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

May 2018
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List of abbreviations

BROK  Basiscursus Regelgeving en Organisatie voor Klinische onderzoekers: Basic Training in the Regulations and Organization of Clinical Research
CBP  College Bescherming Persoonsgegevens: Dutch Data Protection Authority
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 Toetsingscommissie: Central Review Board
CWI  Commissie Wetenschappelijke Integriteit: Committee for Academic Integrity
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
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 Toetsingscommissie: Local 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
UMCG  University Medical Center Groningen
VSNU  Vereniging van Universiteiten: Association of Universities in the Netherlands
Wbp  Wet bescherming persoonsgegevens: Dutch Data Protection Act
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
Colophon

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This Research Code has been drawn up under the authority of the Dean of the UMCG, Prof. M. Joëls

With contributions by: Prof. H.W.G.M. Boddeke (Dean of Research), B. Schoenmaker (Director of Business Operations for Teaching and Research), S.R. van Dijk (UG General Administrative and Legal Affairs), H.H. Dijkhuis (Communication Office), R.E. Jager (Legal Affairs), J.W. Hendriksen (Legal Affairs), A.G. Sterkenburg MSc (UMC Research Policy staff department), M.S.E. Oosterling MA (UMC Research Policy staff department), Dr H. Boter (UMC Research Policy staff department), W. Russchen (UMC Research Policy staff department), J.T. Bottema MSc (Surgery), Dr E.L.M Maeckelberghe (Institute of Education), J.A. Bergsma (UMC Quality staff department.), H.M.M. Banus (Graduate School of Medical Sciences), Dr S. Scholtens (UMC Research Policy staff department), Prof. A. Aleman (Neurosciences), Dr C.M.A. Thuring (Central Animal Facility)

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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. As UMCG researchers often work in collaboration with the University of Groningen (UG), the UMCG Research Code ties in with the University of Groningen Regulations for the Protection of Academic Integrity, in terms of both content and procedure. See attachment. Also the UMCG endorses the UG Code of Conduct on Integrity.

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 University of Groningen website and on the UMCG intranet (search term ‘research code’).

In addition to the Research Code, UMCG staff must also comply with several other regulations, such as the Collective Labour Agreement for University Medical Centres (CAO-UMC), the UG Regulations for the Protection of Academic Integrity, 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.

1.3 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.

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1 www.rug.nl, search term ‘Academic Integrity’.
2 UMCG intranet; P&O Handbook; search term ‘integriteit’.
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.

4 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 must 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 must take place within a clear research context or theme.

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

3 For medical research involving human subjects (within the scope of the WMO\(^5\)), the research protocol must be 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 must also be assessed by a review board. Drug research are subject to the rules of good clinical practice. Before a study is started, its research plan must be registered in the Dutch Trial Register\(^6\) 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 Regulation must be assessed in advance by the Central Review Board (CTc: Centrale Toetsingscommissie) or a recognized Local Review Board (LTc Lokale 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 necessary steps in the research process in good time and contributes to the completeness of the project documentation.

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\(^5\) Medical Research Involving Human Subjects Act (WMO); see www.ccmo.nl

\(^6\) 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’.

8 See Table of Contents
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 must be 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 must be 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 must 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 you must refer to the article or book in which a particular theory or thesis was first mentioned. You must also carefully check all references. 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 must clearly specify 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 must 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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8 See the advice of the Dutch Federation of Academic Hospitals ‘Kwaliteitsborging mensgebonden onderzoek 2.0’, October 2012, NFU-12.6053; www.nfu.nl; search term ‘kwaliteitsborging’.

9 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’.
2.4 Ownership of knowledge

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. 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 must 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, within the framework of which inventors may be eligible for remuneration.

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.

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10 UMCG intranet, search path Personnel, P&O Handbook, search term: ‘Nevenactiviteiten en kennis-eigendom’
11 Copyright Act, Article 7
12 See the UG/UMCG publication ‘The Value of Knowledge’: http://intranet.umcg.nl/onderzoek/valueofknowledge2013.pdf or via www.rug.nl/rv
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.\(^{15}\) 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 must share 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 must have an open and critical attitude – irrespective of the situational hierarchy between them – towards the academic goals originally formulated. They must 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 must ensure 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 must 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,

\(^{14}\) [www.amc.nl](http://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.
report or oral presentation. Sometimes the collaboration is confined to a single work package as part of a larger research project.

5 The supervisor must ensure 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 must 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 must be sufficient consultation about how to achieve the final objective. The consultations should 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 must 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 must enclose 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 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’.

17 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.

In addition, the following ICMJE best practices are adopted:

- The individuals who, on the basis of the above criteria, qualify as author must be named as such.
- Each author must 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. Patient data\(^{21}\) and research data must be kept strictly separated.

2. Wherever possible, the researcher must use anonymous or coded research data and biomaterial. Data on patients 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. 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 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 Data Protection Act (Wbp) is involved as well, this is reported to the UMCG Data Protection Official (functionarisgegevensbescherming@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 the UMCG aims to assess all intended population/clinical studies conducted at or by the UMCG that do not fall under 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, Wbp and the Code Goed Gebruik van 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 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 Review Board (CTc) or one of the Local Review Boards (LTcs).

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23 [http://metcgroningen.nl](http://metcgroningen.nl)
25 CCMO Guideline on External Review 2012; see [http://www.ccmo-online.nl](http://www.ccmo-online.nl) ‘Accredited MRECs and multicentre research’.
26 The nWMO system will be gradually introduced in the course of 2018, and will apply to the entire UMCG by 31 December 2018 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 UMCG patients 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 Review Board (CTc) and Local Review Board (LTc)

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 must 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, a new permission must be obtained.

Hazardous substances, in particular microorganisms and radioactive materials, are sensitive to improper use. Researchers must therefore use these substances and materials, and their associated data, 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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27 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.
28 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 (lvd: Instantie voor Dierenwelzijn) must 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 via a secure connection. 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 must draw 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 must in principle be accurate, complete, reliable and authentic and they must be managed in accordance with the applicable ethical and legal frameworks and codes of conduct\(^\text{29}\) – in other words, adequate management of research data during the entire research process, from the design and data collection phases to archiving and publication.\(^\text{30}\)

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 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.\(^\text{31}\)

The minimum storage period for research data is 15 years.\(^\text{32}\) Longer storage periods may be agreed in consultation with the participants involved.

All scientific research involving human subjects that is conducted within the UMCG or by UMCG staff must be registered in the Research Register.\(^\text{33}\) 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.\(^\text{34}\) 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, genetic data or tracking data. In accordance with applicable legislation and regulations,\(^\text{35}\) 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 General Data Protection

\(^{29}\) See: Board of the University, University of Groningen Research Data Policy (February 2015).
\(^{30}\) See also: http://data4lifesciences.nl/hands/handbook-for-adequate-natural-data-stewardship/
\(^{31}\) The Research Toolbox can be found on the UMCG intranet.
\(^{32}\) See the Good Clinical Practice guidelines and the WGBO.
\(^{33}\) The Research Register can be found on the UMCG intranet.
\(^{34}\) 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.
\(^{35}\) ‘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.
Regulation (GDPR) and the Medical Treatment Contracts Act (WGBO: *Wet op de Geneeskundige Behandelingsovereenkomst*) set out rules on how to process medical and other data for scientific research, which the UMCG complies with.

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 must code or pseudonomize all personal data at as early a stage as possible. Data and data files must be 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 privacy accountability document for scientific research 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.

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.

36 Only in very exceptional cases may the consent requirement for providing patient data to third parties be ignored. The possible traceability of the data plays an important role in this respect.
37 Art. 7:458 BW (WGBO).
38 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.
39 The accountability document can be found in the Research Register under the tab ‘Privacy’.
40 Also referred to as Data Protection Impact Assessment (DPIA). The PIA consists of an assignment model/questionnaire. For more information and a format see: http://informatiebeveiliging.umcg.nl
41 This concerns databanks set up outside the hospital information system (ZIS: *Ziekenhuisinformatiesysteem*) and the electronic patient record (EPD/EPIC: *Elektronisch Patiëntendossier*).
National and international multicentre studies in which personal data are processed 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. Every agreement will be assessed by the Loket Contract Research [contract research desk].

The Privacy Task Force (PWO),\(^\text{42}\) 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 Data Leaks (Reporting Obligation) Act stipulates that data breaches must always be reported to the Data Protection Official via 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.\(^\text{43}\)

### 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. For example, when a participant has given written informed consent, he or she must 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 must 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 legislation and contractual agreements. When this principle is specifically applied to research data, this is referred to as ‘Open Data’.

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\(^{42}\) More information about the Privacy Task Force can be found on the UMCG intranet: http://informatiebeveiliging.umcg.nl.

\(^{43}\) 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
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. 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. 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. 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/.

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’). 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. Within the UMCG, the FAIR data catalogue can be used, 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.

44 UMCG researchstrategie-op-hoofdlijnen 2018, reference 18.3553302/RvB
46 The UG/UMCG policy with regard to Open Access can be found at: http://www.rug.nl/library/open-access/
47 The FAIR data principle discusses the characteristics of research data and states that these must be Findable, Accessible, Interoperable and Reusable.
48 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.
49 See: 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.\(^{50}\) 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\(^{51}\) 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.\(^{52}\) 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.\(^{53}\) The Collective Labour Agreement for University Medical Centres (CAO-UMC) contains clear guidelines pertaining to this matter.


\(^{51}\) [https://www.knaw.nl/shared/resources/actueel/bestanden/wetenschappelijke_onafhankelijkheid.pdf](https://www.knaw.nl/shared/resources/actueel/bestanden/wetenschappelijke_onafhankelijkheid.pdf)


\(^{53}\) UMCG intranet, search path Personnel, P&O Handbook, search term: ‘nevenwerkzaamheden’
6.2.1 Additional activities

The CAO-UMC\textsuperscript{54} stipulates that the Board of Directors must give its prior consent in the event of ancillary jobs that:

- may affect the interests of the hospital
- may harm the functioning of the hospital and its staff
- and that may be incompatible with the staff member’s duties.

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 must 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:

- Research funded by third parties, if the researcher or his/her family have a financial interest in the funding party
- Accepting favours from parties funding research\textsuperscript{55}
- 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
- Situations where UMCG facilities are used
- Putting students and employees to work for a company in which the researcher has an interest
- Improper use of facilities for personal gain or to support a company in which the researcher has an interest
- Associating one’s name or work with the UMCG to benefit from the institute’s goodwill.

Situations where information is used:

- Improper use of confidential information
- 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
- Granting access to the institute’s confidential information to an organization in which the researcher has a financial interest.

\textsuperscript{54} The Collective Labour Agreement is a public law legal status regulation (Art. 9.3) \url{www.nfu.nl}, search term ‘CAO’.

\textsuperscript{55} See also ‘Richtlijn Gunstbetoon door bedrijven’ of the Dutch Federation of Academic Hospitals, \url{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 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

56 [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 Board of the University of Groningen has established Regulations for the Protection of Academic Integrity. 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. These regulations were established on the basis of, and are complementary to, the UG Regulations. 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 UG Regulations for the Protection of 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 University of Groningen Regulations for the Protection of Academic Integrity will be followed.

Below are some examples of additional stipulations for exceptional situations in which the UMCG is (also) involved. This may happen when the accused person is employed by the UMCG or when research is related to the UMCG.

57 The academic background, position and practice of the confidential advisor are set out in the Confidential Advisor Regulations 2013. www.rug.nl search term 'research ethics'.
Exceptional situation: the accused is employed by both the UG and the UMCG, or the accused is involved in a UG/UMCG research project

If a complaint pertains to a person who is simultaneously employed by the UG and the UMCG, the following procedure applies in addition to the procedure set out in the University of Groningen Regulations for the Protection of Academic Integrity:

- Within twelve weeks of the complaint being lodged, the CWI will advise the Board of the University about the validity of the complaint.
- The Board of the University forwards the CWI advice to the UMCG Board of Directors without delay.
- The Board of the University will hear the Board of Directors on the matter and pass an initial ruling within four weeks of the CWI advice.
- The Board of the University will inform the complainant and the accused person(s) and the Board of Directors of this initial ruling. Complainant and the accused person(s) will also receive a copy of the CWI advice.
- The Board of the University, the Board of Directors, the complainant and the accused person(s) can request the LOWI to issue an advice on the initial ruling of the Board of the University and the Board of Directors within six weeks of the initial ruling. The Board of the University will consider the LOWI's advice (if requested) in its final ruling on the violation of academic integrity.

Exceptional situation: the accused person is employed by the UMCG and not by the UG, or the accused person is involved in research at the UMCG and not at the UG

If the complaint concerns a person or research where the accused person is only employed by UMCG and not by the UG, the following procedure applies. It deviates from the procedure set out in the University of Groningen Regulations for the Protection of Academic Integrity where the competent authority is concerned:

- Within twelve weeks of the complaint being lodged, the CWI will advise the UMCG Board of Directors about the validity of the complaint. The Board of Directors will then inform the Board of the University of the advice.
- The Board of Directors will pass an initial ruling within four weeks of the CWI advice and communicate this to the complainant and the accused person(s). Complainant and the accused person(s) will also receive a copy of the CWI advice.
- The Board of Directors, the complainant and the accused person(s) can request that the LOWI issues an advice on the initial ruling of the Board of Directors within six weeks of that ruling. The Board of Directors will consider the LOWI’s advice (if requested) in its final ruling on the violation of academic integrity.

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 must 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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58 UMCG intranet, search path: UMC-staf, Onderdelen, Communicatie, Diensten en Middelen, Persvoorlichting (‘Leidraad media en beeld- en geluidsopnamen medewerkers UMCG’)

59 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 must 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’[^60] [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’[^61] [Physicians and social media – Guide for physicians].

[^60]: UMCG intranet, search path: UMC-staf, Onderdelen, Communicatie, Diensten en Middelen, Social Media
[^61]: https://www.knmg.nl/advies-richtlijnen/dossiers/sociale-media.htm
University of Groningen Regulations for the Protection of Academic Integrity

Preamble

All those involved in academic teaching and research at the University of Groningen are personally responsible for preventing and drawing attention to academic misconduct. The generally accepted standards for the execution of professional academic research must be met at all times.

The Dutch Code of Conduct for Academic Practice (VSNU 2005, adapted in 2012) expands on the provisions for conducting professional academic research. This Code is supported by the University of Groningen and acts as the guidelines for the University in line with the provisions of Article 1.7 of the Higher Education and Research Act (WHW).

One instrument to test academic integrity is the right of complaint regarding violations or suspected violations of academic integrity.

To implement this right of complaint the Board of the University has adopted the Regulations set out below, which also include a regulation for the investigation of suspected violations of academic integrity at the request of the Board of the University.

Violation of academic integrity: An act or omission that contradicts the Dutch Code of Conduct for Academic Practice, including in all cases the actions included in Appendix 1.

Definitions

Complaint: A report of a violation or suspected violation of academic integrity committed by a member of staff or a researcher associated with the University.

Complainant: A person who presents a complaint to the committee, either via the Board of the University or the confidential advisor.

Accused person: The member of staff concerning whose behaviour a complaint has been submitted.

Staff member: A person who has or had an employment contract at the University, or who is or was working under the responsibility of the University.

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

Academic Integrity Committee (CWI: Commissie Wetenschappelijke Integriteit): A committee appointed by the Board of the University to deal with complaints concerning violations of academic integrity.
Article 1: Academic Integrity Committee

The Academic Integrity Committee (CWI: Commissie Wetenschappelijke Integriteit) is authorized to handle complaints about suspected violations of academic integrity.

The complaints procedure is set out in Articles 2 to 16 of these Regulations. The Committee will also investigate suspected violations of academic integrity at the request of the Board of the University. This is governed by Articles 17 and 18 of these Regulations.

Article 2: Right of complaint

1. Everyone has the right to submit a complaint to the CWI concerning a suspected violation of academic integrity, either via the Board of the University or via the confidential advisor.

2. The complaint referred to in Article 2.1 must relate to a suspected violation of academic integrity perpetrated by an employee of the University or perpetrated in the course of research conducted at the University.

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

Article 3: Appointing the confidential advisor

1. The Board of the University will appoint one or more confidential advisors for a period of four years (after due consultation with the Deans). Members may then be reappointed for successive terms of four years.

2. The requirements for appointment are:
   - being a professor/professor emeritus with a great deal of experience in teaching and research, preferably at one or more Dutch universities
   - an irreproachable academic reputation
   - the ability to handle disputes and conflicts

3. The Board of the University of Groningen may terminate an appointment prematurely:
   - at the request of the confidential advisor
   - if the confidential advisor no longer satisfies the requirements for appointment
   - if the confidential advisor does not function adequately (after due consultation with the Deans)

4. Members of the Supervisory Board, the Board of the University and the Deans of the faculties may not be appointed confidential advisor.

Article 4: Duties of the confidential advisor

1. The confidential advisor will function as the point of contact for questions and complaints about academic integrity and will try to mediate where possible or otherwise resolve the dispute amicably.

2. If no solution within the meaning of Article 4.1 can be found, the confidential advisor will inform the complainant of how to submit a complaint to the CWI.

3. The confidential advisor will report on his/her activities to the Board of the University in an annual report compiled for the Annual Report of the University.

4. The confidential advisor must keep confidential all information that he/she acquires in that position.

Article 5: Composition of the CWI

1. The CWI consists of a Chair-member and two members.

2. Every member has one or more deputies. If a member is absent or is directly or indirectly involved in the complaint to be assessed, the deputy member will take his or her place.

3. After receiving recommendations from the Committee of Deans, the Board of the University will appoint the members and deputy members for a term of three years. Members may then be reappointed for successive terms of three years.

4. When appointing members, the Board of the University will aim to achieve a balanced representation of the University’s academic areas. Preferably, one of the members should be a lawyer.

5. When investigating a complaint, the CWI may be temporarily expanded with experts from inside and outside the University of Groningen.

6. The requirements for appointment are:
a. experience in academic research, preferably gained at one or more Dutch universities
b. familiarity with the University’s governance structure
c. demonstrable academic merit, conscientiousness and discretion
d. the ability to handle disputes and conflicts effectively.

7. Members of the Board of the University, members of the Supervisory Board, confidential advisors, the Deans of the faculties and the directors of teaching and research institutes of the University may not be appointed.

8. Dismissal before the end of the fixed term is possible:
   a. at the member’s own request
   b. due to unsatisfactory performance as a member or deputy member of the CWI
   c. due to an appointment to one of the positions referred to in Art. 5.7.

9. The CWI will be assisted by a secretary from the Department of Administrative and Legal Affairs.

Article 6: Responsibilities of the CWI
1. The CWI will take cognizance of the complaints referred to in Article 1.
2. The CWI will make recommendations to the Board of the University regarding the admissibility of complaints.
3. The CWI will make recommendations to the Board of the University concerning the validity of the complaints it has handled and any disciplinary measures that should be taken.
4. The CWI will arrive at its opinion independently.
5. The CWI will submit an annual report of its work to the Board of the University.
6. The members and deputy members of the CWI, the secretary and the Deans will have a duty of confidentiality regarding what they have learned during the complaints procedure.

Article 7: Powers of the CWI
1. The CWI will be authorized to ask all University staff and bodies for information. It may ask to see any documentation and correspondence it considers relevant to assessing the complaint.
2. The CWI may consult internal or external experts. A report will be drawn up of any such consultation.
3. The CWI will keep a file on every complaint it processes. No information in this file which was provided confidentially will be passed on without the consent of those involved.
4. Insofar as the methods of the CWI are not included in these or other regulations, they will be determined by the Chair.

Article 8: Admissibility requirements
1. The CWI will handle complaints which meet the following requirements:
   a. the complaint has been lodged in writing
   b. the notice of complaint is signed and contains at least:
      1. the name and address of the person lodging the complaint
      2. the date
      3. a clear account of the suspected violation of academic integrity.
2. If the notice of complaint is written in a foreign language and a translation is needed for the complaint to be handled properly, the person lodging the complaint must provide a translation.

Article 9: Handling the complaint
1. The CWI will confirm receipt of the complaint in writing and will notify the Board of the University, the accused person and the Dean of the Faculty where the accused person works/worked that the complaint has been lodged.
2. If one of the conditions for handling a complaint within the meaning of Article 8 is not satisfied, the Board of the University, after receiving advice from the CWI, will declare the complaint inadmissible, on condition that the complainant is given the opportunity to remedy the deficiency within a certain period of time.
3. After receiving the CWI’s recommendations the Board of the University may decide that the complaint will not be handled if:
a. it is related to an act about which a complaint has previously been lodged and that complaint has already been handled
b. it is related to an act which took place more than five years before the complaint was lodged
c. the violation is manifestly not sufficiently grave.

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

5. If the complaint relates to a member of the Board of the University, the Supervisory Board will take the decisions referred to in Articles 9.2 and 9.3 instead of the Board of the University.

6. If the CWI decides to handle the complaint, a copy of the notice of complaint and of any documents accompanying it will be sent to the accused person.

Article 10: Withdrawal of the complaint
1. The complaint can be withdrawn at any time.
2. If the complaint is withdrawn, the CWI’s handling of the complaint will cease immediately. The Committee will notify the accused person, the Board of the University and the Dean of the Faculty where the accused works/worked of this in writing.

Article 11: Concessions
As soon as the accused person has resolved the complaint to the satisfaction of the complainant, the Academic Integrity Committee’s handling of the complaint will stop immediately. The Committee will notify the complainant, the accused person, the Board of the University and the Dean of the Faculty where the accused person works of this in writing.

Article 12: Obligation to hear the parties
1. The CWI will hear the parties involved in the complaint. The CWI will at least give the complainant and the accused person an opportunity to be heard.
2. The hearing need not be held if the complaint is clearly unfounded, or if the complainant has refused the opportunity to be heard.
3. The parties involved will be heard together, unless there are compelling reasons to hear them separately.
4. The meetings of the CWI are not public.
5. A report of the hearing will be drawn up.

Article 13: Reporting to the Board of the University
1. Within twelve weeks of receiving the notice of complaint the CWI will submit a report of its considerations regarding a complaint it has accepted for handling to the Board of the University.
2. In this report the CWI will give its opinion regarding the validity of the complaint and make recommendations about any disciplinary measures which should be taken.

Article 14: Decisions of the Board of the University
1. The Board of the University will present its initial decision within four weeks of receipt of the CWI advice. The complainant and the accused person(s) will be informed immediately. The CWI report will be sent with the initial decision.
2. Before arriving at the ruling referred to in Article 14.1, the Board of the University may, within the time limit laid down in Article 14.1, ask the advice of the National Board for Research Integrity (LOWI: Landelijk Orgaan voor Wetenschappelijke Integriteit).
3. If the LOWI’s advice has been requested, the time limit referred to in Article 14.1 will be extended until four weeks after the LOWI’s advice has been received.
4. Both the complainant and the accused person(s) can, within six weeks of receipt of the decision of the Board of the University, request the LOWI to issue an advice on the initial decision by the Board of the University, in so far as this is relevant to the violation of academic integrity. On request, the CWI will immediately send copies of all documents relating to the complaint to the LOWI.
5. If advice of the LOWI is not requested within the time limit stated in Article 14.4, the Board of the University will make its decision concerning the complaint definitive.
6. If the LOWI’s advice has been requested, the Board of the University will consider the LOWI's views before making its final decision. Within four weeks of receiving recommendations from the LOWI the Board of the University will decide whether to proceed to a new handling of the complaint or to give its final ruling on the complaint and the disciplinary measures to be imposed as a result. It will notify the complainant, the accused person, and the Dean of the Faculty where the accused person works/worked of this in writing.

7. If the complaint relates to a member of the Board of the University, the Supervisory Board will take the decisions referred to in Article 14.1 instead of the Board of the University.

Article 15: Protection of those involved
Submitting a complaint within the provisions of these regulations may not lead to any negative consequences for the complainant, either directly or indirectly, unless the complainant has not acted in good faith. The same applies to witnesses, experts, the confidential advisors and the members of the committee.

Article 16: Unforeseen circumstances
For situations which this regulation has not foreseen, the Board of the University shall decide.

Investigation at the request of the Board of the University

Article 17: Request from the Board of the University
The Board of the University may ask the CWI to carry out further investigation into a suspected violation of academic integrity.

Article 18: Applicable articles
If the CWI investigates a suspected violation of academic integrity at the request of the Board of the University, the following articles of the present Regulations will apply mutatis mutandis:
1. Articles 2.2 and 2.3
2. Article 5
3. Articles 6.3 to 6.6
4. Article 7
5. Article 9.6
6. Article 12
7. Article 13
8. Articles 14.1 to 14.6

Transitional and final provisions

Article 19: Date of commencement
These Regulations were adopted on 19 November 2012 and will come into force on 1 December 2012.

Once these Regulations come into force, the Regulations for the Protection of Academic Integrity adopted in February 2010 will lapse. Any complaints submitted before the present Regulations come into force will be handled according to the regulations which applied when they were submitted.

Article 20: Citation and publication of these regulations
These Regulations may be referred to as 'Regulations for the Protection of Academic Integrity'.

These Regulations will be sent to the Faculty Boards and the directors of the Research Schools and Institutes for their information, and will be published on the University of Groningen website.

The advice of the CWI and the decision by the Board of the University relating to complaints whose contents have been investigated by the CWI will be published anonymously on the VSNU website.

Groningen, 19 November 2012

The Board of the University.
Appendix to the Regulations for the Protection of Academic Integrity

Violating academic integrity

In the academic community, there is general agreement on how an academic should behave and which behaviour should be condemned as violating academic integrity. In the Netherlands, this agreement can be found in the KNAW memo on Academic Integrity from 2001 and the VSNU Code of Conduct for Academic Practice from 2004. The most relevant of the many international texts is the ALLEA European Code of Conduct for Research Integrity from 2011.

Mistakes are made everywhere, and there are many types and levels of misbehaviour. The academic world can only function properly if all the requirements of care, reliability, honesty, impartiality, responsibility and respect are honoured. Academic misbehaviour shames the truth, other academics and society as a whole. The person primarily responsible for preventing misbehaviour, and where necessary punishing, is the employer of the researcher, the university or the research institute.

Regarding the behaviour types listed below, the universities hereby declare that they categorically reject them, are actively fighting them, and if necessary will punish offenders with all the sanctions at their disposal. Violations of academic integrity include the following:

1. **Invention**
The entering of fictitious data. The fabrication or invention of data that is presented as the true results of research. This touches on the heart of academic research and teaching – establishing the truth.

2. **Falsification**
Falsifying data and/or secretly rejecting research results. Data that the researcher is not happy about may never be adapted to the expectations or the theoretical results. Omitting data may only occur on the basis of justifiably good grounds.

3. **Plagiarism of publications or parts thereof, or the results of others**
The academic world can only function with the honest recognition of the intellectual property rights of everyone’s contribution to knowledge. This applies to the entire range, from student essays and theses to academic publications and dissertations. This covers not only direct copying, but also paraphrasing, leaving out notes or sources, secretly using data, designs or tables gathered or created by others. Copyright offers victims the possibility of redress via the courts, but even when there is no immediate victim (or not anymore), a researcher can be accused of plagiarism.

4. **Deliberately ignoring and not recognizing the contributions of other authors**
This is a form of misbehaviour related to plagiarism. Deliberate and significant violations that cannot be resolved by the academic community itself should be presented to the Academic Integrity Committee for an independent decision.

5. **Unfairly presenting yourself as author or co-author**
A researcher may only be listed as co-author in a publication if he or she has made a clear contribution in the form of ideas and expertise, research or theory-building. A researcher who links his or her name to a publication has, as far as possible, ensured the accuracy and integrity of the contents.

6. **Deliberately misusing statistical and other methods and/or deliberately misinterpreting results**
The interpretation (statistical or other) of research data and of empirical results is part of the academic discourse, and this also applies to the question of whether the interpretation is correct or incorrect. This can only be marked as misconduct if the incorrect presentation of matters and the presentation of unfounded conclusions is persevered in even after the academic community has come to a unanimous decision. If necessary, the CWI can come to such a decision with external peers.
7 Being culpably careless when conducting research
Misbehaviour is only at issue when the researcher goes further than mistakes and carelessness and does not adapt his or her actions after serious and well-grounded criticism. A CWI can order an investigation to see if this is at issue.

8 Permitting and concealing the misconduct of colleagues
A researcher or manager has a duty of care towards the academic world as a whole, and in particular towards the researchers in his or her direct environment. It must be recognized that the authority relationships in academia, for example between a supervisor and a PhD candidate, do not make it easy to complain about colleagues.