Research Code
University Medical Center Groningen

Basic principles for medical scientific research. Procedure for the reporting of violations and suspected violations of academic integrity.

May 2018
University Medical Center Groningen Research Code

Basic principles for medical scientific research
Procedure for the reporting of violations and suspected violations of academic integrity
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List of abbreviations

AP  Autoriteit Persoonsgegevens: Dutch Data Protection Authority
BROK  Basiscursus Regelgeving en Organisatie voor Klinische onderzoekers: Basic Training in the Regulations and Organization of Clinical Research
CCD  Centrale Commissie Dierproeven: Animal Experiments Committee
CCMO  Centrale Commissie Mensgebonden Onderzoek: Central Committee on Research Involving Human Subjects
CRAZ  CliëntenRaad Academische Ziekenhuizen: Client Board of University Hospitals
CTc  Centrale ethische Toetsingscommissie: Central ethics Review Board
CWI  Commissie Wetenschappelijke Integriteit: Committee for Academic Integrity
DEC  DierExperimenten Commissie: Committee for Experiments with Animals
FAIR data  Findable, Accessible, Interoperable and Reusable data
GDPR  General Data Protection Regulation
GSMS  Graduate School of Medical Sciences
ICMJE  International Committee of Medical Journal Editors
IvD  Instantie voor Dierenwelzijn: Animal Welfare Body
KNAW  Koninklijke Nederlandse Akademie van Wetenschappen: Royal Netherlands Academy of Arts and Sciences
LOWI  Landelijk Orgaan Wetenschappelijke Integriteit: National Board for Research Integrity
LTc  Lokale ethische Toetsingscommissie: Local ethics Review Board
METc UMCG  Medische Ethische Toetsingscommissie van het UMCG: UMCG Medical Ethics Review Board
NFU  Nederlandse Federatie van Universitair Medische Centra: Netherlands Federation of University Medical Centres
nWMO  non-WMO
NWO  Nederlandse organisatie voor Wetenschappelijk Onderzoek: Netherlands Organisation for Scientific Research
O&O-raad  Onderzoek- en Onderwijsraad: Research and Education Council
PIA  Privacy Impact Assessment
PWO  Privacy Werkorganisatie: Privacy Task Force
RDMP  Research Data Management Plan
UG  University of Groningen
RvB  Raad van Bestuur: the UMCG Board of Directors
SD-CRO  Service Desk - Clinical Research Office
TTP  Trusted Third Party
UAVG  Uitvoeringswet Algemene Verordening Gegevensbescherming: Dutch Implementation Act of the General Data Protection Regulation
UMCG  University Medical Center Groningen
VSNU  Vereniging van Universiteiten: Association of Universities in the Netherlands
Wet BIG  Wet Beroepen in de Individuele Gezondheidszorg: Individual Healthcare Professionals Act
WGBO  Wet op de Geneeskundige Behandelingsovereenkomst: Agreement on Medical Treatment Act
WMO  Wet medisch wetenschappelijk onderzoek met mensen: Medical Research Involving Human Subjects Act
Wod  Wet op de dierproeven; Experiments on Animals Act
Colophon

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Foreword

We are delighted to present the fully revised UMCG Research Code. Although it is not a document that immediately appeals to all, we kindly ask you to take some time to read it. As a researcher you will undoubtedly recognize a lot of the situations described here.

This code is important for everyone who conducts research within the UMCG, from student to professor, as well as for all UMCG staff members who conduct research elsewhere in the world. Rather than functioning as a code of law with articles, a Research Code provides frameworks for how we should behave when conducting research. The UMCG endorses the six important principles that determine good research practice: Honesty & Scrupulousness; Reliability; Verifiability; Impartiality; Independence; Responsibility. Even though they may seem trivial at first sight, every researcher in fact regularly encounters dilemmas that require evaluation in the light of these principles.

We are all jointly responsible for creating an academic climate in which such evaluations are made whenever the situation requires them, and in which everyone feels safe to openly discuss dilemmas with colleagues. In a time when the reliability of science is being closely scrutinised, each and every researcher must be as incorruptible as possible and treat academic integrity as a top priority. This will enable us to maintain the high quality of our work and embody our firm belief that progress and social wellbeing require good research.

Marian Joëls, Dean of the UMCG
Groningen, May 2018
1 Background & aim

All UMCG employees performing research within or on behalf of the UMCG have the responsibility and duty to do so with integrity and in accordance with the current norms, and to prevent and signal behaviour that transgresses safety regulations or the boundaries of academic integrity. The UMCG has therefore laid down the basic principles of medical research in the UMCG Research Code.

1.1 Starting date

The UMCG Research Code 2018 will replace the 2013 version of the Code as of 1 May 2018. This implies that all reports processed after 1 May 2018 will be subject to the UMCG Research Code 2018.

1.2 Scope of applicability

The UMCG Research Code applies to all individuals performing research within the UMCG as well as UMCG staff involved in medical research elsewhere. The Code also applies to students, visiting staff and scholarship PhD students, even though they are not employed by the UMCG. Furthermore, the Code may be useful for third parties, such as commissioning parties, funding bodies, politicians, and societal and patient organizations, as it gives them insight into the basic principles stipulated by the UMCG for its scientific research. The latest version of the UMCG Research Code is available on the website of the UMCG (search term ‘research code’).

In addition to the Research Code, UMCG staff are also expected to comply with several other regulations, such as the Collective Labour Agreement for University Medical Centres (CAO-UMC), the UMCG Regulations for the Protection of Academic Integrity (Appendix), which govern the right of complaint in the event of a suspected violation of academic integrity, and the UMCG Integrity Code, which this Research Code elaborates on.¹

1.3 Structure of the document

The starting date and the scope of applicability of this Research Code are discussed above. Chapter 2 covers the six main principles of medical research and an elaboration of these into rules concerning behaviour and writing. In chapters 3, 4 and 6, these principles will be further discussed on the basis of the themes mentoring and authorship (Chapter 3), and respect for human subjects and animals (Chapter 4). Chapter 5 will discuss the principles of Open Science and how to deal with research data. Chapter 6 will provide several examples of violations of academic integrity and describe the procedure for reporting violations and suspected violations. Finally, Chapter 7 will provide some suggestions on how to deal with publicity in various non-academic media like newspapers, television and social media.

If you have any questions or doubts concerning academic conduct or integrity issues, please discuss these with your manager. If this does not resolve the issue, please contact the UMCG confidential research advisor, see Section 6.4.1.

¹ UMCG intranet; P&O Handbook; search term ‘integriteit’ (link)
2 Basic principles for medical research at the UMCG

This Research Code enables the UMCG to show the importance it attaches to academic integrity. Academic integrity refers to the willingness of researchers to account for the moral and academic quality of their research. This willingness can only be maintained and blossom in an organization that safeguards a climate of integrity. This Code contributes to such a climate.

It is important to honour and cherish the value of academic integrity, for a violation of this integrity directly affects the reliability of science. It is of the utmost importance that society’s trust in science is sustained.

The UMCG Research Code has been drawn up as a code of conduct and is therefore of a regulatory nature. However, the ambition of safeguarding academic integrity calls for more than just observing the code, as the norms and values of scientific practice are complex. Matters often arise that require integrity assessments. It is important that the complex reality can be morally tested in an environment where there is constant reflection and accountability.

This chapter contains the ground rules for medical research used by the UMCG. They form the basis for a research environment that guarantees integrity.

2.1 Six principles

The Dutch Code of Conduct for Scientific Practice came into effect at all Dutch universities on 1 January 2005 and was updated in 2014. As an academic institute the UMCG endorses the six principles of the Code of Conduct. Whenever these principles are compromised there is an increased risk of violation of academic integrity. Therefore, these six principles apply to all research and all researchers to whom the UMCG Research Code applies.

1 Honesty & Scrupulousness
Academic practitioners are open and honest about their research and its applications. Academic activities are performed with due care, unaffected by the pressure of time or the pressure to achieve.

2 Reliability
The reputation of science as being reliable is confirmed and enhanced through the conduct of every academic practitioner. An academic practitioner is reliable in the performance of and reporting on his or her research and in the transfer of knowledge through teaching and publication.

3 Verifiability
The information presented is verifiable. Whenever research results are published, it is specified what the data and the conclusions are based on, where they were derived from and how they can be verified.

4 Impartiality
In their academic activities, academic practitioners heed no other interests than the academic interest. They are always prepared to account for their actions in this respect. In the case of medical research involving human subjects, the interests of patients must also be carefully considered.

www.vsnu.nl/wetenschappelijke_integriteit.html: A new edition has been published in autumn 2018, including the description of five principles.

Reference is often made in this context to ‘regulations to protect the integrity both real and perceived of the finest institute of the world’. Bill Pearce, Dept. of Health and Human Services (HHS), Genetic Engineering News, April 2005 on integrity and the FDA.
5 Independence
Academic practitioners operate in a context of academic liberty and independence. Insofar as restrictions of that liberty are inevitable, these are clearly stated. See also Section 6.1.

6 Responsibility
Academic practitioners are aware of their responsibility for the societal implications of their academic work. They can be held accountable for their choice of research themes and are able to explain this.

2.2 Rules concerning research
Academic integrity is best achieved by collaboration with peers, research evaluation and a publication policy with independent and thorough peer review. The working environment of researchers should offer as little opportunity as possible for the violation of academic integrity.

This is why the UMCG has devised the following rules concerning the performance of research:

1. All research takes place within a clear research context or theme.

2. The objectives, working methods, research methods and so on, of scientific research are laid down in a research protocol.

3. For medical research involving human subjects (within the scope of the WMO⁴), the NFU guideline ‘Kwaliteitsborging mensgebonden Onderzoek (Quality assurance in human research)’ is adhered to, and the research protocol is assessed in advance by a review board: either the Medical Ethics Review Board (METc) or the Central Committee on Research Involving Human Subjects (CCMO). Changes to a research protocol are also assessed by a review board. Drug research is subject to the rules of good clinical practice. Before a study is started, its research plan must be registered in the Dutch Trial Register⁶, www.clinicaltrialsregister.eu and/or in www.clinicaltrials.gov. This is a public register that can be freely consulted. Registration is also required in order to be eligible for publication in medical journals.⁷

4. Research or research activities within the scope of the nWMO Framework are assessed in advance by the Central ethics Review Board (CTc: Centrale ethische Toetsingscommissie) or a recognized Local ethics Review Board (LTc Lokale ethische Toetsingscommissie) (Section 4.2).

5. Most research within the UMCG is performed within a research group or by various research groups jointly. Although within a research group there can be a clear allocation of tasks, certain aspects are performed by the team as a whole, such as determining the study methods and data collection, assessing and interpreting the data and reporting (the writing process). Regular mutual checks and feedback limit the risk of misinterpretation and fraud. The risk of plagiarism is limited by good supervision, feedback and the use of plagiarism scanners.

6. The different steps and decisions within the research process are properly documented. Keeping a log (electronically or on paper) of the decisions made during the research process will make it easy to reconstruct considerations afterwards. This offers the researcher and others insight into the course of events during the research. The Research Toolbox helps researchers to follow all the research steps and decisions, making it easier to reconstruct the research process.

⁴ Medical Research Involving Human Subjects Act (WMO); see www.ccmo.nl
⁵ www.nfu.nl; search term ‘kwaliteitsborging’ (link)
⁶ The data kept by CCMO only show a partial overlap with the Dutch Trial Register. http://www.trialregister.nl. The Trial Register mainly focuses on randomized intervention studies (e.g. randomized controlled trials), while the CCMO register contains all research that falls within the scope of the WMO.
⁷ This is in accordance with the appeal made by the International Committee of Medical Journal Editors, www.icmje.org; search term ‘recommendations registration’. (link)
necessary steps in the research process in good time and contributes to the completeness of the project documentation.

7 Critical feedback is organized regularly via work discussions or by appointing a supervisory or steering committee. For larger clinical trials an external committee is recommended, and, if necessary, a Data Safety Monitoring Board. Regularly discussing the progress of a study and presenting the results to third parties will help reduce the risk of fraud. The participation of UMCG employees in supervisory committees is therefore of great value for the quality and integrity of research within the UMCG.

8 A peer review procedure is used for the publication of research findings in scientific journals. In addition to providing useful feedback on the issue at hand, peer review may also uncover misleading data representations and/or plagiarism.

2.3 Rules concerning writing

An important element of sound academic practice involves writing and publication. The UMCG uses the following rules for citations and references in scientific writing.

1 References are included in the introduction, the section on materials and methods, and in the discussion of a paper. The introduction describes the relevance of the research, often with reference to theories, theses and research results from others. The section on materials and methods may refer to procedures developed by others. In the discussion section, the achieved results are compared to the results of others.

2 References are stated as accurately as possible. There are explicit rules about how to refer to articles. When referring to books and reports, the pages containing the relevant information should also be mentioned, especially when referring to a particular theory or thesis. Linking a single thesis or concept to an entire book is insufficient.

3 In references one refers to the article or book in which a particular theory or thesis was first mentioned. All references should be carefully checked. Although it is convenient to use references made in other papers, this may lead to errors. Every author is expected to be familiar with all the references that are mentioned in his or her own article. Although authors should preferably refer to the primary source material, referring to review articles is becoming increasingly common as a result of journal requirements regarding the size of manuscripts. In this case, the author must be aware of the content of the source articles.

4 The text clearly specifies when it cites a source and where citations start and end. The suggestion of plagiarism may arise when a primary source is briefly mentioned, yet upon checking it turns out that sometimes entire paragraphs or sections have been copied almost verbatim. Even though extensive citation is certainly not forbidden, it must be evident which parts of the text are citations (including a reference and page number) and which parts are newly formulated. If citations are used extensively, it is wise to consult the original author(s). It may be that certain rights come into play, for example a vested copyright.

5 When publishing academic articles, authors should always specify their interests (financial or other possibly conflicting interests), in accordance with the appeal by the International Committee of Medical Journal Editors (ICMJE).

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See the guideline of the Dutch Federation of Academic Hospitals ‘Kwaliteitsborging mensgebonden onderzoek’, 2019; www.nfu.nl; search term ‘kwaliteitsborging’. (link)

More information about this, and about the reuse of own material without reference to the source, can be found in the KNAW memorandum ‘Correct Citation Practice’; www.knaw.nl; search term ‘correct citeren’. (link)
2.4 Ownership of knowledge\textsuperscript{10}

In accordance with the Copyright Act, the UMCG, as the employer, is regarded as the first legal owner of all products and ideas created by researchers (article, dataset, etc.): the UMCG owns all of the rights comprised in the copyright.\textsuperscript{11} This means that no researcher may benefit financially from such products or use them for any purpose other than within the context of their position at the UMCG without the UMCG’s permission.

Sometimes a UMCG staff member (researcher) will invent something or comes up with an innovative treatment method or other method. In accordance with Article 9.4 of the CAO-UMC, staff members are expected to report any possibly patentable inventions related to the context of their positions to the Board of Directors.

The UG and the UMCG have a joint valorization policy,\textsuperscript{12} within the framework of which inventors may be eligible for remuneration.\textsuperscript{13}

If while creating or inventing a product the staff member satisfies the criteria for authorship, then the rules set out in section 3.2 will also apply.

\textsuperscript{10} UMCG intranet, search path Personnel, P&O Handbook, search term: ‘Nevenantiviteiten en kenniseigendom’ (link)
\textsuperscript{11} Copyright Act, Article 7
\textsuperscript{13} See the UG/UMCG publication ‘The Value of Knowledge’, Chapter 6: ‘Distribution Model for Patent Revenues’
3  Good mentorship

Research is often conducted by junior researchers, including PhD students, interns from a university of applied sciences, university students, analysts, scholarship PhD students and postdocs. Their research usually takes place under the supervision of the principal investigator. This means that often the responsibility lies with an assistant professor, associate professor, full professor or trainer. The adequate supervision and training of junior researchers is an important part of good academic practice. Within the UMCG the relationship between PhD students and their supervisors is regulated by the Graduate School of Medical Sciences (GSMS). Outside the scope of the Graduate School it is also important to lay down the tasks and responsibilities related to the supervision of junior researchers, as described in this chapter.

3.1  Duties of the supervisor

In general, the supervisor of a junior researcher has the following duties:

- supervising the junior researcher with an appropriate degree of intensity and respect
- shaping or helping to shape the teaching and research and the desired activities of the junior researcher in concrete terms
- promoting the activities of the junior researcher
- teaching the junior researcher with an eye to his or her future work environment.

In order to fulfil these duties, supervisors must observe the following aspects:

1. The supervisor shares his or her knowledge, experience and network with the junior researcher to guarantee the progress of the project. This allows the junior researcher to build his or her own network, in order to grow as an independent researcher.

2. The supervisor and junior researcher have an open and critical attitude – irrespective of the situational hierarchy between them – towards the academic goals originally formulated. They should be aware that their original hypotheses may prove incorrect, given their own research results or those of others. If this is the case, the original hypotheses, goals and work plans may have to be revised.

3. The supervisor ensures that the activities the junior researcher is expected to perform are based on a clear plan. The plan may take different forms depending on the stage the research project has reached. A plan could pertain to the elaboration of an idea, drawing up a research protocol, conducting literature research or experiments, collecting data, analysing the collected data or preparing a publication or presentation. For PhD students at the Graduate School of Medical Sciences (GSMS), this has been regulated in the Training and Supervision Plan, which is kept in the electronic registration system Hora Finita that tracks the design and progress of PhD research. PhD students and their supervisors are responsible for recording their teaching and research activities in Hora Finita, where the GSMS will file and process them.

4. The junior researcher and supervisor agree on the purpose of their collaboration and have specified this purpose in clear terms, for example the writing of a PhD thesis (dissertation), article, report or

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14 www.amc.nl, search term: ‘researchcode’; research at the AMC
15 See Chapter 6.4 for the procedure on ‘Handling complaints in the field of academic integrity’ in the event of serious issues between junior researchers and their supervisors.
oral presentation. Sometimes the collaboration is confined to a single work package as part of a larger research project.

5 The supervisor ensures that the junior researcher has access to facilities and is adequately supported in its use in compliance with relevant regulations and standards. This does not just concern the laboratory or clinical facilities but also support from people with specific expertise within or outside the department.

6 In performing the research work the junior researcher can expect regular help, advice and support from the supervisor. Such can be provided at scheduled times, yet there should also be room for interim consultations in the event of unexpected developments.

7 The intensity and the form of the supervision depend on the level, the working method and the approach taken by the junior researcher. The supervision of a Master’s student will be different from the support given to a PhD student in the final stages of PhD research. In a clinical setting the patients’ interest should also be factored in where the support given to a junior researcher is concerned.

8 The supervisor and the junior researcher hold regular work meetings. Such meetings should at least cover the progress of the project and any problems the researcher is encountering. The next steps to be taken may also be discussed during these meetings. Finally, there should be sufficient consultation about how to achieve the final objective. The consultations preferably lead to specific agreements on short-term and (if necessary) medium-term goals.

9 It should be easy for the junior researcher to contact the supervisor. The supervisor should set time aside to provide proper, critical feedback on the content of the work. This includes returning corrected manuscripts, reports and so on within an acceptable period of time.

10 The junior researcher and the supervisor have a performance appraisal interview or career development interview at least once a year. This will enable both parties to reflect on each other’s performance and to make agreements for the coming year. In the case of PhD research, the supervisor and the junior researcher must agree on a concrete, phased teaching plan, if possible before the start of the research. The teaching plan is part of the plan referred to under point 3, and can comprise course units from various categories, such as:
   • Generic skills (and deepening/broadening of knowledge)
   • Research-related skills (idem)
   • Skills (idem) specifically aimed at the PhD research in question.
   The teaching plan must factor in the junior researcher’s specific needs.

11 The supervisor may not use the junior researcher’s research results without consultation. All agreements made in this context must be set out in writing.

12 In the case of PhD research, the primary supervisor encloses with the thesis approval a statement confirming that the thesis has been checked for plagiarism and indicating the storage location of the raw data on which the thesis is based. The departmental head or the director of the research institute will be asked to approve the proposed composition of the Assessment Committee in Hora Finita.

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16 For example good clinical practice (GCP, including addendum 2016), good laboratory practice (GLP), good manufacturing practice (GMP).
17 The University of Groningen PhD regulations specify that the supervisor must support the PhD student and ensure that there are regular consultations and that the proceedings concerning the thesis and the defence run properly. http://www.rug.nl search term ‘PhD Regulations’.
18 UMC employees are subject to the rules of the CAO-UMC where performance appraisal interviews are concerned.
3.2 Authorship & order of authors

At the start of the research, all researchers, including the supervisor and the junior researcher, must make clear arrangements regarding the publication and/or presentation of the research outcomes. If necessary, they can modify these arrangements during the course of the project. The qualification as author and the subsequent author order allocation are part of these arrangements (see Section 3.2.1).

3.2.1 Authorship

Authorship is an explicit way to assign responsibility and intellectual ownership and to give credit for intellectual labour as reported in academic publications, presentations and abstracts. Authorship is important for the reputation, academic promotion and appeal of the individual researcher. In addition, authorship is also important for the strength and reputation of the UMCG and thus also that of underlying parts of its organization, e.g. the departments, research institutes and research programmes. Various institutes, academic societies and journals have developed guidelines for authorship. The UMCG endorses the guidelines of the Committee of Medical Journal Editors (ICMJE) as a basis for authorship. Staff members are obliged to follow these guidelines.

Authorship implies that the following four criteria are met:19

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

All individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript. The authors are responsible for identifying who meets these criteria.

In addition, the following ICMJE best practices are adopted:

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

3.2.2 Order of authors

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

contribution to the paper. In the event of a series of publications, it may be decided that the first and second author alternate per article as well as the last and penultimate author.

### 3.2.3 Responsibilities of those involved in research

Here is an overview of the responsibilities of the various people involved in a research project, including the researcher or junior researcher performing the research, the day-to-day supervisor, the project leader, the primary supervisor (who may also act as project leader), and the director of the Graduate School of Medical Sciences.

A) The researcher / junior researcher is primarily responsible for:
- The careful conducting of the research
- The careful handling of patients or laboratory animals and their rights and data, and the observation of legal guidelines, regulations and codes of conduct
- The correct reporting and adequate archiving of the data (and materials); see Section 5.4.2.

B) The day-to-day supervisor is primarily responsible for:
- The day-to-day supervision of the researcher – this implies that the supervisor must be available on an almost daily basis
- The practical check on the careful conducting of the research
- The practical monitoring of the research progress.

C) The research or project leader is primarily responsible for:
- The quality of the problem definition, design, analysis and reporting
- A coherent research programme in the research line
- The supervision of progress made by the research line in question
- Quality policies
- The monitoring of teaching and training activities (e.g. BROK\textsuperscript{20} and GSMS courses) and the researcher’s career path.

D) The primary supervisor is primarily responsible for:
- The quality of the PhD thesis so that it can be defended.

E) The director of the relevant research institute and the director of the Graduate School of Medical Sciences are responsible for:
- The process and the total educational package to be followed by the junior researcher.

F) The Board of Directors, in particular the Dean (and the Dean of Research as a delegated official), is responsible for:
- All research conducted within the UMCG

\textsuperscript{20} Basic course on Regulations and Organization for Clinical investigators.
4 Respect for human subjects and animals

Respect for the privacy of human test subjects and study participants, and respect for laboratory animals, staff members and the environment, is part of sound academic conduct. This also implies that medical and research data must be properly protected, i.e. that the protection and security of personal data for healthcare and medical research, as well as biomaterial, are ensured. Here are some examples:

1 Directly traceable personal data (e.g., name, postal address, Bank account number) and research data must be kept strictly separated.

2 Wherever possible, the researcher should use anonymous or coded research data and biomaterial. Data on patients\(^{21}\) that can be traced back to the individual are only collected and used for research with the patient’s consent. To this end, the patient will receive written information about the nature of the research and the data needed. The researcher must ensure that the patient understands what he or she has consented to. If no specific and explicit consent has been given, the researcher may not assume that the person in question has consented to the publication of research data that include his or her personal details. Only in exceptional cases may the data of a patient be used for scientific research without his or her consent.\(^{22}\)

3 In addition to ethical and legal considerations, respect for the interests of patients/healthy volunteers is a prerequisite for motivating participants to take part in medical research. Two types of medical research involving human subjects can be distinguished: research that falls under the Medical Research Involving Human Subjects Act (WMO) and research that does not (nWMO). These two types will be further discussed in Sections 4.1 and 4.2.

4 Animal experiments may be necessary in order to answer fundamental or applied scientific questions or for teaching purposes. Researchers are expected to treat laboratory animals with respect.

5 The safety of human test subjects, study participants and staff members has the highest priority. Staff members are also expected to treat the environment with respect.

4.1 WMO Research

The Medical Research Involving Human Subjects Act (WMO) applies to: ‘medical research that includes subjecting individuals to interventions or imposing a particular course of conduct upon them’. As such the WMO forms an integral part of the UMCG Research Code.

The researcher will start by answering the question whether the intended research falls within the scope of the WMO. Examples include medical studies that aim to answer a concrete research question and in which a new product/drug is tested, blood samples are taken, new diagnostic methods are tested, new medical instruments are researched or a new surgery technique is studied. Research like this can only start if the research protocol has been approved by a review board recognized by the CCMO. The research protocol of certain specific types of research will be assessed by the CCMO itself.

\(^{21}\) In Chapter 4, the term ‘patient’ also includes donors, participants in medical studies and test subjects.

\(^{22}\) Art. 7:458 BW (WGBO)
The UMCG METc is a review board that is recognized by the CCMO.\textsuperscript{23} The organization and working method of the UMCG METc have been laid down in regulations and a large number of Standard Working Methods. The CCMO Guidelines on External Review 2012\textsuperscript{24} applies to multicentre research and to the external review of monocentre research. Researchers are expected to comply with these guidelines.

If the processing of personal data as defined by the General Data Protection Regulation (GDPR) is involved as well, the Privacy Tab of the UMCG Research Register needs to be completed. Biobanks and Databanks for future scientific research are reported to the UMCG Data Protection Officer (privacy@umcg.nl).

### 4.2 nWMO research

nWMO research activities concern the acquisition, processing, storage, and distribution of personal data (and associated biomaterial) for future scientific research, for example the establishment of a biobank. These research activities also concern scientific research involving human subjects that does not include subjecting individuals to interventions or imposing a particular course of conduct upon them, for example because the required data are taken from a databank or because the nature of the intervention or imposed course of conduct does not violate the physical or psychological integrity of the participant.

With the nWMO system\textsuperscript{25} the UMCG aims to assess all intended population/clinical studies conducted at or by the UMCG that do not fall under the scope of the WMO in accordance with the applicable legislation and regulations. This will enable the UMCG to satisfy several important legal and societal preconditions for research, such as assessment of compliance with legislation and regulations (e.g. WGBO, GDPR, and the Code Goed Gebruik van Federa [Code of Conduct for responsible use by Federa]), risk mitigation in the field of health and safety, and the promotion of transparency, control and privacy. Key concepts within the nWMO system include:

- Promotion of transparency. Patients and participants must be adequately informed about the studies and their results, in particular if the research is based on healthcare data that is made available through the ‘no objection’ procedure (see Section 5.2).
- Promotion of control on the part of participants. In principle, participants always have to give written informed consent. The ‘no objection’ procedure can only be applied if the conditions set out in the WGBO are satisfied.
- Promotion of the privacy of participants. The privacy of participants must be optimally protected. Researchers may only have research data at their disposal that they cannot trace back to an individual person, unless this is necessary to perform the study and the participant in question has given written informed consent for this.

The main components of the nWMO system are (1) the nWMO Framework Regulation and (2) the assessment of intended research and research activities by the Central ethics Review Board (CTc) or one of the Local ethics Review Boards (LTcs).

\textsuperscript{23} \url{http://metcgroningen.nl}
\textsuperscript{24} CCMO Guideline on External Review 2012; see \url{http://www.ccmo-online.nl}; ‘Accredited MRECs and multicentre research’.
\textsuperscript{25} The nWMO system will apply to the entire UMCG in October 2021 at the latest. This system will replace the UMCG Biobank Regulations [UMCG document 12.272.770].
The UMCG nWMO Framework Regulations
The Framework Regulations set out the scope of the nWMO system and the rules and conditions under which nWMO research activities may take place. Everyone who wishes to collect or use data (including image material) or biomaterial from participants for current or future scientific research that does not fall under the Medical Research (Human Subjects) Act must comply with the stipulations of the Framework Regulations.

Assessment by the Central ethics Review Board (CTc) and Local ethics Review Boards (LTcs)
The CTc was appointed by the Board of Directors of the UMCG to assess scientific research and to assess the initiation and management of biobanks and databanks that fall under the nWMO Framework Regulations. This also includes reviewing the internal regulations of new and existing LTcs. An LTc is an institution approved by the CTc that assesses scientific research, based on the Framework Regulations as well as its own internal regulations.

4.3 Safety of staff and the environment
It is very important that researchers and staff members work in a safe way, for themselves as well as for the environment. Risks may arise in research, for example if laboratory work involves hazardous substances, genetically modified organisms or radioactive material/X-ray devices. The UMCG complies with regulations in the field of health, safety and the environment to mitigate these risks. Special facilities, manuals and protocols, risk analyses and specially appointed safety officers are but a few examples of how the safety of staff and their environment is assured and risks are being limited and managed. Researchers should familiarize themselves with the applicable regulations at the department before the start of the research activities, verify whether the risks of their research fall within the available frameworks, and conduct the activities in accordance with the regulations.

Permits are legally required to conduct research involving hazardous substances, genetically modified organisms and radioactive materials/X-ray devices. These have been elaborated into internal permissions within the UMCG. Researchers must verify in consultation with the designated officers at the UMCG whether an internal permission is in place for their intended activities. If this is not the case, an appropriate permission should be obtained.

Hazardous substances, in particular microorganisms and radioactive materials, are sensitive to improper use. Researchers who use these substances and materials, and their associated data, should do so with particular care and confidentiality. Some scientific publications containing sensitive knowledge may require an export permit. Suspected misuse of knowledge and material must always be reported to the relevant manager and, if necessary, to Security.

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26 In addition to UMCG patients this also includes ‘healthy’ volunteers such as physicians, and patients/clients of other care providers (such as GPs) who are recruited for research in which the UMCG bears final responsibility for the scientific quality.
27 UMCG intranet, under UMC-Staf: ‘Veiligheid & Vergunningen’ and under Bouw & Facilitair: ‘Milieu’
4.4 Respect for laboratory animals

Animal experiments may be necessary in order to answer fundamental or applied scientific questions or for teaching purposes. The UMCG has the required institutional license for this. Researchers are expected to treat laboratory animals with respect. Animal experiments may only be conducted if there are no suitable alternatives, including replacement, reduction or refinement – so-called ‘3R Principle’ (also known, in Dutch, as the ‘3 Vs’: vervanging, vermindering, verfijning). The Wet op de dierproeven (Wod 2014, Animal Procedures Act), including this 3R approach, applies. The Wod stipulates, among other things, that animal experiments may only be conducted if they have been authorized by the national Centrale Commissie Dierproeven (CCD, Central Authority for Scientific Procedures on Animals). The procedure for obtaining such authorization comprises several steps. First, the local Animal Welfare Body (IvD: Instantie voor Dierenwelzijn) needs to be consulted about matters such as the technical feasibility of the proposed animal experiments and the 3R approach chosen. A member of the local review committee will provide feedback, in particular on the academic quality of the project proposal. Once the draft application is completed, it is sent to the CCD. The CCD will subsequently consult an Animal Ethics Committee (DEC: DierExperimenten Commissie) for ethical advice, based on which it will then make its final considerations and decide whether or not to grant conditional or unconditional authorization. The researcher subsequently draws up an IvD protocol based on the project authorization and discusses this within the IvD, which the researcher is a member of at this stage. The IvD protocol aims to prepare the practical and technical aspects of the animal experiment. The animal experiment can now begin. The researcher draws up an evaluation of each animal experiment conducted, reporting on matters such as the suffering experienced by the animals in the experiment and providing suggestions for possible modifications to be made in follow-up studies. The implementation of animal experiments is internally monitored by the IvD and externally by inspectors from the Netherlands Food and Consumer Product Safety Authority.
5 Research data & Open Science

5.1 Research Data Management

Research data are recorded observations that are the result of scientific research. These data can be numerical, descriptive or audio-visual in nature. Research data are in principle expected to be accurate, complete, reliable and authentic and managed in accordance with the applicable ethical and legal frameworks and codes of conduct— in other words, adequate management of research data during the entire research process, from the design and data collection phases to archiving and publication.

Adequate management of research data is an integral part of the regular research process. Clear agreements have therefore been made within the research departments about the roles and responsibilities with regard to research data management. As part of the research protocol, a Research Data Management Plan (RDMP) is drawn up for each research project with human subjects and approved by the principal investigator. This plan sets out how research data will be dealt with during and after the project, how the data is collected and kept available and traceable and who is responsible for this. Examples of and writing instructions for RDMPs are available from the various funding bodies and in the UMCG Research Toolbox on the intranet.

The minimum storage period for research data depends on the nature of the study:

- 30 years for research with advanced therapeutic medicinal products (medicines with products such as gene therapies, cell therapies and tissue engineered products)
- 25 years for research with medicines
- 15 years for other studies that are subject to the WMO and research that are not subject to the WMO

Longer storage periods may be agreed if necessary and in consultation with the participants involved.

All scientific research that is conducted within the UMCG or by UMCG staff (both studies that are subject to the WMO and studies that are not) must be registered in the Research Register. If you have any questions about the Research Toolbox or the Research Register, please contact the Service Desk Clinical Research Office (SD-CRO) via clinical-research-office@umcg.nl.

5.2 Aspects concerning data protection

In line with the core values and ambitions of the UMCG, the privacy of participants in scientific research is treated with respect. Medical research often involves processing personal data, including sensitive personal data. This concerns information that can directly or indirectly be traced back to an individual, for example their name and address, patient number, certain types of image material.

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28 See: Board of the University, University of Groningen Research Data Policy (February 2015).
29 See also: https://www.health-r.nl/services/hands
30 The Research Toolbox can be found on the UMCG intranet.
31 See the Guideline Kwaliteitsborging Mensgebonden Onderzoek 2019 (NFU).
32 The Research Register can be found on the UMCG intranet.
33 Personal data are all data that can be traced back to a participant in a scientific study either directly, indirectly or via a key (pseudonomized/coded data). Anonymous data or the details of deceased individuals or of organizations are not considered to be personal data.
genetic data or tracking data. In accordance with applicable legislation and regulations, UMCG researchers may only process personal data for very specific, explicitly described and justified purposes, and they must process these data in legitimate, fair and transparent ways. The UMCG endorses the VSNU code of conduct on the use of personal data in scientific research. The GDPR, UAVG and the Medical Treatment Contracts Act (WGBO) set out rules on how to process medical and other data for scientific research. These are complied with in the UMCG.

Any data that can be traced back to an individual or that is derived from a patient file may in principle only be used for medical research with the written informed consent of the person involved. Consent is given on the basis of written information about the nature and the purpose of the research. Consent is also required if other researchers wish to use the patient data or consult the medical files. In some cases patient data may be used for medical research without the patient’s consent, unless he or she objects to this. The use of patient data without the patient’s consent is only permitted if it is not reasonably possible to ask for consent and if in processing the data the patient’s privacy is guaranteed. In addition, the patient may not have objected to the use of his or her data for medical research in the past. The responsible researcher or the manager of the relevant ‘secondary use’ biobank or ‘secondary use’ databank must always check the UMCG objections register to make sure that no healthcare data or biomaterial from patients who have objected are made available for scientific research.

The GDPR applies to the processing of directly or indirectly traceable personal data. The GDPR does not apply when fully anonymized data is used. However, personal data are very often merely coded or ‘pseudonomized’ and thus indirectly traceable to an individual, which means that additional measures may have to be taken to guarantee the privacy of participants.

Researchers may only collect data that are necessary for the research and should code or pseudonomize all personal data at as early a stage as possible. Data and data files are linked in a secure manner, for example via a Trusted Third Party (TTP). In addition, within the framework of data protection, authorizations are adapted to the position of the staff member in the research process.

Within the framework of data protection, the use of personal data will be explained and justified before the start of a research project. The principal investigator is responsible for drawing up a Privacy Compliance Dossier before the start of every research project, comprising a Research Data Management Plan, the completed Privacy Tab (included in the UMCG Research Register) and in some cases a Privacy Impact Assessment (PIA). A PIA must be conducted for research and other projects that involve the processing of personal data which may potentially involve great risks for the person involved, for example the establishment of a new databank or biobank.

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34 ‘Processing data’ includes at least the following activities: collecting, recording, organizing, storing, editing, modifying, requesting, consulting, using, forwarding, distributing or in any other way making available, combining, linking, shielding, deleting or destroying data.
35 Only in very exceptional cases may the consent requirement for providing patient data to third parties be ignored. The privacy protection plays an important role in this respect.
36 Art. 7:458 BW (WGBO).
37 Pseudonomizing/coding is a special way of processing data, in which the link between a set of identifying data and the data subject is removed and a new link is created between a certain set of characteristics that refer to the data subject and one or more pseudonyms.
38 Also referred to as Data Protection Impact Assessment (DPIA). The PIA consists of an assignment model/questionnaire.
39 This concerns databanks set up outside the hospital information system (ZIS: Ziekenhuisinformatiesysteem) and the electronic patient record (EPD/EPIC: Elektronisch Patiëntendossier).
The privacy of participants is also guaranteed during and after the research, for example when research data are archived and shared. The IT facilities and software packages used satisfy the UMCG’s security standards to guarantee the safety and validity of personal data.

National and international multicentre studies in which personal data are processed, and in other situations when these data are shared with parties outside the UMCG, may also involve the signing of a processors’ agreement in addition to a collaboration agreement and a Material & Data Transfer Agreement. International multicentre research may require additional measures in the field of data protection, particularly with an eye to differences in privacy legislation with countries outside the EU. The sharing of personal data with parties outside the UMCG is submitted to the Loket Contract Research (Contract Research Office) in advance and every agreement will be assessed by the Office.

The Privacy Task Force (PWO),40 which includes officials such as the Data Protection Officer, has an advisory role within the UMCG and functions as an internal watchdog in the field of privacy and information protection. If you have any questions or need advice in the field of data protection and information security, please contact the Privacy Task Force via privacy@umcg.nl. If you need advice or would like to have a contract checked, please contact Loket_Contract_Research@umcg.nl.

The GDPR stipulates that data breaches must always be reported to the Data Protection Official via the SOS button on intranet or the UMCG extension 11111. A data breach occurs when an unauthorized individual has had access to personal data, or when the possibility that this has happened cannot be entirely ruled out.41

5.3 Responsibility for and control of data
Participants in scientific research have control rights over their own personal data. The UMCG strongly believes in transparency in science and aims to give the participants in its research a clear idea of the policies concerning how their data is processed and used in research.

Participants have the right to be informed, to access their own data and to request rectification and erasure of their data. In the participant information letter, participants are referred to this by means of a link to the UMCG Privacy Statement on the UMCG website (http://uwprivacy.umcg.nl). For example, when a participant has given written informed consent, he or she should be able at all times to withdraw this consent for any future use of the data without this compromising his or her healthcare interests. Even if no written consent is required for a certain study, participants can still object. In this case researchers always check the UMCG objections register.

5.4 Open Science
Open Science is a worldwide movement towards a more open way of conducting research. This involves becoming more transparent and open about how researchers work, collaborate, communicate, share resources and disseminate research results. In accordance with the UG Strategic Plan, the UMCG actively stimulates the implementation and practice of Open Science in the academic community. A recent phenomenon in the field of research results is ‘Open Access’. This means that scientific research results are made as widely available as permitted within the framework of privacy

40 More information about the Privacy Task Force can be found on the UMCG intranet
41 For more information about the obligation to report data breaches as set out in the Data Protection Act see: http://wetten.overheid.nl/BWBR0037346/2015-12-16
legislation and contractual agreements. When this principle is specifically applied to research data, this is referred to as ‘Open Data’.

5.4.1 Open Access
The UG and the UMCG support the principle of Open Access with regard to publications: free, open online access to the full text of academic publications. The UMCG follows the ambitions of the VSNU, which means that by 2020, 80% of all publications must be Open Access.\(^\text{42}\) There are several types of Open Access publishing. The preferred type is what is known as the ‘gold road’, which means publishing in journals that are fully Open Access.\(^\text{43}\) Within this road, there are also ‘hybrid’ journals, which only make articles available as Open Access after payment by the author. If an article is published in a traditional, non-Open Access subscription-based journal, the author can take the ‘green road’, which means that the author’s final version of a peer-reviewed journal article is also placed in a public research database that is managed by an academic institution. Since 1 January 2017, UMCG researchers are asked to post their articles in the public UG research database PURE.\(^\text{44}\) More information about Open Access publishing and the support provided for this by the Central Medical Library can be found on [http://www.rug.nl/cmb/](http://www.rug.nl/cmb/).

5.4.2 Open Data and FAIR data
Open Data is all about increasing the findability, availability and usability of research data for the benefit of the replicability of research and the reuse of research data. The UMCG supports Open Data and the associated FAIR data principle (‘Findable, Accessible, Interoperable and Reusable’).\(^\text{45}\) As soon as possible after the completion of a research project, the data is stored in such a way that it is easily accessible to the public and made available for replication research and reuse. The questions where the data can be found and how it can be accessed, must be answerable for the data used in each and every publication.

Research data can be made findable and accessible through a publicly available catalogue containing a description of the data collection combined with a reference to the storage location of the data, if possible with a persistent identifier.\(^\text{46}\) Within the UMCG, the FAIR data catalogue can be used\(^\text{47}\), which is connected to national and international catalogues and PURE. Researchers can set additional restrictions on the availability of research data, on condition that they can provide good arguments for this. Such restrictions may be based on ethical, legal or contractual objections, and may result in the establishment of an embargo period or the signing of additional agreements on the use of the data.

\(^{42}\) UMCG researchstrategie-op-hoofdlijnen 2018, reference 18.3553302/RvB
\(^{43}\) An overview of Open Access journals is available on the website of the Directory of Open Access Journals (DOAJ): [https://doaj.org/](https://doaj.org/).
\(^{44}\) The UG/UMCG policy with regard to Open Access can be found at: [http://www.rug.nl/library/open-access/](http://www.rug.nl/library/open-access/)
\(^{45}\) The FAIR data principle discusses the characteristics of research data and states that these must be Findable, Accessible, Interoperable and Reusable.
\(^{46}\) A persistent identifier is a unique label that is permanently attached to a digital object, such as a text document, audio-visual file or data collection. Using a persistent identifier, a digital object can always be found and referred to, regardless of any changes to its name or location.
\(^{47}\) See: [https://www.groningendatacatalogus.nl/](https://www.groningendatacatalogus.nl/)
6 Transparency and violations of academic integrity

In 2001, the Royal Netherlands Academy of Arts and Sciences (KNAW), the Association of Universities in the Netherlands (VSNU) and the Netherlands Organisation for Scientific Research (NWO) jointly wrote the Memorandum on Academic Integrity. The UMCG endorses this Memorandum and expects its employees to act accordingly.

The Memorandum contains the general principles for professional medical research and specifies different ways in which academic integrity might be compromised. In addition, it lists ways in which the violation of standards can be prevented. Finally, the National Board for Research Integrity (LOWI) was established. This institution advises the Boards of academic organizations about violations of academic integrity and complaints in this field.

6.1 Relationship of researchers with external parties, including funding bodies

Traditionally, scientific research performed by academic medical institutes is financed by intramural funds as well as funds provided by external organizations, such as the Netherlands Organisation for Scientific Research (NWO), non-commercial sponsors (e.g. the health funds), the European Union or companies.

The researcher and the research remain independent of the commissioning or funding party. The KNAW’s statement of independence must be observed by all parties subject to this UMCG Research Code. It is not the researchers themselves (nor their supervisors) who enter into agreements with the external party, but, excluding all others, the UMCG Board of Directors. Only the Board of Directors, or individuals authorized by the Board of Directors, may sign research contracts with external funding bodies. This is why every research project that receives part or all of its funding from external sources is first reported to and registered with the UMCG External Project Funding Office. Among other things, the External Project Funding Office handles the compulsory review of the prospective agreements by the Loket Contract Research [Contract Research Desk], which is part of the UMC Legal Affairs staff department. Since 1 January 2009, the assessment of research contracts involving patients or healthy test subjects is a statutory task of the METc. The assessment is limited to the rules on premature termination of the research and the publication of research data.

6.2 Additional activities and conflicts of interests

UMCG employees are expected to dedicate their knowledge and capabilities to the UMCG. Any additional activities or jobs, whether paid or not, may lead to the presumption of a conflict of interest. This is prevented by a transparent way of working and a sound consideration process. The Collective Labour Agreement for University Medical Centres (CAO-UMC) contains clear guidelines pertaining to this matter.

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49 https://www.knaw.nl/shared/resources/actueel/bestanden/wetenschappelijke_onafhankelijkheid.pdf
51 UMCG intranet, search path Personnel, P&O Handbook, search term: ‘nevenwerkzaamheden’
6.2.1 Additional activities
The CAO-UMC\textsuperscript{52} stipulates that the Board of Directors gives its prior consent in the event of ancillary jobs that:
\begin{itemize}
\item may affect the interests of the hospital
\item may harm the functioning of the hospital and its staff
\item and that may be incompatible with the staff member’s duties.
\end{itemize}

6.2.2 Conflicts of interest
The UMCG considers it important that the results of medical research performed within the UMCG are published as soon as possible, for example in scientific journals. Furthermore, these results must be quickly used in new diagnostic and therapeutic options wherever possible. This sometimes requires a longer route, because the interests of commercial participants must also be considered. This is where a conflict of interest may occur, an area where the academic integrity of the individuals involved in the joint venture is at risk of being compromised. The independence of medical research at the UMCG should never be called into question, for this may damage both the reputation of the UMCG and the academic careers of individual researchers. Below are some examples of situations that may cause a conflict of interest.

Situations that may lead to research bias:
\begin{itemize}
\item Research funded by third parties, if the researcher or his/her family have a financial interest in the funding party
\item Accepting favours from parties funding research\textsuperscript{53}
\item Consulting positions with funding bodies, such as companies, government funds and charities. Consulting positions must be transparent to all stakeholders, e.g. by publishing them on the staff pages (professional profile) of the public website of the University of Groningen
\item Situations where UMCG facilities are used
\item Putting students and employees to work for a company in which the researcher has an interest
\item Improper use of facilities for personal gain or to support a company in which the researcher has an interest
\item Associating one’s name or work with the UMCG to benefit from the institute’s goodwill.
\end{itemize}

Situations where information is used:
\begin{itemize}
\item Improper use of confidential information
\item Accepting support for the research on the condition that the results remain confidential or will not be published, or that their publication is severely delayed
\item Granting access to the institute’s confidential information to an organization in which the researcher has a financial interest.
\end{itemize}

\textsuperscript{52} The Collective Labour Agreement is a public law legal status regulation (Art. 9.3) \texttt{www.nfu.nl}, search term ‘CAO’.

\textsuperscript{53} See also ‘\textit{Richtlijn Gunstbetoon door bedrijven}’ of the Dutch Federation of Academic Hospitals, \texttt{www.nfu.nl}; search term ‘gunstbetoon’
Situations in which the researcher negotiates with him- or herself:
- The purchase of materials, instruments or stock from a company in which the researcher has a financial interest
- Influencing the negotiation of contracts between the UMCG and the company in which the researcher has a financial interest
- The specification (compulsory and non-compulsory) of publications that were written or cowritten by the staff member.

6.3 **Examples of fraud and other violations of academic integrity**

Below are some examples of violations of academic integrity. These examples are taken from the Memorandum on Academic Integrity mentioned above, the AMC Research Code\(^{54}\) and the University of Groningen Regulations for the Protection of Academic Integrity.

1. Providing misleading information (dissimulating expertise, deliberate misrepresentation of results achieved earlier or creating false expectations) in order to apply for grants or assignments
2. Making up data derived from literature research, observations or experiments
3. The selective reporting of results, particularly the omission of any unwanted results
4. Presenting fictitious data as results of observations or experiments (including making up such data)
5. Embellishing figures such as original blots, gels or other pictures and illustrations
6. The deliberate improper use of statistical methods in order to arrive at different conclusions than justified by the data
7. The incorrect or deliberately distorted representation of research results and conclusions
8. Plagiarizing the results or publications of others, copying text or results of other people’s research without crediting the source
9. Paving the way to the incorrect interpretation of research outcomes by the media through careless conduct
10. Treating colleagues and subordinates unfairly to influence the outcomes of research
11. Deliberate misrepresentation or biased representation of the results and research reports of others. This includes presenting oneself as author or co-author without having made a significant contribution to the design or execution of the reported research or the interpretation and the description of the methods and findings
12. Omitting the names of co-authors who made a substantial contribution to the research from publications, or listing people as an author who did not make a significant or other contribution to the research (or exaggerated self-citation)
13. Carelessness in performing research or the omission of actions that would bring to light any flaws, e.g. wholly or partly failing to observe the inclusion and exclusion criteria in the protocol
14. Ignoring established codes of conduct for the handling of data on test subjects
15. Copying test designs or software without permission
16. Unreported multiple submissions or publications

\(^{54}\) [www.amc.nl](http://www.amc.nl), search term: 'researchcode'; onderzoek in het AMC.
17 Unreported submissions or publications where the sample increases with every subsequent publication and new data are added to data published previously while the outcomes remain unchanged

18 Unreported conflict of interests

19 The use of original ideas offered by referees or editors

20 Allowing and covering up the misconduct of colleagues

21 A researcher and/or person with administrative responsibility (member of the Board of Directors, departmental head) has a duty of care towards science in general and towards the researchers in his or her immediate circle in particular.

6.4 Handling complaints in the field of academic integrity

The UMCG Board of Directors has established Regulations for the Protection of Academic Integrity (Appendix). These Regulations set out the rules and procedure to follow in the event of a complaint about a violation or suspected violation of academic integrity. The procedure in place at the UMCG ties in with the University of Groningen Regulations.

6.4.1 Procedure

A description of how complaints about alleged violation of academic integrity are handled is given below. For complaints about academic integrity the UMCG uses the procedure drawn up by the Committee for Academic Integrity (CWI). This procedure is described in the Complaints procedure Academic Integrity.

The UMCG has appointed a confidential advisor on academic integrity. This advisor is the first port of call for questions or complaints about academic integrity. The confidential advisor will try to mediate or settle the complaint amicably. The confidential advisor may also make the complainant aware of the possibility of filing a complaint with the UG CWI. The committee handles cases for the UG as well as the UMCG.

Everyone involved in scientific research is personally responsible for preventing and drawing attention to violations of academic integrity. Anyone who suspects or finds that a person subject to the UMCG Research Code (see Chapter 1) is violating academic integrity may report this to the UMCG confidential advisor (vertrouwenspersoon.research@umcg.nl). Complaints may also be lodged through the Dean or with the UG CWI directly (via email). When the CWI receives a complaint, the procedure as set out in the Complaints procedure Academic Integrity will be followed.

The UMCG aims to establish a safe climate for reporting and acknowledging violations of academic integrity. For this reason, the complainant will not suffer any direct or indirect negative consequences as a result of lodging a complaint, unless of course the complainant did not act in good faith. The same applies to witnesses, experts, the confidential advisors and the members of the committee. In specific cases when a PhD student lodges a complaint about a supervisor and the complaint is considered founded, the UMCG will continue to facilitate the PhD process as far as possible, for example by appointing a substitute supervisor, to limit the damage for the complainant as much as possible.
7 Dealing with the media

UMCG researchers regularly make it into the media. This is important for several reasons. At the UMCG a lot of high-quality research is being conducted that is relevant to the general public. Publicity brings this to the attention of the general public. It strengthens the UMCG’s reputation as a research institute and raises awareness of the names of researchers and research groups. In addition, the media can be used to account for the spending of public funds. Nevertheless, there are risks attached to publicity and media contacts. It is not always easy to present academic insights in a comprehensible way. Moreover, publicity is often guided by the interests of third parties. Furthermore, certain media appear to be more interested in a scoop about positive data than in the negative aspects of a particular study. Researchers should therefore be aware that dealing with the media requires a different set of skills than scientific practice. In these situations the ‘Guidelines for dealing with the media and video and sound recordings for UMCG staff’ apply. These guidelines also comprise the ‘UMCG Media Protocol’.

Professional support is vital in these cases. For this reason, publicity about medical research should always be handled by the UMCG press officers. Furthermore, the University of Groningen and the UMCG have made arrangements about joint communication on medical research.

7.1 Due caution regarding media contacts

Popularizing scientific research in a responsible manner can be very tricky, in the case of medical research perhaps even more so than for other academic disciplines because almost all medical research directly concerns patient interests. Overly enthusiastic statements may create expectations among patients that cannot be fulfilled. Researchers must therefore be cautious when making statements about the possible clinical applications of fundamental research. Many ‘medical breakthroughs’ reached the general public because the research was led by exciting theoretical vistas rather than the actual scope of the results. When presenting clinical research data, similar caution is required, for example concerning the question of which patients will actually benefit from a new drug or the actual availability of a drug for patients. Caution is also necessary when intermediate results appear to point to success. It is very tempting to publicize results prematurely.

7.2 Publicity by third parties

Researchers may be confronted with funding bodies or commissioning bodies who want to handle the publicity themselves. In most cases this is not desirable. Publicity by third parties may raise doubts about the independence of the research, for example if the publicity is based on commercial motives. The institute in question must always handle its own publicity. If necessary, the press officers may make arrangements with third parties about a particular allocation of tasks. Ensuring that publicity always carries the UMCG’s certification underpins the independence of the research. Clarity about the funding may prevent any doubts on this issue.

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55 UMCG intranet, search path: UMC-staf, Onderdelen, Communicatie, Diensten en Middelen, Persvoorlichting (‘Leidraad media en beeld- en geluidsopnamen medewerkers UMCG’)
56 The UMCG press officers are available by telephone 24 hours a day, 7 days a week. During office hours they can be reached via the secretariat of the UMC Communications Staff, tel. (+31) (0)50 361 22 00, and outside office hours the press officer who is on call can be contacted via the UMCG switchboard at tel. (+31) (0)50 361 61 61.
7.3 Publicity regarding scientific publications

With important scientific publications, it is advisable to contact one of the press officers at an early stage, especially if a lot of media attention is expected, if the outcomes of the research can easily be misinterpreted, or if the research touches upon a controversial issue. You must also factor in the strict guidelines that apply when a manuscript is included in a journal. In this case premature publicity is often not desirable. The press officers and the researcher will jointly examine the possibilities for publicity: they determine whether the issue is newsworthy and which media would be suitable, and prepare the researcher for possible interviews with journalists. For more information please refer to the brochure ‘Media contacts for scientific staff’ on the UMCG intranet under UMC staf, Communicatie.

7.4 Social media

Several aspects need to be taken into account when using social media. On the one hand, social media offer great opportunities: they enable researchers to join networks, share research results with fellow researchers at other institutes, gain insight into other fields and get an idea of what is happening in certain groups and target groups. On the other hand, everything that is posted on social media will always remain visible and can always be traced back to the author of the original post, and this is not without risks. When sharing announcements, for example, about research or new medical treatments, think about whether you should post these in your own name or through a corporate UMCG account. Consider the interaction, signals and consequences of a post on social media. Bear in mind that as a social media user you are not only regarded as a person, but possibly also as a UMCG representative of a certain profession and as a UMCG ambassador. It is therefore important to maintain a distinction between personal and professional use and always to refrain from making unfounded statements and comments. Finally, you must never post any information, including confidential information, about patients or colleagues, or information that can be traced back to them, on social media. A ‘Handreiking voor UMCG’ers bij gebruik van social media’ [Manual on the use of social media for UMCG staff] is available from the UMC Communication department, and the KNMG has published the ‘Artsen en Social Media – Handreiking voor artsen’ [Physicians and social media – Guide for physicians].

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37 UMCG intranet, search path: UMC-staf, Onderdelen, Communicatie, Diensten en Middelen, Social Media (handreiking)

38 https://www.knmg.nl/advies-richtlijnen/dossiers/sociale-media.htm
Appendix

University Medical Center Groningen Complaints Regulation concerning Academic Integrity

Explanatory notes to the Complaints Regulation concerning Academic Integrity

This Complaints Regulation has been compiled following the ‘National Model for Complaints Regulations concerning Academic Integrity’ (Landelijk Model Klachtenregeling Wetenschappelijke Integriteit), which was drafted by the joint Dutch universities to serve as a basis and an example for a Complaints Regulation to be adopted by each individual university. It may also be used by other institutions that have endorsed the Netherlands Code of Conduct for Research Integrity. The UMCG has endorsed the Netherlands Code of Conduct.

The objective of a joint model regulation is to obtain equal treatment of assumed violations of academic integrity as much as possible. The starting points, terminology and procedures will then be as equal as possible to each person dealing with complaints about or about assumed violations of integrity. That is important, as institutions consider themselves accountable for the conduct of each researcher that performs or performed academic research under its responsibility. The institution promises to investigate any substantiated violation of academic integrity.

This Complaints Regulation has been compiled with due regard for Section 9 of the Dutch General Administrative Law Act, as this act may apply to complaints involving public institutions and also because the act provides an adequate guideline for the careful processing of complaints.

1 April 2020
UMCG Complaints Regulation concerning Academic Integrity

Preamble

The Netherlands Code of Conduct for Research Integrity 2018 and the UMCG Research Code that is based on it contain the leading principles of proper and ethical scientific practice and the ensuing standards for proper research practice that are endorsed by the institution and that function for a university as guidelines as meant in Section 1.7 of the Dutch Higher Education and Research Act (WHW).

All those involved in academic research at the institution are personally responsible for maintaining academic integrity. Each person should always strive to carefully comply with the standards. If a violation of academic integrity is assumed, a complaint may be lodged. The institution ensures a careful and fair procedure for the processing of the complaints and the subsequent decision-making. With these aims in mind, the board of the institution has adopted the following Complaints Regulation.

This complaint regulation will be applied by analogy as much as possible if an investigation into a possible violation of academic integrity is started at the request of the board of an institution without a formal complaint.

Article 1 Terms

1.0 Code of Conduct: The Netherlands Code of Conduct for Research Integrity 2018

1.1 Violation of academic integrity: Acts or failures to act that may cause a violation of academic integrity as meant in article 5.2.A.1, 5.2.A.2 or 5.2.A.3 of the Code of Conduct.

1.2 Complaint: A written report about a suspected violation of academic integrity committed by a staff member.

1.3 Complainant: A person lodging the complaint with the Board.

1.4 Respondent: The staff member about whose acts a complaint has been lodged, or of whose acts the Board has requested the Committee to start an investigation into.

1.5 Staff member: A person who has or has had an employment contract with the institution, or who is or has been working otherwise under the responsibility of the institution; this includes persons that are not or are only part-time engaged by the institution to the extent that they participate in the institution’s research or publish their research under the name and responsibility of the institution. Persons having only a supportive role in the research are excluded.

1.6 Confidential Advisor: A person who has been appointed as the confidential advisor for academic integrity by the Board.

1.7 Committee: The committee set up by the Board to handle complaints regarding the violation of academic integrity, in this case the Academic Integrity Committee (Commissie Wetenschappelijke Integriteit, CWI) of the University of Groningen.

1.8 Board: The Board of Directors of the UMCG.

1.9 Supervisory Board: The Supervisory Board of the institution.

1.10 Institution: The University Medical Center Groningen (UMCG).
Article 2 General

2.1 Anyone is entitled to consult the confidential advisor in case of a suspected violation of academic integrity.

2.2 Anyone is entitled to lodge a complaint with the committee, who informs the Board about the receipt of the complaint without delay. A complaint may only be lodged about suspected violation of academic integrity. The complainant must adequately substantiate why they think that academic integrity has been violated.

The CWI will notify the complainant as soon as possible, but at the very latest four weeks after receiving the complaint, whether or not the complaint will be handled. The respondent and the Dean of the Faculty where that person works will also be notified.

2.3 The Board may also request the committee to investigate a case of suspected violation of academic integrity without a formal complaint.

2.4 An anonymous complaint will only be handled if the Committee sees reason to do so as it is of the opinion that:
   a. there are compelling public interests or compelling interests of the institution or the persons involved for doing so, and
   b. the investigation of the facts may be done without the complainant’s contribution.

2.5 If the complaint concerns a member of the Board, the Supervisory Board will perform the role and the powers attributed to the Board in this Complaints Regulation.

2.6 If the complaint concerns a staff member or a former staff member of multiple institutions that have endorsed the Code of Conduct and if the complaint therefore could be investigated by multiple institutions, joint complaint handling may be done, or the institutions concerned could make arrangements about the handling of the complaint. In such a case, the Board will make a decision about the handling of the complaint.

2.7 Everyone is required to cooperate with the confidential advisor or the committee within the reasonable time period set and to answer any questions that may reasonably be put to them within the scope of their powers.

2.8 Everyone involved in the handling of a complaint has a duty of confidentiality regarding the content of the complaint as well as the information that becomes known in relation to the complaint or procedure. The duty of confidentiality continues after the procedure, with the exception of an anonymized report of cases in annual reports or on the website of the VSNU (Association of Universities in the Netherlands). In the case that this duty of confidentiality is violated, the Committee or the Board may apply suitable consequences.
Article 3 Confidential Advisor

3.1 Appointment
a. The Board will appoint one or more confidential advisors for a period of four years. Members may then be reappointed for successive terms of four years.
b. The confidential advisor should have an academic background, have an irreproachable academic reputation and be able to deal with controversies and conflicts well. The confidential advisor may not hold any additional positions that may hinder their functioning as a confidential advisor.
c. Members of the Supervisory Board, members of the Board, the Deans and the Vice Deans of the faculties and the members of the committee may not be appointed as confidential advisor.
d. The Board may terminate an appointment prematurely
   - at the request of the confidential advisor
   - if the confidential advisor no longer satisfies the requirements for appointment
   - due to unsatisfactory performance as a confidential advisor.

3.2 Duties
The confidential advisor
   - is an easily accessible port of call for questions or complaints about academic integrity
   - will try to mediate or settle the complaint if they see possibilities for doing so
   - will show the complainant how to lodge a complaint with the Board
   - may not represent the complainant and the respondent at the same time
   - only acts on behalf of the complainant and the respondent with their consent.

3.3 Accountability
The confidential advisor will report on their activities to the Board afterwards in an annual report compiled for the annual report of the institution. The report covers the cases handled and the activities performed in general terms. The report may not be traceable to any persons. Further, the confidential advisor must keep all information that they acquire in their position confidential. This point may only be deviated from with the explicit consent of the complainant and the respondent.

Article 4 Academic Integrity Committee

4.1 Appointment and composition
a. The Board should set up an Academic Integrity Committee, consisting of a chair and at least two other members. One of them should preferably be a legal specialist.
b. The chair and the members are to be appointed by the Board.
c. The provisions of Article 3.1 apply equally with the proviso that a confidential advisor may not be eligible to be appointed chair or member of the Committee.
d. When appointing members, the Board will aim to achieve a balanced representation of academic areas.
e. When investigating a complaint, the Committee may be temporarily expanded with experts or ad hoc members from within and outside the institution.
f. The Committee will be supported by a secretary.

4.2 Duties
The Academic Integrity Committee investigates complaints, assesses whether academic integrity has been violated and advises the Board on the matter. It may also start an investigation at the request of the Board and issue advice without a formal complaint.
4.3 Powers
a. The Committee will be authorized to ask all staff members and bodies of the institution for information. The Committee may request access to or copies of all documents and correspondences which it considers relevant to its investigation and may seize them or have them placed under seal if the Committee deems it necessary.
b. The documents referred to in the previous paragraph also include the data of the research to which the complaint relates. If the Committee deems it necessary, any non-publicly available parts of the academic research and the related data must be given for inspection to two persons appointed by the Committee. These persons will conduct their inspection under the strictest confidence and will share their findings only with the Committee. The findings concerned will be represented in the advice to the Committee in such a way that the confidentiality of the research or the research data will not be harmed.
c. The Committee may consult experts or other third persons, whether connected to the institution or not. A report will be drawn up of any such consultation. The parties will be informed about the identity of the experts or third persons that were consulted.

4.4 Methods
a. Insofar as the methods of the Committee are not included in these or other regulations, they will be determined by the chair.
b. Unless Article 2.6 is relevant, a complaint will be handled by the chair of the Committee and two other members, as the case may be supplemented by one or more experts or ad hoc members. The experts and ad hoc members will be appointed by the Board at the request of the Committee.
c. Members of the Committee who, in whatever capacity, have been involved with the persons or facts of the complaint, or who have another interest in the case, will not be eligible for handling the complaint.

4.5 The start of the procedure
a. Within two weeks of receipt of the complaint, the Committee will inform the complainant and the respondent in writing that it has received a complaint, which procedure will be followed and what the complaint is about.
b. The Committee will assess the admissibility of the complaint on the basis of the following requirements:
   I. the complaint contains a clear description of the suspected violation of academic integrity by one or more staff members and is accompanied by any relevant documents in writing or other means of proof
   II. the complaint is dated and states the name, position and contact details of the complainant. This requirement does not apply in the case of Article 2.4.
c. If the complaint is incomplete, the Committee will invite the complainant to complete their complaint within a period of time specified by the Committee. In that case, the period mentioned in Article 4.5.f will be extended by the period mentioned in the previous sentence or the period in which the supplemented information is given.
d. The Committee has the power to advise the Board to reject a substantive handling of a complaint if:
   I. too much time has lapsed since the suspected violation, or if the complainant has waited unreasonably long with lodging the complaint. As such, a period of 10 years applies in principle
   II. the Committee or a similar Committee has already investigated the complaint
   III. the complainant has violated the duty of confidentiality referred to in article 2.8.
e. The Committee also has the power to advise the Board to reject a substantive handling of a complaint if, after a first assessment, it has come to the conclusion that:
   I. the complaint is evidently unfounded
   II. the complaint is evidently of insufficient interest
   III. the complaint only covers a professional difference of opinions
   IV. the complaint only refers to a conflict in the workplace
   V. the complaint cannot lead to the decision that the acts of the respondent relate to a violation of academic integrity.
f. If the Committee is of the opinion that no substantive handling of the complaint is required, it will advise the Board as such within four weeks.
g. Thereupon, the Board will decide as soon as possible about its rejection of substantive handling and will send its decision to the complainant and the respondent. If the decision is made not to handle the complaint substantively, this is considered an initial decision as meant in Article 5.1.
h. If 4.5.f does not apply, or if the Board applies 4.5.g and decides on substantive handling, the Committee will handle the complaint substantively. The starting point is that the respondent will be deemed innocent until the contrary can be proven.
4.6 Substantive handling of a complaint

a. The Committee will check whether other interested parties, in addition to the complainant and the respondent, must be involved in the procedure. The Committee will hear the parties involved in the complaint. It will at least invite the complainant and the defendant to be heard.

b. The involved parties will be heard together, unless there are compelling reasons to hear them separately. In such a case, each of them will be informed of what has been brought up in the hearing in their absence.

c. A written verbatim report will be made of the hearing.

d. The Committee may make audio recordings of the hearing. The recordings are only intended to assist in making the report. After the Board has made its definitive decision, the recordings will be destroyed. Except for the Committee, no-one is allowed to make audio recordings of the hearing.

e. The complainant and the respondent may be assisted, but not represented, during the hearing.

f. The Committee may hear witnesses and experts, or request experts for a written expert opinion.

g. In view of fair treatment, all relevant information that the Committee collects will be made available to all parties concerned, unless the Committee has serious reasons to deviate from this provision. Any reasons for not making certain information available must be stated in the advice.

h. The hearings and other meetings of the Committee are not public.

i. Within 10 weeks of the receipt of the complaint, the Committee will submit a report of its findings and its advice about the admissibility of the complaint to the Board. It will use the weighting criteria as included in Article 5.2.C of the Code of Conduct. The Committee may extend the 10-week period by four weeks. It will inform all parties involved of the extension in writing. A further extension is possible if the parties involved agree to this in writing.

4.7 Accountability

The Committee will report on its activities to the Board afterwards in an annual report compiled for the annual report of the institution. The report covers the cases handled and the activities performed in general terms. The report may not be traceable to any persons. The members of the Committee and any experts consulted will be otherwise bound to confidentiality about what they have learned about the case in their capacity. This point may only be deviated from with the explicit consent of the complainant and the respondent.

Article 5 Follow-up procedure

5.1 The Board will present its initial decision as soon as possible, but at least within four weeks of receipt of the Committee’s advice. It will inform the complainant, the respondent and any other interested parties of its decision in writing without delay. The report of the findings and the advice of the Committee will accompany the initial decision.

5.2 Within six weeks of the initial decision, the complainant, the respondent and any other interested parties may request the National Board for Research Integrity (Landelijk Orgaan voor Wetenschappelijke Integriteit, LOWI) to give an advice on it.

5.3 If advice of the LOWI is not requested within the time limit stated in Article 5.2, the Board will make its decision concerning the complaint definitive.

5.4 If the LOWI’s advice has been requested, the Board will consider the LOWI’s views before making its final decision.

5.5 The decision of the Board, together with the report of the findings and the advice of the Committee, will be published in an anonymized version on the website of the VSNU after completion of the procedure.

Article 6 Protection of the persons involved

The Board of the institution will ensure that the rights of the complainant and the respondent will be protected and that they will not meet with any adversary consequence in their careers or otherwise. The same applies to any other interested parties, witnesses, experts, the confidential advisors and the members of the Committee.

Article 7 Final provisions

This Complaints Regulation will enter into force on 1 April 2020 and replaces all previous Complaints Regulations in the area of academic integrity in so far as it regards complaints lodged at this date or later.

This Complaints Regulation will be published on the institution’s website.