aims, objectives, hypotheses and research methods are described in a research protocol, supported by a critical analysis of the literature.



- Personnel involved in a research project are knowledgeable, well trained and aware of the rules and regulations that apply to their work. Specific regulations or procedures must be complied with for specific types of research, for example that involving:
 - **Radioactive material.**
 - **Genetically modified organisms** (for which in some cases the **Nagoya protocol** on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization must be taken into account).
 - Laboratory animals, see **Chapter 3** of this Research Code.
 - Humans subjects involved in research, see **Chapter 4** of this Research Code.
 - **National Knowledge Security Guidelines** for secure international collaboration.
- Research laboratories are safe and well equipped. All equipment must be maintained properly and regularly, with relevant documentation and records available. The Medical Technology department (**location AMC** or **location VUmc**) can be contacted for technical management of equipment.
- Procedures are well described, validated and up to date. The procedural descriptions must be stored digitally in a central location as part of the department's data storage. Tracing their location should be simple, transparent and clear.
- Research findings are recorded in an electronic laboratory notebook (see below).
- Opportunities for discussion and critical feedback among research group members and their peers are organized regularly.

Proper recording of research hypotheses, experiments, methodology and observations in an official laboratory notebook is a vital part of laboratory work. This is also essential for demonstrating how potential inventions came about (see **Chapter 9 Valorization**). Below is a set of rules for keeping a laboratory notebook. Basic principles and best practices for keeping a laboratory notebook can also be found online, such as those published by the **National Institutes of Health**.

- A laboratory notebook should be digital. Amsterdam UMC uses the eLABJournal Electronic Lab Notebook



(Bio-ITech). Contact eln@amc.nl or eln@vumc.nl for more information. Only when there is no digital solution available should research data be recorded in a hard copy official laboratory notebook.

- Enter into your laboratory notebook all original concepts, data and observations, using separate headings to differentiate each one. Record the date for each entry. Include enough details for someone else to successfully duplicate the work you have recorded.
- PIs are responsible for the quality of the laboratory notebooks of members of their research group and should check them on a regular basis.
- Laboratory notebooks should be kept in a safe place and stored for 10 years after the last entry.



3 Dealing with laboratory animals

Animal experiments can be necessary to answer basic, translational and applied scientific questions, or for teaching. This chapter reiterates the demands formulated by legislation and society to respect laboratory animals.

3.1 Legal framework

Respect for laboratory animals is enshrined in the Experiments on Animals Act (**Wet Op de Dierproeven**). Under this legislation, it is forbidden to perform an animal experiment to answer a question that can also be answered using an experimental setup that involves fewer or no animals. Laboratory animals must be housed, cared for and handled in accordance with the **European Directive 2010/63**, resulting in the least possible harm or discomfort for the animals.

3.2 Ethical principles

The general principle of the Act, which holds for any animal experiment, is the 'recognition of the animal's intrinsic value'. This is based on the ethical principle that an animal has more than just instrumental value; that is, its value is not identical to its utility to humankind. Recognition of the intrinsic value of animals implies that researchers have direct moral obligations towards them. The intrinsic value of animals also means that when designing an experiment, a researcher must endeavor to take into account the animals' species-specific behavior and their self-sufficiency.

3.3 Animal experiments committees

The Experiments on Animals Act stipulates that animal experiments can only be conducted after



authorization by the national competent authority (**Centrale Commissie Dierproeven, CCD**). A proposal for research on laboratory animals is made by a 'Section 9 officer' from the research department (see 3.4 for definition), using forms to describe the project proposal and the experimental procedures. The researcher is required to keep the effects of the interventions and the number of animals to a minimum, based on the three Rs: replacement, reduction and refinement. These forms are submitted to the CCD and ethically reviewed by an animal experiments committee (*Dierexperimentencommissie, DEC*), which advises the CCD accordingly. The DEC weighs the degree of animal discomfort caused by the procedures, and decides if this is proportional to the scientific and/or social benefits of the study. In other words, moderate or even severe discomfort must be accompanied by a significant scientific benefit, and/or a clear and large societal benefit. The CCD will decide whether or not to grant the permit after taking into consideration the ethical review by the DEC.

3.4 Performing animal research

The Experiments on Animals Act also describes the competence of persons who are permitted to carry out or supervise animal experiments. The Act prescribes that they must have taken preparatory training such as a master's degree in biomedical sciences, medicine or zoology and a compulsory 'Animal Science Course' complemented by an appropriate species-specific course. These researchers are referred to as 'Section 9 officers'. For further information, see the website of the Animal Welfare Body (AWB or *Instantie voor Dierenwelzijn, IvD*, see section 3.5).

The Act further states that the people who look after the animals and may also carry out experiments must be trained animal attendants and biotechnicians. Each institution that conducts animal experiments must have an AWB. The AWB ensures the well-being of laboratory animals by providing advice and training and by internal auditing of the researchers, experiments and animal facility. In order to limit animal discomfort, appropriate binding agreements are made between the researchers and the AWB regarding the experiments. These are documented in a work protocol for each study.



With regard to animal welfare, the Experiments on Animals Act requires that each institution licensed to conduct animal experiments has a designated veterinarian or another, sufficiently qualified 'Section 14 officer', formerly known as 'laboratory animal scientist specialist' (see the intranet pages of the AWB (IvD) at [location AMC](#) or the intranet pages of the [VU IvD for location VUmc](#)).

Amsterdam UMC has institutional licenses for animal experiments at both locations. Responsibility for legal enforcement of the Experiments on Animals Act within the institution rests with the license holders. The Act further states that the inspectorate ('Section 20 officer') is responsible for enforcing the legislation. Every year, each licensee (location AMC or location VUmc) sends the data on all animal experiments (number of animals, species, level of discomfort, etc.) to the inspectorate (*Nederlandse Voedsel- en Warenautoriteit, NVWA*). The inspectorate publishes an overview of all animal experiments in the Netherlands in its annual report (entitled '[Zo doende](#)').

3.5 Support

Information about the Animal Science Course in Amsterdam, to obtain a 'Section 9 certificate', can be found [here](#). For contact, please email cursuspdk@amc.nl or call 020-5661824.

For information about laboratory animals at location AMC, see the intranet pages on [Laboratory Animal Research](#).

For information about laboratory animals at location VUmc, see the website of the VU about [laboratory animals](#) or the [VU IvD intranetpages](#) (in Dutch). The VU IvD can be contacted via [email](#).



4 Dealing with human subjects involved in research

An absolute prerequisite for research involving human subjects—both patients and healthy volunteers—is that they are treated with respect, and have their health and rights protected. Researchers have a responsibility to ensure the well-being of research subjects and their voluntary participation in research. Moreover, researchers must be aware of the potential conflict between the interests of the research subjects and the interests of the research.

4.1 Regulatory framework

The interests of human subjects involved in medical research are protected by a number of (supplementary) laws, decrees, regulations, directives and codes of conduct ³. Applicable legislation depends on the specificities of the research (such as research using a medicinal product or medical device, trials with embryos, population screening, or research involving children or incapacitated subjects). A comprehensive list of all requirements for all types of research is presented on the website of the Central Committee on Research Involving Human Subjects (*Centrale Commissie Mensgebonden Onderzoek*; [CCMO](#)).

Currently, the main legislation governing clinical research conducted in the Netherlands is the Medical Research Involving Human Subjects Act (*Wet Medisch-wetenschappelijk Onderzoek met mensen*; [WMO](#)), which is based on the Nuremberg Code, the [Declaration of Helsinki](#) and the ICH Good Clinical Practice guideline ([ICH-GCP](#)). 'Medical research that includes subjecting persons to interventions or imposing a particular course of conduct upon them' is subject to the WMO. The main purpose of the WMO is to protect those who participate in medical scientific research while ensuring the integrity of research data. The WMO

³ For an overview of relevant laws, decrees, regulations and codes of conduct, see the website of the [CCMO](#) or the Appendix of the [VSNU, Netherlands Code of Conduct for Research Integrity, 2018](#), p. 28.



is designed to protect human subjects in various ways:

- Research must be as safe as possible for human research subjects and impose the least possible burden on them.
- Proposed research that falls under the WMO must be reviewed and approved for its compliance with medical, scientific and ethical standards (see section 4.2).
- The research subject must be provided with written information about the research (see [CCMO Template Subject Information](#)).
- An independent expert must be available to inform the research subject.
- Written consent must be obtained by research subjects before they participate in the research.
- Liability and clinical trial insurance must be taken out or arranged to cover any damage endured by the research subject.
- The law imposes additional requirements on research involving subjects under the age of 16 years, women who are pregnant or breast-feeding, and people who are not capable of giving informed consent (e.g. those suffering from dementia).
- Those carrying out the study must ensure that the privacy of the research subject is adequately protected.

The ultimate responsibility for medical research involving human subjects carried out at Amsterdam UMC lies with the executive board, and entails the implementation of systems, mechanisms and procedures for quality assurance and control at all stages of the research process. Amsterdam UMC adheres to the guideline [Kwaliteitsborging mensgebonden onderzoek 2020](#) (only available in Dutch), formulated by the Netherlands Federation of University Medical Centres (*Nederlandse Federatie van Universitaire Medische Centra*; NFU). This guideline defines the minimum requirements for WMO research in UMCs and focuses on the quality assurance of the research. In accordance with this guideline, Amsterdam UMC has described central policies and procedures on conducting scientific research involving human subjects in a Research policy ⁴. Dedicated [Research Support](#) teams are in place to help researchers comply with quality requirements.

Amsterdam UMC employees, interns and students are not allowed to participate as healthy volunteers or

⁴ The Research policy is accessible via the internal quality system K2.



patients in clinical research executed by their own department, due to the dependent relationship between the subject and (more senior) colleagues and/or department head. Exceptions are conceivable, for example when an employee is a patient who would otherwise be denied potential therapeutic benefit. These specific cases must be submitted to the Dean of the executive board for review, to make sure sufficient measures are taken (e.g. involvement of an independent physician) to assure the independence and voluntary participation of the employee, intern or student.

4.2 Types of research

Two types of research involving human subjects can be distinguished:

1. Scientific research that is subject to the Medical Research Involving Human Subjects Act (WMO research).

A study is subject to the WMO if both of the following criteria are met:

- It concerns medical scientific research, and
- Participants undergo procedures or are required to follow rules of behavior.

2. Scientific research with human participants that does not comply with one or both of the abovementioned criteria is not subject to the WMO (nWMO research).

The **CCMO** provides guidance to determine whether or not a study is subject to the WMO.

All proposals for WMO research to be carried out by Amsterdam UMC must be approved by an accredited independent medical research ethics committee (MREC). The accreditation of the MREC is granted by the competent authority. Both Amsterdam UMC locations have an accredited independent MREC; **METC AMC** and **METc VUmc**. In Amsterdam UMC, all investigator-initiated studies subject to the WMO must be monitored. The Clinical Monitoring Center (**location AMC** or **location VUmc**) can be consulted for monitoring services. After completion of a research study, the principal investigator has the ethical obligation to make the research results publicly available, irrespective of the study outcomes. For research involving a medicinal product, study sponsors are legally required to publish the results in the EU Clinical Trials Database (EudraCT) within one year after the end of a clinical trial.



nWMO research may concern retrospective analysis of data from patients' medical records as well as prospective research in which data is obtained from human subjects through direct interactions, such as use of questionnaires, without infringement of the physical and/or psychological integrity of the subject. To satisfy important legal and societal preconditions for nWMO research, Amsterdam UMC in principle assesses all nWMO research according to certain predefined ethical and legal criteria. This assessment is performed by a dedicated review board under the responsibility of the MREC. Applicable legislation and regulations include the Medical Treatment Contracts Act (*Wet Geneeskundige Behandelingsovereenkomst*; **WGBO**), General Data Protection Regulation (**GDPR** or **AVG** in Dutch), the **Code of Conduct for Responsible Use** and the **Code of Conduct for the Use of Data in Health Research**. The two Codes describe rules of conduct for care providers and researchers who wish to use patient material (biomaterials or data) ⁵.

For research involving human biomaterial, the following requirements apply. The collected biomaterial was either explicitly obtained for the purpose of research (de novo biobank or primary use), or obtained in the course of diagnosis or regular treatment ('further use'). De novo biobank research may be subject to the WMO. A specific legal framework is currently not available for the use of human tissue for medical research. The Ministry of VWS is currently preparing a Control over Body Materials Act (*Wet zeggenschap lichaamsmateriaal*; *WZL*) which will serve as a legal framework in the future. The executive board of Amsterdam UMC has developed a regulation to ensure that setting-up a biobank or conducting research with material from an existing biobank is reviewed for legal and ethical aspects in accordance with the Code of Conduct for Responsible Use. In accordance with this regulation, proposals to create a biobank and/or using materials from an existing biobank has to be submitted to the Biobank Review Committee (**BTC at location AMC** or **TcB at location VUmc**).

Research involving the processing of personal data is regulated by the GDPR. See also **Chapter 5 Research data management** on proper handling and organization of research data, ownership of data and data protection. The **Standard Operating Procedure (SOP) Reuse of care data** for the purpose of research describes the requirements for reuse of patient data for research purposes at Amsterdam UMC.

⁵ A new integrated version of these Codes is currently being prepared and is expected to take effect in 2021.



Personal data and biomaterial collected for scientific research at Amsterdam UMC could also be transferred to third parties in case of a research collaboration, provided that it is used in accordance with the original objectives. Obviously, all arrangements with third parties should also be in accordance with the applicable laws and regulations. See also [Chapter 8 Research collaboration agreements](#).

4.3 Training

All Amsterdam UMC clinical investigators performing research that is subject to the WMO are obliged to follow the e-learning module Basic course on Regulations and Organisation for Clinical investigators (*Basiscursus Regelgeving en Organisatie voor Klinisch onderzoekers*; **eBROK®**), provided by the NFU, which teaches researchers about the specific laws and regulations that govern research involving human subjects. Information about the eBROK® course and the Amsterdam UMC center-specific meetings are provided on the [intranet](#). Amsterdam UMC employees other than clinical researchers who are involved in clinical research (such as research nurses, data managers, students and study coordinators) are obliged to follow a Good Clinical Practice (GCP) course (for detailed information about the different GCP courses, see the intranet of [location AMC](#) or [location VUmc](#)).

4.4 Support

For the aspects discussed in this chapter, the following Amsterdam UMC support teams can be contacted for expert advice and support:

- MREC at [location AMC](#) or [location VUmc](#).
- [Clinical Monitoring Center](#).
- Biobank Review Committee at [location AMC](#) or [location VUmc](#).
- [Research data management department](#).
- [Privacy- or data protection officer](#)
- Legal research support department at [location AMC](#) or [location VUmc](#).

Furthermore, the [Research Roadmap](#) contains numerous useful guidelines related to various types of research involving human subjects.



5 Research data management

Management of research data is an integral part of the entire research process, from study design, data collection and data processing, to publication and archiving. Accurate research data management contributes to scientific quality, reproducibility and reuse of data. Modern scientific and IT technologies have transformed scientific practices and require increased attention to the privacy, integrity and transparency of research data.

Various national and international laws, disciplinary standards and ethical guidelines are applicable to the proper handling and organization of research data. The GDPR sets out general rules on how to process health and other data for scientific research. Furthermore, funding organizations and publishers have set conditions for the proper management of data, with some requiring that data be made available with the publication, to the extent possible. **The VSNU Code of Conduct for Research Integrity** emphasizes the importance of proper data management and promotes the implementation of the **FAIR data principles** to make research data Findable, Accessible, Interoperable and Reusable. These standards apply to any kind of research (for example, clinical studies, laboratory studies or qualitative research).

For more practical information about sustainable care of research data, the NFU Data4lifesciences program has developed the Handbook for Adequate Natural Data Stewardship (**HANDS**), with guidelines on data stewardship for UMCs. Based on the HANDS guidelines, Amsterdam UMC has developed the SOP Research data management which is accessible via intranet at **location AMC** or **location VUmc**.

5.1 Research data management

Research data management (RDM) starts with a data management plan (DMP), which is drawn up for each research project as part of the research protocol and is under the responsibility of the principal investigator. It



sets out how research data will be dealt with during and after the project. The DMP covers:

- Privacy and security safeguards.
- The type or types of data that will be generated and collected.
- The data collection software that will be used.
- Methods of data processing and analysis, to ensure traceability and reproducibility.
- Archiving and sharing of the data after the research project.

The data management process should be well documented in the DMP in order to create a FAIR data set, which makes the study verifiable and reproducible. A template for the Amsterdam UMC DMP (compliant with ZonMW requirements) is available on the intranet of [location AMC](#) or [location VUmc](#). The DMP is stored in the study file, together with other study documents such as the code book, procedures or protocols for data collection, data validation plan, data protection impact assessment (DPIA, see section 5.3) and statistical analysis plan.

The international Open Science movement aims to implement a new approach to conducting research based on cooperative work and sharing of knowledge. In this context, research data can be made accessible for reuse by third parties after publication. Amsterdam UMC encourages the reuse of data for future research by other groups. This reuse may be either unconditional or subject to conditions covering data protection issues, fair agreements about publication, or intellectual property (see also [Chapter 6 Authorship](#) or [Chapter 8 Research collaboration agreements](#)).

For more information (e.g. on research data capture tools, archiving and open data services) and support, including procedures and templates, see the Research data management department's intranet pages at [location AMC](#) or [location VUmc](#). For contact, email the [Research data management department](#).

5.2 Ownership of data

Data obtained in the process of research performed in Amsterdam UMC by one of its employees remains the



property of the employer, providing it is not personal or coded data. However, special agreements may have to be made in certain situations:

1. A research group can reach agreement about the sharing of data within the group during the study process. For example, the principal investigator might remain the primary owner until the original research question has been answered. Sharing of data can also result in shared authorship (see [Chapter 6 Authorship](#)).
2. If data are expected to be suitable for patents, they can be withheld from publication for an agreed period (see [Chapter 9 Valorization](#)).
3. When a researcher leaves the institution and is interested in preparing further publications based on the data gathered, agreement must be reached between this researcher and the principal investigator or the departmental head about the conditions under which this is acceptable.

Under Dutch law, there is no legal ownership of personal or coded data. Hence, in this case Amsterdam UMC serves as 'data custodian'. At all times, the rights of human research subjects with regard to protection of their personal data must be respected. Research participants have the right to be informed about the use of their data, to request access to their data, and to request rectification or erasure of these data. For example, participants should at all times be able to withdraw their consent for any future use of their data.

5.3 Data protection

Protection of the privacy of human subjects in scientific research is of utmost importance. All data that can be traced back to an individual are personal data. Also encrypted or coded data are personal as they can be traced back to individuals. The processing (collecting, using and retaining) of personal data for medical research is subject to the GDPR and the Medical Treatment Contracts Act (WGBO). Research involving human subjects involves explicit procedures for this purpose and must be submitted for ethical review (see [Chapter 4 Dealing with humans involved in research](#)). Amsterdam UMC keeps records of every occurrence of personal data processing, including research projects, in the Central Registration of Personal Data registers (see the intranet of [location AMC](#) or [location VUmc](#)).



Personal data can only be used by researchers if there is a sound legal reason to do so. Personal data may, in principle, only be used for research if the subjects have been fully informed and have actively given consent for the use of their data (see paragraph 10 of the [CCMO Template Subject Information](#)). Permission is also required if other researchers (at Amsterdam UMC or elsewhere) wish to use the data.

The use of personal data without the subject's consent is only permitted if the following grounds for an exception apply: it is not reasonably possible or desirable to obtain permission, the privacy of the subjects is guaranteed, and the subjects were informed in the past about the use of their data for scientific research and did not object to this use. The applicability of this exception has to be assessed by a dedicated review board under the responsibility of the MREC ⁶, as part of the process in which in principle all nWMO research is evaluated (see [Chapter 4 Dealing with humans involved in research](#)).

Another key requirement regarding data protection is that researchers can explain and justify the use of personal data. All variables to be used must be essential for answering the research question or questions. Data not strictly necessary for answering the research question or questions cannot be processed.

The privacy of subjects must be guaranteed during all phases of data handling. Before the start of every research project that will involve the processing of personal health data, a data protection impact assessment (DPIA) has to be conducted. This is a structured evaluation of the risks for data subjects and how to mitigate them. In Amsterdam UMC, DPIAs can be conducted in various ways; the evaluation can be done together with a privacy officer, a data protection officer or a legal officer from the Legal Research Support department, or the various aspects of the DPIA are incorporated into the assessment that is, in principle, performed for all nWMO research. For each research project, the following important aspects of the DPIA must be addressed: The infringement of a subject's privacy must be minimized. For instance, traceable data must not be used if coded data can be used.

Prior to data analysis, data must be converted into the least identifiable form without losing the analytical value of the data (for example the conversion of birth dates to ages).

⁶ Previously, this assessment was performed by the privacy officer or a legal officer of the Legal Research Support department at location AMC, and the executive committee (*dagelijks bestuur; db*) of the METc at location VUmc.



The whole process of data collection, processing, sharing and storage must be properly protected against loss, theft, and unauthorised viewing and use.

Data access authorizations must be limited to the staff members involved in the study, and are dependent on the phase of the research process.

After the study has been finalised, temporary files and other non-essential data must be destroyed, and the remaining essential data must be archived in a secure way.

Collaboration with third parties in data collection, management and storage requires data protection agreements between Amsterdam UMC and the third party. See [Chapter 8 Research collaboration agreements](#).

Organizational and technical measures taken by Amsterdam UMC alone are not sufficient to mitigate all privacy risks for research participants. The individual researchers have to make sure they are familiar with the laws, regulations (such as the [National Knowledge Safety Guidelines](#)) and local procedures and guidelines that are applicable to their research projects, including the data breach procedure.

5.4 Support

For further information, see the [SOP Reuse of Data](#). The [Research Roadmap](#) contains numerous useful guidelines related to handling of research data. If you have questions or need advice, please contact the [Research data management department](#), a legal officer of the Research Support Legal Research Support team at [location AMC](#), or the privacy- or data protection officer at [location AMC](#) or [location VUmc](#), respectively.



6 Authorship

Publishing is an essential way of presenting the results of scientific endeavors and discoveries to the outside world, thus contributing to the body of knowledge. Authorship is a researcher's main instrument to gain credit for scientific work. Because it has important academic, social, and financial implications, authorship must be assigned fairly and reported honestly. As authorship is often a contentious issue, Amsterdam UMC researchers and research groups are encouraged to discuss this topic and related cases with colleagues or at research meetings.

6.1 Authorship

Authorship is based on criteria included in the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals from the International Committee of Medical Journal Editors (ICMJE). Amsterdam UMC endorses these recommendations.

The ICMJE recommends that authorship be based on the following four criteria:

1. Substantial contributions to the conception **or** design of the work; **or** the acquisition, analysis, **or** interpretation of data for the work; **AND**
2. Drafting the work or revising it critically for important intellectual content; **AND**
3. Final approval of the version to be published; **AND**
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The Committee on Publication Ethics (**COPE**) provides useful information and tools (flowcharts, checklists, cases) on the subject of authorship and for managing potential disputes. Moreover, the American Psychological Association (**APA**) has an interesting tool to determine authorship and the order of author listing.



Further considerations and implications:

- The term 'authorship' refers to both sole or first authorship and co-authorship.
- All persons who fulfil the requirements for authorship should be offered authorship.
- All persons designated as authors should meet the criteria for authorship. Thus, an 'author' is generally someone who has made substantial intellectual contributions to a research publication. Not fulfilling or only partially fulfilling these requirements is not in line with research integrity standards. The 'senior' or supervising author (usually the study's principal investigator; PI) has to take responsibility for ensuring these requirements are met.
- An author must take responsibility for at least one component (with respect to content) of the work described and should be able to identify who is responsible for the other components. He/she should have no reason to doubt his/her co-authors' ability and integrity. Some journals request and publish information about the contribution of each person ('qualified authorship') named as having participated in a submitted study, at least for original research.
- Authorship is preferably agreed upon and documented in an early phase of the research project. Agreements about publications and authorship can be included in research collaboration agreements (see also **Chapter 8**). However, early agreements about authorship are provisional as contributions may change over time and therefore need to be discussed again. The study's PI must coordinate discussions about authorship. The bottom line is that all authors must meet the four ICMJE criteria cited above.

It follows from the foregoing that:

- Acquisition of funding, collection of data, or merely general supervision of the research group or department where the research took place does **not** justify authorship.
- Demanding or accepting an authorship for which one does not qualify (gift authorship or honorary authorship) is a breach of research integrity.
- Leaving out someone who does qualify as an author or not giving such a person the opportunity to qualify (e.g. by not asking for input on drafts of the article) is a breach of research integrity.



6.2 Types of authorship and other contributions

With respect to the author list, there are huge interdisciplinary differences in views regarding the acceptable numbers of authors and the significance of the various order positions. For the biomedical field, the following general guidance applies:

First author: it is customary for the researcher who did the majority of the work and prepared the first version of the manuscript to be listed as the first author. That will often be the PhD student or postdoc working on the research project. If the first and second authors contributed equally, this can be mentioned as shared first authorship in a footnote ('these authors contributed equally to this study').

Last author, also referred to as senior author: usually the researcher who is most broadly involved in the successive components of the project (conception and design, data acquisition, analysis and interpretation), and has taken on most responsibilities with respect to supervision of the first author or authors. As with the shared first author construction, shared last authorship ('joint last authorship') can be acknowledged in a footnote.

Corresponding author: the first or last author is usually the corresponding author. There might, however, be good reasons to assign this role to another author, for example if the first/last author will be leaving the group soon after publication.

Other authors: the remaining authors are listed in order of contribution. In some cases, however, the order is based on other principles (e.g. alphabetical order or balancing authors from different contributing disciplines or institutes). The order in which the authors are listed should be a joint decision, in which the last author ultimately decides after consulting all authors (see below).

Guarantors: some journals now also request that one or more authors, referred to as guarantors, be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information. This is usually combined with information on 'qualified authorship', in which all authors specify for which part of the publication they are responsible (while still fully meeting the criteria for authorship).

Group authorship: when a large, multicenter group has conducted or contributed to the work, the group



should identify those individuals who fully meet the criteria for authorship defined above, and accept direct responsibility for the manuscript. Such manuscripts may be published with these individuals as authors, or may be submitted with the group as author. In the latter case, the individual authors need to be listed as 'collaborators' under a separate heading. The intention to use group authorship instead of individual authorship should preferably be discussed in the early phase of the project.

In an acknowledgments section of a manuscript, contributors who do not meet the criteria for authorship may be listed as 'collaborators', 'clinical investigators' or 'participating investigators', with their title, function and specified contribution. Those included need to consent to being listed and for the way they are listed, by approving the final version of the manuscript.

Financial and other substantial material support for the project should always be mentioned in the acknowledgements or funding statements section. In the case of research that involves human participants, this requirement is laid down in the Medical Research Involving Human Subjects Act (*Wet Medisch-wetenschappelijk Onderzoek met Mensen*, **WMO**). These funding statements are complementary to the Conflict of Interest Disclosure Forms filled out by each author, as standard procedure for manuscript submission to a journal. This obligation of disclosure also applies to sponsorship of journal supplements in which authors publish original or review articles. Sponsors and parties with whom sponsorship has been agreed (authors, journal editors and others) have a mutual responsibility to disclose these potential conflicts of interest.

6.3 Professional considerations when preparing publications

Members of a research group involved in a joint research study must not prepare separate publications without the prior consent of the other members. Any proposal to use the results of a project for special publications (e.g. a thesis) not envisaged at the start of the project should be agreed upon by the research group as a whole. Finally, it is prudent to designate at the start of a research study a senior researcher (usually the study's PI) who will be responsible for resolving any possible conflicts regarding publication of the work.



7 Peer review of research proposals and manuscripts

Reviewing research proposals and manuscripts written by other researchers is an important aspect of a researcher's work. The principal investigator (PI) can teach young researchers how to review publications or projects, by including them in the review process. Moreover, various online training tools are available. For example, the Committee of Publication Ethics (**COPE**) provides useful information regarding the review process, including guidelines, podcasts and e-learning; the comprehensive **BMJ reviewer training package** is helpful; and the **EQUATOR** (Enhancing the QUALity and Transparency Of health Research) network lists a range of peer review training resources. A reviewer's opinion on submitted articles and grant applications can have serious consequences for the authors. It is important, therefore, that these appraisals demonstrate expertise, respect and lack of bias. Several aspects need to be considered.

Factual quality

- Start a review with a concise summary of the research question, design and main findings.
- When in doubt about aspects of the work, refrain from judgement or check with experts or the literature.
- Any criticism should be factually correct, based on scientific arguments and ideally supported by literature. Provide suggestions for change and make comments as specific as possible.
- Researchers should decline a peer review request if they lack sufficient expertise in this field.

Respect

- Authors deserve positive feedback in addition to criticism. Include strong points of the paper or project in your review comments, as well as limitations or weak points.
- The review should be constructive: suggestions for improvement are part of proper scientific conduct.



- If there are serious, fundamental shortcomings, refrain from further criticizing details and state clearly that these were not included in the review.
- The review process should not be delayed unnecessarily and reviewers should adhere to the timeline proposed by the editor. If this is not feasible, the invitation to review should be declined.

Integrity

- It is inappropriate to talk to outsiders about the content and/or quality of the reviewed work.
- Contacting the authors is undesirable. If necessary, this should be done through the organization requesting the review.
- Care should be taken when suggesting the inclusion of references to one's own work. Although perhaps merited, this should never be used to increase one's own citation rankings.
- If any form research misconduct is suspected, the reviewer should immediately inform the editor of the journal or the funding agency.
- A researcher should decline a request to review in the event of a conflict of interest. This could arise from any professional, personal, or financial relationship to the applicant. Such conflict also arises from being employed at the same institution as any of the authors, or having recently (i.e. within the past three years) been associated with any of the authors as a mentor, mentee, close collaborator or joint grant holder. For additional information, see the [Code for Dealing with Personal Interests](#) of the Dutch Research Council (NWO) and the [Committee on Publication Ethics \(COPE\)](#) website.
- Copying ideas from other researchers or taking ownership of other people's intellectual property (IP) is fraudulent. Peer reviewers of manuscripts or research project proposals have early access to other researchers' ideas and IP, and therefore must be especially scrupulous in this regard.



8 Research collaboration agreements

Amsterdam UMC researchers collaborate with a wide range of parties, including academic institutions, companies, local and national governmental agencies, charities, and the European Commission. These collaborations impose a responsibility to carefully weigh the obligations of Amsterdam UMC against the interests of the collaborating partners. The independence of the researchers and the research from the collaborating or funding party must be protected. In all collaborations with third parties, conflicts of interest should be avoided, and the general principles of research integrity, transparency and independence must be respected.

The **Dutch Code of Conduct for Research Integrity** provides the following guideline for good research practice with respect to collaborations. “Enter into joint research with a partner not affiliated with an institution which has adopted this or a comparable Code only if there is sufficient confidence that your own part of the research can be conducted in compliance with this Code and the joint research results meet generally accepted principles of integrity in research”.

For cross-boundary collaborative research, which can present extra challenges for the responsible conduct of research because of differences in legal systems, organization and culture, the **Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations** provides guidance. Particular attention should be paid to research collaborations with parties in low- and middle-income countries, to guard against ‘ethics dumping’—the practice of exporting unethical research practices to lower-income settings. The **Global Code of Conduct for Research in Resource-Poor Settings** aims to combat ‘ethics dumping’ and to achieve fair research partnerships in such settings.



Research collaboration agreements entered into by Amsterdam UMC include clear definitions of rights and responsibilities towards third parties, which can help us to uphold our commitment to the highest standards of research integrity.

8.1 Responsibilities regarding research collaboration agreements

For liability reasons, it is not the researchers themselves who enter into research collaboration agreements with third parties; all agreements have to be signed by the Amsterdam UMC executive board, or a delegate. The principal investigators (PIs) are responsible for the proper conduct of the research project. When considering collaborative research with third parties, researchers must ask themselves whether the proposed research can potentially help to advance medical knowledge. They must also verify with their supervisor and/or a legal expert of the Legal Research Support department that the project does not conflict with other legal commitments of Amsterdam UMC.

8.2 Ruling principles for research collaboration agreements

When research agreements with third parties are being prepared, the following principles should be adhered to:

1. Work plan The work plan is the most important part of the agreement. It is attached to the agreement as an appendix. The plan should contain a description of the scientific objectives of the project and the methods to be used, state what each partner will contribute, both separately and in collaboration, and describe when (parts of) the project should be completed.

2. Reasonable efforts Since the course of research is by its nature unpredictable and research results are inherently uncertain, Amsterdam UMC research is generally conducted on a reasonable efforts basis, performed at a standard that is consistent with research at UMCs.



3. Conflicting obligations Amsterdam UMC will not enter into research agreements that involve commitments and obligations that are in conflict with those accepted under other research agreements, and does not accept provisions that preclude the PI or the institution from performing research for or with other parties in related areas.

4. Publications It is essential to Amsterdam UMC that publication of scientific results is guaranteed, even if these results are negative or disprove the hypothesis. Therefore, publications may never be subject to final approval by the collaborating party. However, they may be subject to review by the collaborating party with respect to protection of that party's confidential information and intellectual property. Therefore, it is necessary to include in the collaboration agreement how a proposed publication may be amended and how long it may be delayed in order to accommodate the interests of the relevant parties. Delay should be for a reasonable period and in general not longer than 90 days from first submission to the reviewing party.

5. Intellectual property (IP) It is important to establish whether contracting partners require access to Amsterdam UMC's know-how, materials and/or IP rights, and, if so, under what conditions. Also, researchers must ensure that no IP right licensed to Amsterdam UMC by a third party—including materials obtained under a Material transfer agreement (MTA)—will be used outside the scope of its license or MTA without the third party's prior consent. Generally, Amsterdam UMC retains ownership of all inventions and discoveries arising from the conducted research, whether or not these are patentable. Amsterdam UMC may grant the other party a first right to negotiate a commercial license to use the results arising from the research under terms that are at arm's length and market-conform. See also [Chapter 9 Valorization](#).

6. Confidentiality Amsterdam UMC encourages open discussion and exchange of ideas. At times, however, it may be necessary to maintain the confidentiality of information. This will then be arranged in a confidentiality agreement (see for more information section 8.3).



7. Warranties, liability and risks Amsterdam UMC cannot accept penalty clauses or contractual/payment obligations that establish rigid deadlines or rigid deliverables. Research agreements will have appropriate provisions to limit Amsterdam UMC's liability.

8. Termination arrangements Arrangements on early termination of research projects have to reflect the parties' investments and efforts in the project, and assure payment for work already performed and uncancellable costs reasonably made.

9. Data protection If research collaborations involve third parties obtaining access to personal data, the rights and privacy of the respective subjects must be guaranteed. Data protection agreements are required, and they must specify how to protect the rights of data subjects, the allocation of data protection responsibilities, and the legal ground for processing the personal data (see section 8.3).

8.3 Types of research collaboration agreements

To give an overview of the various types of research agreements and associated considerations, the list below describes the most common types of agreements.

1. Research grant agreement Concerns funding for a specific research project or a certain research area. Research grants typically come from governments or charities, but industry can also provide research grant.

2. Collaborative research agreement Covers collaborative fundamental, experimental or applied research of mutual interest to Amsterdam UMC and the collaborator, which is usually performed by both parties. Each party may provide the other party access to its proprietary IP rights, materials, software or other valuable background IP for the performance of the project. Collaborative research projects may not always be conducted on the basis of (full or partial) cost recovery by the collaborator. Therefore, the IP is always subject to negotiation (see also [Chapter 9 Valorization](#)). If more than two parties are involved in the



collaboration, the agreement may also be called a consortium agreement; this can be a supplementary agreement in relation to a research grant agreement.

3. Sponsored research agreement Covers well-defined research of specific interest to the sponsor that is performed solely by Amsterdam UMC, usually at the sponsor's request. The sponsor usually drafts the project plan or protocol, and provides a financial contribution and/or access to the sponsor's proprietary IP rights, materials, software or other valuable background IP. Sponsored research projects are generally conducted on the basis of (at least) full cost recovery, including payment of indirect costs, at Amsterdam UMC's established rate and IP fees. Prepayment or early payment may be necessary, as Amsterdam UMC does not utilize its working capital to finance large expenditures incurred in the course of sponsored research.

4. Research service agreement (contract research) This agreement facilitates the performance of specialized services by Amsterdam UMC, using the institution's existing expertise and equipment. No further intellectual research efforts are required for the provision of these services. Research services are provided for a market-conform reimbursement value, as all results will be owned by the other party. If the service encompasses advisory activities only, this may be a consultancy agreement (see below).

5. Clinical trial agreement (CTA) In accordance with the ICH Good Clinical Practice guideline (**ICH-GCP**), a CTA specifies arrangements made between the sponsor/sponsors of a clinical trial and the investigators' institution or institutions regarding the allocation of tasks and obligations, and any financial matters. CTAs are important to allocate risks and responsibilities, and to protect academic, legal and intellectual property and integrity. CTAs must be submitted to the MREC for approval on the topics of publication and early termination. Various templates for CTAs, compliant with all laws and regulations and approved by the relevant organizations, are provided by the **CCMO**. For the general rules and regulations on clinical research, see also **Chapter 4 Dealing with human subjects involved in research**.



6. Consultancy/advisory agreement This is a contract under which advisory activities are provided by Amsterdam UMC employees to third parties (e.g. participation in an advisory board). Importantly, researchers providing consultancy to companies must not share novel ideas and inventions relating to their own research; they should only contribute their expert knowledge of their research field (current state of the art). See also [Chapter 11 Conflicts of interest](#) and the regulations in article 9.3 of the Collective Labor Agreement for University Medical Centers ([CAO UMC, 2018-2020](#)) regarding external employment or outside activities.

7. Material transfer agreement (MTA) This type of agreement defines the basis upon which parties transfer or obtain access to biological or chemical compounds or research tools. MTAs regulate the terms relating to material transfers, in particular terms regarding the purpose, ownership, liability, publications, and inventions. Body material from human subjects involved in research may be transferred to other parties under MTAs, provided that it is used in accordance with applicable laws and regulations. Transfer of body material to companies is generally not appropriate under an MTA; in most cases this requires a collaborative research agreement.

8. Data transfer agreement (DTA) Describes the basis upon which parties transfer or obtain access to personal data. These agreements regulate the terms relating to the purpose, data protection responsibilities, ownership, publications, and inventions.

9. Data processing agreement (DPA) This agreement is required when the research institution in its role as 'data controller' engages a third party (such as a hosting or database building service provider) to process personal data. At Amsterdam UMC, use of the [Template Data Processing Agreement of the BoZ](#) (*Brancheorganisaties Zorg*) is encouraged.

10. Confidentiality agreement (CDA, or non-disclosure agreements) A CDA is typically put in place in order to allow conversations exploring the possibility of entering into a research collaboration. This agreement obligates the parties to treat as confidential all information that should only be shared between



them, such as information regarding project proposals, budgets and IP matters. Inventions can only be patented if they are novel, i.e. not previously disclosed to any third party. Nevertheless, it may be necessary to share a not-yet patented invention with a third party during discussions about a potential collaboration. A CDA allows the invention to be shared without harming its novelty.

11. Visiting scientist agreement A visiting scientist agreement is intended to safeguard the IP rights and confidentiality with regard to information provided to temporary scientific staff and scientific trainees.

8.4 Support

For all aspects discussed in this chapter, the Legal Research Support department (**location AMC** or **location VUmc**) or **Innovation Exchange Amsterdam** (IXA)—the joint knowledge transfer office of HvA, UvA, VU and Amsterdam UMC (info@ixa.nl)—provide expert advice and support.



9 Valorization

Valorization is 'the creation of value from knowledge by making it appropriate or available for societal and economic use'. This chapter focuses on economic valorization, which entails the commercialization of academic knowledge, such as a new reagent, software, technique, application or machine. Through valorization, research findings can make meaningful contributions to innovations that advance society. Amsterdam UMC therefore values the valorization of knowledge, expertise and research results.

If valorization involves the use of body material or data obtained from human subjects, the rights and privacy of the respective subjects must be guaranteed (see [Chapter 4 Dealing with human subjects involved in research](#) and [Chapter 5 Research data management](#)). To ensure that the institution upholds its commitment to the highest standards of research integrity, Amsterdam UMC has organized valorization support for researchers through [Innovation Exchange Amsterdam](#) (IXA) and established IP regulations. The IP regulations are captured in the [Regeling Kennisexploitatie](#) (in Dutch). They are applicable to any person within Amsterdam UMC and include rules on remuneration for inventors. The IP regulations are in accordance with the basic rules for valorization formulated by the Dutch federation of university medical centers (NFU) in the guideline [Naar een goede waarde](#) (only available in Dutch).

The sections below describe basic information about the valorization processes that are typical for Amsterdam UMC.

9.1 Ownership of research results and intellectual property (IP) rights

To ensure that an invention retains commercial potential, protection of the invention is crucial. According to the Dutch Patent Act of 1995 ([Rijksoctrooiwet](#)), all research results and inventions – including data, computer software, apps, computer databases, prototype devices, and biological materials (cell lines,



plasmids, etc.) – developed by UMC employees are owned by the institution. In addition, the UMC owns the corresponding IP rights.

According to article 9.4 of the [CAO UMC, 2018-2020](#), employees are obliged to notify their employer of any potentially patentable invention produced or coproduced by them in connection with the performance of their job, and to do so at the earliest possible stage. If an inventor works for multiple employers, it may be the case that the invention is jointly owned. If a collaborative research project with a third party results in an invention, it is important that the parties have made specific arrangements about the ownership of IP at the start of the collaboration (see [Chapter 8 Research collaboration agreements](#)).

9.2 Protection of knowledge

Research results can be protected through various legal means, for instance through copyright, trademark or patents. Patents are the most relevant means of knowledge protection for research inventions, granting the owner exclusive rights for new products or processes. A patent consists of a set of claims that when granted by a sovereign state to an applicant can be used by the owner to prevent a third party from using or marketing the invention (or products/methods based on the invention) without permission. Patents provide this right for a limited period of time (20 years) in exchange for the public disclosure of an invention.

Bringing a new invention to the market is a costly and risky process. A patent allows a company the time for return on investment associated with the design, development and marketing of the innovation. Thus, a successfully filed patent can represent a great financial and social value if there is a market for the invention it describes.

Patentable inventions include novel products, processes, apparatuses, compositions of matter, and living organisms, or improvements to existing technology in these categories. Inventions must have an industrial applicability; abstract ideas, services, principles, and phenomena of nature cannot be patented.



Premature disclosure of knowledge in the form of articles and publications, conference presentations, or public discussions jeopardizes patent protection. Prior to any disclosure, it is therefore obligatory to verify whether knowledge protection is necessary. Once a patent application has been filed, the knowledge can be published in whatever form is preferred.

9.3 Valorization of research results

Patented inventions may lead to new products or processes for which commercial licenses can be granted to external parties. In some cases, further development of an invention in a spin-off company can be the preferred route to successful commercialization. New entities such as spin-off companies or foundations that make use of Amsterdam UMC knowledge, staff or resources, can only be set up with the approval of the executive board.

9.4 Support

For all aspects discussed in this chapter—advice on the publication of research results, patenting of inventions, management of IP, negotiating contracts with external parties, and setting up start-up companies based on Amsterdam UMC technologies—IXA should be involved (info@ixa.nl). In close collaboration with researchers, IXA ensures that the UMC's interests are safeguarded. See for more information the [IXA website](#), or contact IXA via [email](#).



10 Dealing with the media

10.1 Introduction

Biomedical research attracts ample attention from the media. Such interest has its advantages. Explaining research results publicly can make people aware of recent developments derived from science. It may also enable scientists and their institutions to justify the spending of public and private funds. Favourable reporting can speed up fundraising and, if sustained, give research institutions a reputation for solidity and expertise.

At the same time, there is a risk that information shared via the media may be too simplistic or too positive. Briefly communicating complex scientific messages to the general public is not easy and journalists prefer spectacular results. This may, for example, lead people to become overly optimistic about treatment possibilities, especially patients desperately hoping for an effective therapy.

The influence of third parties may compromise the full and unbiased sharing of scientific information. Pharmaceutical and biotechnology companies, suppliers of biomedical equipment and other parties in the private sector, may try to use scientific research results in their marketing, to generate and boost positive publicity for their products. In the public sector, leaders may want to marginalize or even suppress research results that are inconsistent with their political or policy goals. Charitable funds, which depend on political and societal support, may use the results of research they sponsor for their own profiling and branding. Patient organizations may depend on financial support from commercial companies that support their meetings or supply products for the patient group. Finally, the media themselves are not devoid of commercial self-interest. News may be related to acquisition and the possibility to earn advertising revenue. Even reputable journals like *The Lancet* or *Science* bombard the media with weekly press releases to uphold their authority.



Researchers, too, might be tempted to overstate their findings and the implications of these findings. Spectacular results get much more media attention, which can be a significant asset when applying for new grants, promotion or tenure. Furthermore, having some 'minutes of fame' can be a nice, ego-boosting experience and might substantially elevate your standing among family members, friends or colleagues.

Social media have a special role among media, as they offer opportunities to inform people in a more direct manner. This may be helpful for finding suitable participants for clinical studies, communicating interesting developments or stimulating a constructive scholarly debate. However, it also allows fake or biased information to spread widely and rapidly. News sites and blogs do not always respect the principles of fair journalism. On social media, where the dividing line between news and opinion is thin, the integrity of a researcher or institution can all too easily be called into question.

10.2 Recommendations

Researchers should carefully consider their contribution to public statements before these are released. The scientific independence of both the researcher and the institution can be compromised by:

- overly positive presentation of the study results;
- selective presentation of results;
- stretching the implications of the results beyond the scope of the study.

The following guidelines will help researchers to avoid publicity pitfalls. Special attention is paid to publicity in which industry plays a role.

1. Before scientists share their research outside scientific channels and/or have contact with the media (including social media) about this research, it is highly recommended that they consult with the Communication department of Amsterdam UMC. The independent nature of the research is then emphasized by the institution's seal of approval. What's more, the experience of seasoned communication



professionals can be a great support. In any case, it is crucial to require the right to review the text and correct any factual inaccuracies before it is published.

2. Examples of potential conflict of interest related to cooperation with commercial parties are:

- A symposium related to a thesis or major publication that is sponsored by and/or associated with publicity from a commercial party;
- Sending out press releases in an attempt to speed up the registration of a drug or facilitate the listing of a biotech company on the stock market;
- Lending equipment on the condition that favourable publicity is generated;
- Organizing a sponsored meeting about a new treatment, product, drug or therapy for media with expert opinion leaders. In the case of government-commissioned research, researchers frequently find that a commissioning ministry or municipal authority want to arrange publicity themselves. The independent status of their institution enables researchers to resist pressure from external parties. Again, researchers are strongly advised to consult the Communication department and, at least, demand the right to see and approve press releases before they are issued.

3. To avoid a potential conflict of interest, researchers are advised not to feature in media productions created by a company.

4. Openness regarding the funding of research is inherent to research integrity. Transparency prevents suspicion of conflict of interest. It is mandatory to acknowledge the important contribution of charities or other funding bodies.

5. Popularizing research results and raising expectations can involve risks. The media almost always gauge the importance of basic research in terms of potential clinical applications. If researchers allow themselves be led by exciting theoretical vistas rather than the precise significance of their findings, they may raise hopes of 'medical breakthroughs' that later fail to eventuate. When patients' expectations cannot be met, this



understandably leads to disappointment or even anger. Clarity is also needed regarding patients' access to a new test or drug.

6. Caution is needed when interim findings point to a successful outcome. The researcher may be tempted to release results prematurely to secure funding for follow-up research.

7. Researchers are advised to take the initiative when they expect media to be interested in their findings. An effective approach is to issue a press release or a statement via social media. This must be done with the permission and support of the Communication department.

8. Publicity about a study is most undesirable when a manuscript about that study has been submitted to a scientific journal but not yet published. Top journals, in particular, have strict rules in this respect, with sanctions that can include refusal to publish the article. Journals' regulations regarding the presentation of research at conferences or participation in promotional ceremonies prior to publication are not always clear. Again, the Communication department may be helpful.

9. When using a press release or advertisement to recruit trial subjects, take care to describe the trial conditions accurately. Transparency and accuracy are critical when it comes to describing the potential effects of the drug, especially in trials involving patients. Potential participants must be informed about possible side effects and uncomfortable tests, as well as the likelihood of being assigned to a placebo group. The information given must correspond completely with the research protocol. In the case of multicentre trials not coordinated by the institution, the researcher is still responsible for what is asked from their patients. The medical research ethics committee must review and approve the text before it is used.

10. Publishing in commercial media, such as editorials funded by pharmaceutical companies, is prohibited. These publications may not fall under the responsibility of the editor-in-chief and can be considered as advertisements.



10.3 Support

Situations relating to integrity and conflict of interest differ widely, as do the kinds of media. The Communication department can provide support if further questions about publicity arise. The professionals from this department can not only recommend whether and when a media interview or presentation is likely to be beneficial, but also advise researchers on what to do, what not to do, and how to get their message across most effectively.

For location AMC, the Communication department can be contacted by **email** or telephone (020–566 2421 during office hours and 020–566 9111 outside office hours through the switchboard). For location VUmc, the Communication department can be contacted by **email** or telephone (020–444 3444 during office hours or 020–444 4330 outside office hours through the switchboard).

For further information, the following guidelines (in Dutch) can be consulted:

NFU **Richtlijn Gunstbetoon door bedrijven.**

External professional activities (intranet links):

AMC **Richtlijn nevenwerkzaamheden.**

VUmc **Regeling nevenwerkzaamheden.**

Media (intranet links):

VUmc **Regeling omgaan met de media.**

Amsterdam UMC **Social media beleid** (via VUmc intranet).



11 Conflicts of interest

Conflicts of interest occur when researchers or their institutions have financial or personal ties with other persons or organizations that influence their work or the way it is presented. Financial relationships, such as an employment or consultancy relationship, or stock ownership, are among the most obvious reasons for a conflict of interest. In addition, intellectual passion, dependence on external funding, academic competition, and the interests that funding bodies may have in scientific research can jeopardize a researcher's independence. Lack of independence can result in substandard science, damage the reputation of the researcher and the research group or institution, and ultimately even negatively affect patient care.

Because some conflicts of interest (particularly those of a non-financial nature) are intrinsic to research, they can never be completely avoided. That is all the more reason to report conflicts of interest as fully and transparently as possible. That will allow peer reviewers, editors, readers or the general public to judge the credibility and plausibility of researchers' statements against the background of reported conflicts of interest.

11.1 Causes of conflicts of interest

Two situations that may lead to conflicts of interest are external professional activities and collaboration with commercial parties. They are briefly described below:

External professional activities Amsterdam UMC is generally supportive of its researchers having additional professional responsibilities elsewhere (*nevenfuncties*), as these external activities often support their scientific work and strengthen the institutions engagement with society. External professional activities, whether remunerated or not, are only permitted when they are compatible with the employee's responsibilities at Amsterdam UMC and do not interfere with the interest or reputation of Amsterdam UMC. Article 9.3 of the Collective Labor Agreement for university medical centers (**CAO UMC, 2022-2023**) contains clear guidelines for employees who are considering external professional activities ('outside activities'). These



guidelines state that external activities must be reported to the employer if they could potentially give rise to conflicts of interest, and that it may be necessary to obtain explicit approval from the executive board for external activities. The guidelines also cover payment for such activities.

Collaboration with funding parties Amsterdam UMC values collaboration with third parties, provided this is conducted in accordance with institutional policies (see **Chapter 8 Research collaboration agreements**). Moreover, Amsterdam UMC advocates that, whenever feasible, research results should be rapidly converted into new diagnostic and therapeutic tools in order to allow patients or society to benefit from innovations. This usually requires collaboration with (commercial or non-commercial) funding parties (see **Chapter 9 Valorization**). However, a relationship with an external funding party may make researchers vulnerable to conflicts of interest. Therefore, funding bodies may demand disclosure of potential conflicts of interest from researchers applying for grants. Collaboration with funding parties must not cast doubt on the independence of the researchers or research performed at Amsterdam UMC. The arrangements that can be made to safeguard researchers' independence and publish the results of research collaborations with external funding bodies or commercial partners are described in **Chapter 8**.

Besides these two situations, conflicts of interest can have numerous other causes. A few other examples, originally provided by the **Association of American Medical Colleges**, are:

- Undertaking research when the researcher or the researcher's immediate family has a financial, managerial or ownership interest in the sponsoring company or in the company producing the drug/device under evaluation.
- Accepting gratuities or special favors from research sponsors ^{7 8}.
- Unreimbursed or unauthorized use of institutional resources (e.g. equipment, supplies or facilities) for personal purposes or to support the activities of an independent entity in which a researcher holds a financial or other interest.
- Accepting support for research under terms and conditions that require results to be kept confidential, unpublished or significantly delayed in publication.

⁷ See NFU Guideline **Richtlijn Gunstbetoon door bedrijven**, 2010.

⁸ Regarding relationships with pharmaceutical and medical device companies, the **Code of Conduct for Pharmaceutical Advertising** (*Code genesmiddelenreclame*) and the Code of **Conduct regarding Medical Devices** (*Gedragcode Medische Hulpmiddelen*) also need to be taken into account.



- Requiring or recommending a product, such as a medicinal product, diagnostic test or a textbook, in which one has interest. In such cases an independent advice should be asked for.

11.2 Procedures for reporting potential conflicts of interest

Amsterdam UMC endorses the VSNU regulation for external professional activities (**Sectorale regeling nevenwerkzaamheden**); the **Code for the prevention of improper influence due to conflicts of interest**, drawn up by the Royal Netherlands Academy of Arts and Sciences (KNAW) and other parties in 2012 and updated in 2016; as well as the Valorization guideline **Naar een goede waarde** (in Dutch), issued by the Netherlands Federation of University Medical Centres. The following procedures to handle potential conflicts of interest have been established:

Transparency of activities Employees should report any external professional activities that might lead to conflicts of interest their departmental or division head, as well as to HR. Guidelines and policies on external professional activities are published on the intranet of **location AMC** or **location VUmc** (in Dutch). Relevant external professional activities are disclosed on the website of **location AMC** and **location VUmc**. Furthermore, the financial relationships between UMC health care providers and commercial parties can be consulted in the Healthcare **Transparency Register**. Potential conflicts of interest must also be discussed during the annual performance appraisal interview between the employee and their head of department or division. Although disclosure itself does not eliminate bias or conflicts of interest, it can make financial relationships widely known and be used as a starting point for asking questions.

Report of potential cases Researchers are required to report immediately to the business manager of their division (*directeur bedrijfsvoering*) if they believe they might be caught up in a conflict of interest or are exposed to potentially conflicting interests outside the institution. The business manager will inform the head of the department of all such notifications. The notification may be discussed with the legal advisor to the executive board, if appropriate. The executive board may decide to publish notifications. Both the notification and any approval granted by the executive board are recorded in the employee's personnel file.



12 Research misconduct: bad practices, prevention and dealing with suspected violations

12.1 Introduction

A lack of integrity in research may lead to research misconduct, which has important negative consequences. First, presentation of invalid scientific results undermines scientific progress. Second, research misconduct in biomedical studies compromises the trust that patients, research organizations and society have in research methods and results. Third, such misconduct can damage patients' health and healthcare in general. Fourth, fellow scientists need to be confident of the absence of misconduct to enable collaboration and to use or build on the research findings of others. Also, institutions must be sure that research conducted in their name is worthy of dissemination, support and grants. Finally, research misconduct can have serious consequences for the individual researcher committing it. Although their embellished output may attract increased funding and boost their reputation in the short term, the long-term consequences can be disastrous.

The executive board of Amsterdam UMC aims to prevent research misconduct and correct any cases that occur. In this chapter, we explain more extensively what research misconduct entails, what can be done to prevent it and how to proceed if you suspect violations of good scientific conduct.

12.2 Types of research misconduct

The [VSNU Code of Conduct for Research Integrity](#) describes research integrity and misconduct. Research



misconduct may take many forms. The clearest and most serious forms of misconduct, as defined in the VSNU Code, are:

- 1. Fabrication** – making up data or results and documenting them as if they were real.
- 2. Falsification** – manipulating research material, apparatus or processes to change, withhold or omit data or research results without justification.
- 3. Plagiarism** – appropriating other people’s ideas, methods, results or texts without giving proper credit.

The VSNU Code lists 61 standards of research integrity. Violations of these standards are not necessarily criminal or malicious acts: they may be subtle failings that could apply to any researcher. Indeed, all researchers should be alert to the risk of questionable research practices (QRPs) and vigilant about avoiding them. The standards formulated in the VSNU Code lay the basis for judging the integrity of research conduct and determining sanctions for misconduct. Examples of misconduct include:

In the study design phase:

- Not being transparent about the parties commissioning or funding the research.
- Not reporting the role of external stakeholders and potential conflicts of interest.
- Agreeing to do research that should not be conducted, according to the Code.

In the research phase:

- Basing the choice of research methods on non-scientific interests or preferences.
- Not ensuring that all sources of information are verifiable.
- Not describing the data used honestly, scrupulously and transparently.

In the reporting phase:

- Not enabling all authors to review and approve the final version of the research publication.
- Not being explicit about any relevant data that are not reported.
- Not being transparent about uncertainties and contraindications.
- Not providing references for all previously published data used in the analysis.
- Withholding information about external stakeholders.
- Not publishing data when that would have been possible.



Regarding assessment and peer review:

- Using information acquired when assessing other researchers' work, without their consent.
- Assessing other researchers' work when doubts could arise about your independence.

Communication:

- Being dishonest, not being clear about the limitations of the research, and/or reporting research results to the public prematurely.
- Not mentioning potential conflicts of interest.

In all phases of research:

- As a research supervisor or director, taking any action that might encourage a researcher to violate research integrity.
- Delaying the work of other researchers to gain unfair advantage.
- Deliberately making a false accusation of research misconduct.
- Not sufficiently investigating claims of misconduct for political/reputational reasons.

12.3 Preventing research misconduct

As mentioned in the introduction of our Amsterdam UMC Code, the basic premises of research integrity are honesty, carefulness, transparency, independence and responsibility (see [VSNU Code of Conduct for Research Integrity](#)). Although research misconduct can never be ruled out, it is important to take preventive measures and create a culture that both stimulates research integrity and minimizes the risk of research misconduct. Many preventive measures are presented in earlier chapters of the Research Code.

Institutions have the duty to provide a working environment that promotes and safeguards good research practices. These duties of care include 1) training and supervision, 2) fostering a research culture promoting integrity, 3) proper data management, 4) stimulating fair communication and dissemination of research, 5) establishing and safeguarding ethical norms and procedures. These duties are defined in Chapter 4 of the VSNU Code of Conduct for Research Integrity. Here we focus on activities at the level of the individual and his/her working environment. Moreover, specific attention is paid to the prevention of plagiarism.



12.3.1 The individual researcher

Responsibility Each researcher should be aware of the high standards required for performing scientific research and know the VSNU Code of Conduct for Research Integrity. Individual researchers are ultimately responsible and accountable for their own behavior as scientists (see also [KNAW advisory report, Responsible research data management and the prevention of scientific misconduct, 2012](#)). A researcher should keep in mind that all of his/her actions should be open to scrutiny and discussion. In fact, as soon as you feel inclined to conceal certain aspects of your work, you should ask yourself why and discuss the issue with your supervisor or colleagues. If you don't feel safe to do so, you may contact the confidential counsellors focusing on research integrity (see section 12.4.1).

Transparency Precise documentation of data, research progress and decisions is crucial to ensure that the work can be understood, verified and reproduced by others. Data and lab notebooks are the institution's property and should therefore be stored in a safe and transparent manner in accordance with the regulations described in this Code (see also [Chapter 3 Dealing with laboratory animals](#), [Chapter 4 Dealing with human subjects](#), and [Chapter 5 Research data management](#)). Research supervisors should make sure that everyone involved in a research project is aware of the importance of collecting and storing data according to protocol.

Open discussion Research is not an isolated activity: it is always important to seek feedback from and collaborate with other researchers. This allows any doubts to be resolved and questionable conduct to be prevented more easily. Discuss dilemmas with peers and supervisors: the ultimate aim is not winning a competition but contributing to the progress of reliable science (see also [Chapter 1 Expectations regarding supervisors and early-career researchers](#)).

12.3.2 The department or research group

A culture in which the importance of research integrity is evident and explicitly discussed will foster the right mind set and minimize the risk of research misconduct. Heads of departments, research group leaders, supervisors and senior researchers in general are responsible for creating a culture where good science



flourishes. According to the VSNU Code of Conduct for Research Integrity, two prerequisites are: a safe environment for open discussion and continuous attention to good research practices.

Research leaders should:

- Raise awareness of research integrity through education and training of early-career researchers, support staff and team leaders.
- Ensure that relevant scientific regulations, guidelines and instructions are understood and followed.
- Implement appropriate measures to prevent non-adherence to standards. The quality of supervision and the composition of doctoral examination committees is important in this regard. Regular audits of studies conducted within a research group may help to prevent errors, questionable research practices (QRPs) and research misconduct.
- Encourage collaboration among researchers by organizing project teams to perform the research. The team should work as a unit to decide how data will be collected, assessed and interpreted, and how results will be reported. Regular checks of one another's work reduce the risk of errors and fraud, as isolated individuals may be more prone to research misconduct. This also applies to reporting: proper supervision and feedback prevent plagiarism and various forms of data manipulation.
- Organize regular reporting and discussion sessions within the research group and, where applicable, with external experts. Research projects conducted by larger research groups and consortia have a steering committee in addition to the project team. Again, the risk of errors and fraud is reduced if the progress of the project is presented to, and discussed with, the steering committee regularly.
- Create a safe environment where scientists feel free to discuss dilemmas and possible errors, without fearing negative reactions or sanctions. More early-career researchers, in particular, may need encouragement to ask questions or express their doubts and concerns.



12.3.3 Preventing plagiarism

Researchers are constantly building on the work of predecessors. Along with the more general preventive measures for research groups and individual researchers described above, avoiding plagiarism warrants specific attention. Giving credit to the use made of other people's ideas, methods, results or texts is necessary in terms of integrity and honesty. Authors risk being guilty of plagiarism if they neglect to provide proper references. The following rules help to avoid problems.

- Provide references when a theory, methods, results or text are taken from elsewhere.
- References should be presented accurately. Different instructions are given in different fields of science (for examples, see [APA](#) and [Vancouver](#) referencing guides).
- Refer to the article or book in which the theory or other text was first published. Mistakes are often made when referring to secondary references. Authors are expected to know all references they use. However, citing review articles is acceptable.
- Indicate clearly in the text when you are quoting literally and where each quote begins and ends.
- Quotes from one's own previously published text, should also be referenced and put between quotation marks. Note that extensive citing of one's own text may be seen as undesirable and 'self plagiarism'.
- Too many, possibly unnecessary, references can make a text unreadable, and including large numbers of self-citations to increase one's citation ranking is particularly annoying.

12.4 Dealing with suspected violations of research misconduct

While prevention of research misconduct should be the priority, any suspected misconduct must, obviously, be investigated. The principles underlying such investigation are based on the [VSNU Code of Conduct for Research Integrity](#) and the standards it describes, as well as the [ALLEA European Code of Conduct for Research Integrity](#). Responsibility for addressing questions or complaints regarding research integrity lies with confidential counsellors and/or the university committees established for this purpose. For more information, see the [Academic Integrity Complaints Regulations of UvA](#) and the [Academic Integrity Complaints Procedure of VU-VUmc](#) ⁹, which apply to AMC and VUmc employees, respectively.

⁹ 'In the event of any discrepancies between this Research Code and the UvA regulations or VU-VUmc procedure, the guidelines of the relevant university should be followed.'



12.4.1 Confidential counsellors

Amsterdam UMC has confidential counsellors focusing on research integrity ¹⁰. The essential criteria for this role include a firm scientific background, an impeccable reputation and the ability to deal with difficult, complex situations. The confidential counsellors work independently from the executive board.

Any employee or external party involved in research at Amsterdam UMC who has a question about research integrity, suspects research misconduct, or has been accused of such misconduct, can discuss this with the confidential counsellors. They are easily accessible in the institution. They can give advice about any question regarding research integrity, including whether or not to file a complaint. They can also mediate if needed and wanted, and they can support the submission of a formal complaint to the research integrity committee (see section 12.4.2). Given the confidential nature of their role, they will not share the information discussed with anyone else unless the person reporting the possible research misconduct gives them explicit permission to do so.

12.4.2 Research integrity committees

Universities hold responsibility for research done in their institution, including the medical faculties. Consequently, the executive boards of the **UvA** and **VU** have established committees for research integrity which handle complaints ¹¹.

These committees consist of a chairperson and at least two other members, preferably from different scientific disciplines. The committee can, if needed, invite other persons to support its judgement in areas of specific expertise.

The committee first decides whether a complaint is admissible – that is, whether the complainant has provided sufficient grounds for further consideration. If so, the committee will decide whether the behavior reported by the complainant amounts to research misconduct, based on the Dutch code of conduct mentioned earlier. The committee can gather information from all relevant employees and bodies of the

¹⁰ Prof. Ed van Bavel and Prof. Jan Heimans are the research integrity confidential counsellors for location AMC and VUmc, respectively. Employees from one Amsterdam UMC location can consult a confidential counsellor from the other location, or from another faculty of the university to which they are affiliated, if they prefer.

¹¹ Complaints should be submitted to the university to which the defendant is affiliated (for AMC employees, UvA and for VUmc employees, VU). Complaints should be submitted directly to the research integrity committee of **UvA**, or to the executive board of the **VU**. It is strongly recommended to seek guidance from a confidential counsellor before submitting a complaint.



institution, and consult with internal or external experts or third parties before making its assessment. On the basis of this assessment, the committee issues an advice to the university's executive board, which issues its own initial judgement based on this advice, and informs the complainant and defendant accordingly. This initial judgement becomes final six weeks later, unless the complainant or defendant has requested a second opinion from the Netherlands Board on Research Integrity (**LOWI**). If a second opinion has been requested, the executive board takes that into consideration in its final judgement.

12.4.3 Additional remarks

- An anonymous complaint of alleged research misconduct will be considered only if there are compelling reasons to do so and the factual basis for the complaint can be investigated without input from the complainant. The UvA recommends that a person who wishes to submit an anonymous complaint first seeks guidance from a confidential counsellor; such guidance is mandatory according to the VU-VUmc procedure.
- If complainants feel that they are being treated unfairly, they can take action in accordance with the Amsterdam UMC Whistleblowing Procedure ¹². For example, initiating a complaint of research misconduct may not cause financial or contractual repercussions for the whistle blower.
- All Amsterdam UMC employees are obliged to cooperate with investigations into research integrity.
- The Amsterdam UMC guidelines for handling suspected cases of data fabrication or falsification are described separately ¹³.

¹² See intranet pages of **location AMC** or the document *Klokkenluiders: regeling VUmc*, accessible via the internal quality system K2 (document ID 045239), for location VUmc.

¹³ See **Aanpak en aandachtspunten bij vermoeden en/of vaststellen van falsificatie / fabricatie van data of onderzoeksresultaten** (in Dutch).



Abbreviation list

APA	American Psychological Association	EQUATOR	Enhancing the QUALity and Transparency Of health Research
AVG	see GDPR (<i>Algemene Verordening Gegevensbescherming</i>)	EU	European Union
AWB	Animal Welfare Body	FAIR	Findable, Accessible, Interoperable and Reusable
ALLEA	All European Academies	GCP	Good Clinical Practice
BROK	Basic course on Regulations and Organization for Clinical investigators (<i>Basiscursus Regelgeving en Organisatie voor Klinisch onderzoekers</i>)	GDPR	General Data Protection Regulation
BTC	Biobank Review Committee (<i>Biobank Toetsings Commissie</i>)	GLP	Good Laboratory Practice
CAO	Collective Labor Agreement (<i>Collectieve Arbeidsovereenkomst</i>)	HANDS	Handbook for Adequate Natural Data Stewardship
CCD	Central Committee on Animal Experiments (<i>Centrale Commissie Dierproeven</i>)	ICH	International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
CCMO	Central Committee on Research Involving Human Subjects (<i>Centrale Commissie Mensgebonden Onderzoek</i>)	ICMJE	International Committee of Medical Journal Editors
CDA	Confidentiality agreement	IP	Intellectual property
COPE	Committee on Publication Ethics	IT	Information Technology
CTA	Clinical trial agreement	IvD	see AWB (<i>Instantie voor Dierenwelzijn</i>)
DEC	Animal Experiments Committee (<i>Dierexperimentencommissie</i>)	IXA	Innovation Exchange Amsterdam
DMP	Data Management Plan	KNAW	Royal Netherlands Academy of Arts and Sciences (<i>Koninklijke Nederlandse Akademie van Wetenschappen</i>)
DPA	Data processing agreement	LOWI	Netherlands Board on Research Integrity (<i>Landelijk Orgaan Wetenschappelijke Integriteit</i>)
DPIA	Data protection impact assessment	MD	Medical doctor
DTA	Data transfer agreement	MREC	Medical Research Ethics Committee (<i>Medisch-Ethische Toetsingscommissie; METC/METc</i>)



MTA	Material transfer agreement
NFU	Netherlands Federation of University Medical Centres <i>(Nederlandse Federatie van Universitaire Medische Centra)</i>
NVWA	Netherlands Food and Consumer Product Safety Authority <i>(Nederlandse Voedsel- en Warenautoriteit)</i>
NWO	Dutch Research Council <i>(Nederlandse Organisatie voor Wetenschappelijk Onderzoek)</i>
PhD	Doctor of philosophy
PI	Principal investigator
QRP	Questionable research practice
RDM	Research data management
SOP	Standard Operating Procedure
TcB	Biobank Review Committee <i>(Toetsingscommissie Biobank)</i>
UMC	University Medical Center
VSNU	Association of Universities of the Netherlands <i>(Vereniging van [Samenwerkende Nederlandse] Universiteiten)</i>
VWS	Ministry of Health, Welfare and Sport <i>(Volksgezondheid, Welzijn en Sport)</i>
WGBO	Medical Treatment Contracts Act <i>(Wet Geneeskundige Behandelingsovereenkomst)</i>
WMO	Medical Research Involving Human Subjects Act <i>(Wet Medisch-wetenschappelijk Onderzoek met mensen)</i>
WZL	Control over Body Materials Act <i>(Wet zeggenschap lichaamsmateriaal)</i>

Acknowledgements

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We extend special thanks to Hanneke de Haes, who played a leading role in the development of the Research Code. Very sadly, she passed away suddenly shortly before the publication of this document.

We are grateful to Lex Bouter, Marij Hillen and Louis Ates for their critical review of the draft text and constructive comments, which substantially improved the contents.

We thank Nienke Dijkers for her valuable contributions, and Jessika van Kammen, Miriam van Strien, Janine Stolwijk, Marlies Stouthard, Ed van Bavel, Henriette Griffioen, Leonie van Rijt, Selma Camic, Rudy Scholte, Karien Stronks, Yvo Smulders, Jan Hol, Joris Bod, Simone van der Heijden, Zsofia Ottoway, Jeroen van Leur, Désirée de Lange, Joris Heus, Nicole Burger and Yvonne Donselaar for their insightful input.

Translation and editing:

Andrea Dingemans Communications BV

Lay-out and design:

Bibo Expression Amsterdam

This Amsterdam UMC Research Code replaces the AMC-VUmc Research Code in place.

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