

Researchcode

University Medical Center Groningen

Basis principles for
medical scientific
research

September 2013



university of
 groningen



University Medical Center Groningen

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Basic principles for medical scientific research

Procedure for the reporting of (suspected) breaches of academic integrity

September 2013

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List of Abbreviations

BROK	Basic Training in the Regulations and Organization of Clinical Research
CBP	Dutch Data Protection Authority
CCMO	Central Committee on Research Involving Human Subjects
CRAZ	Client Board of University Hospitals
CWI	Committee for Academic Integrity
DEC-RUG	University of Groningen Institutional Animal Care and Use Committee ¹
GSMS	Graduate School of Medical Sciences
ICMJE	International Committee of Medical Journal Editors
KNAW	Royal Netherlands Academy of Arts and Sciences
LOWI	National Board for Research Integrity
METc UMCG	UMCG Medical Ethics Review Committee
NWO	Netherlands Organization for Scientific Research
O&O-raad	Research and Education Board
VSNU	Association of Universities in the Netherlands
Wbp	Dutch Data Protection Act
Wet BIG	Individual Healthcare Professionals Act
WGBO	Medical Treatment Agreement, book 7, part 5 of the Netherlands Civil Code
WMO	Medical Research in Human Subjects Act

Colophon

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www.umcg.nl

¹ <http://www.rug.nl/umcg/research/animal-testing/animal-care-and-use-committee>

Preface

Over the past decades, the scope of academic research has grown explosively and its societal significance has increased. The number of commissioned studies is growing and the general public wants to be informed about the latest developments in science. In addition, external funding bodies often want more control over the (interpretation of) outcomes. This may lead to a significant pressure to produce publications and to achieve positive results. Moreover, because often funding can only be acquired in competitive program, competition among scholars increases as well. Such factors may compromise the carefulness and independence of scientific research.

The UMCG Board of Directors has drawn up a Research Code for the protection and promotion of academic integrity. The UMCG Research Code offers researchers and their supervisors a code of conduct for the correct and ethical performance of research. The Client Board of University Hospitals (CRAZ), the Staff Assembly (Stafconvent), the Works Council (OR), and the Research and Education Board (O&O-raad) all endorse this Research Code. All UMCG employees who carry out or conduct research within or on behalf of the UMCG must be aware of the Research Code and act accordingly. For third parties – e.g., funding bodies and sponsors, patients and patient organizations, politicians and society at large - the Research Code provides insight into UMCG's basic principles for research.

The Board of Directors wants to thank the UMCG Research Code Committee for its efforts, which led to this Research Code. The UMCG acknowledges the AMC for making available its Research Code, which partly served as a basis for the present and earlier versions of the UMCG Research Code.

A great deal of dedication is required to turn the Research Code from a document into a practical guideline. This applies to conducting research, but also to education and training. The Board of Directors hopes that the shared rules embodied by this Research Code allow UMCG researchers to maintain their independence and, as a result, their academic integrity. I wish you the best of success with your research!

On behalf of the Board of Directors,
Prof. Dr. F. Kuipers
Dean of the Faculty of Medical Sciences

1 Background & aim

All UMCG employees performing research within or on behalf of the UMCG have the responsibility and duty to prevent and signal behavior that transgresses the boundaries of academic integrity. The UMCG has therefore laid down the basic principles of medical research in the UMCG Research Code. Seeing how, for their research, UMCG employees often work in collaboration with the University of Groningen, the UMCG Research Code ties in with the Regulations concerning the Safeguarding of the University of Groningen Regulations for the Protection of Academic Integrity², both in terms of content and in terms of procedure. These regulations have been added as an appendix to the UMCG Research Code.

1.1 Effective date

The UMCG Research Code 2013 will substitute the UMCG Research Code 2007. The effective date of the UMCG Research Code 2013 is September 1 2013. This implies that all reports written after September 1 2013 will be subject to the UMCG Research Code 2013.

1.2 Scope

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, PhD students and scholarship students, even if they are not employed by the UMCG. Furthermore, the Research Code is useful for third parties, e.g., commissioning parties, funding bodies, politicians, society at large and patient organizations. 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 this Research Code UMCG employees are also subject to other regulations, including the UMC Collective Bargaining Agreement (CAO) and the UMCG Integrity Code³.

1.3 Reader's Guide

Chapter 2 contains the five main principles for medical research and an elaboration of these into rules on behavior and writing. In the next three chapters, these principles will be elaborated on the basis of the themes: mentoring and authorship (Chapter 3), respect for human subjects and animals and the relationship with external parties (Chapter 4). Using a number of examples Chapter 5 describes what is meant by the violation of academic integrity. It also describes the procedure for reporting (suspected) violations. Finally, Chapter 6 gives suggestions on how to deal with publicity in various non-academic media like newspapers and television.

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 5.2.1.

² University of Groningen Regulations for the Protection of Academic Integrity

³ This can be found on the UMCG intranet, under *Handboek P&O*.

2 Basic principles for medical research at UMCG

With its Research Code the UMCG shows how it values academic integrity. Academic integrity concerns the willingness of researchers to give account of the moral and scientific quality of their research. This willingness can only be maintained and blossom in an organization that safeguards a climate of integrity. This code contributes towards such a climate.

It is important to honor and cherish the value of academic integrity, for a violation of this integrity has a direct impact on the reliability of science. It is of the utmost importance that society's trust in science is sustained.

This 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 for scientific practice. Matters will arise that require integrity assessments. It is important that the capricious 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 Five principles

Since 1 January 2005 the Dutch Code of Conduct for Scientific Practice⁴ has become effective at all Dutch universities. The Code of Conduct was updated in 2012. As an academic institute the UMCG endorses the five principles of the Code of Conduct. Whenever these principles are compromised there is an increased risk of violation of academic integrity⁵. Therefore, these five principles apply to all research and all researchers to whom the UMCG Research Code applies.

1. *Due care:*
Scientific 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 his research and in his reporting, and equally in the transfer of knowledge through teaching and publication.
3. *Verifiability:*
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

⁴ URL http://www.vsnul.nl/wetenschappelijke_integriteit.html

⁵ In this context one speaks of "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.

interest. In this respect, they are always prepared to account for their actions. In the case of medical research involving human subjects, the patient's interest must also be carefully considered.

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.

2.2 Rules concerning research

Academic research 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 takes place within a clear research context or theme.
2. The objectives, working method, research methods and so on, of academic research are laid down in a research protocol.
3. In case of medical research involving human subjects (within the scope of the WMO⁶), the research protocol must first be assessed by a review committee: either the Medical Ethics Review Committee (METc) or the Central Committee on Research Involving Human Subjects (CCMO). Changes to a research protocol must also be assessed by a review committee. Clinical trials are subject to the rules of good clinical practice. Before a study is started, its research plan will be registered in the Dutch Trial Register⁷ 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 a number of medical journals, including The New England Journal of Medicine and The Lancet⁸.
4. Most research within the UMCG is performed within a research group or by various research groups jointly. Within a research group there can be a clear allocation of tasks, while certain aspects are performed by the team as a whole, such as determining the method of data collection, assessing and interpreting the data and reporting (the writing process). Regular mutual checks and feedback limit the risk of fraud. Good supervision and feedback prevent plagiarism.
5. The different steps and decisions within the research process are properly documented. By keeping a log (electronically or on paper) of the decisions made during the research process, it is easy to reconstruct considerations afterwards. This offers the researcher and others insight into the course of events during the research.
6. Critical feedback is organized regularly. This could take the form of a discussion on progress or a supervisory or steering committee that is established for guidance of a (PhD student-related) project. For larger clinical trials an external committee is recommended, and, if necessary, a Data Safety Management Board⁹. If the progress of a study is discussed at regular intervals and the results are presented to third parties the risk of fraud is reduced. The participation of UMCG

⁶ Medical Research in Human Subjects Act (WMO) see: www.ccmo.nl

⁷ The data kept by CCMO only show a partial overlap with the Dutch Trial Register.

URL <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. URL <http://www.ccmo-online.nl/main.asp?pid=2&sid=9>

⁸ This is in accordance with the appeal made by the International Committee of Medical Journal Editors.

URL <http://www.icmje.org/>

⁹ See the advice of the Dutch Federation of Academic Hospitals 'Kwaliteitsborging mensgebonden onderzoek 2.0', October 2012, NFU-12.6053, published on the website www.nfu.nl.

employees in supervisory committees is therefore of great value to the quality and integrity of research within the UMCG.

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

2.3 Rules for writing

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

1. References are included in the introduction, the section on materials and methods, and in the discussion of a paper. In the introduction, the relevance of the research is described, often with reference to theories, theses and research results from others. The section on materials and methods refers to the procedures developed by others. In the discussion section, the achieved results are set off against the results of others.
2. A reference is stated as accurately as possible. The rules for referring to papers are fairly explicit. When referring to books and reports, the pages containing the relevant information should also be mentioned, especially when referring to a particular theory or thesis. Linking a single thesis or concept to an entire book does not suffice.
3. In references you must refer to the paper or book in which a particular theory or thesis was first mentioned. You must also check all references personally. Although it is convenient to use references made in other papers, it may lead to errors. Every author must know all references that are mentioned in his own papers. Referring to the primary source material is preferred, yet referring to review papers is becoming increasingly common because of journal requirements regarding the size of a manuscript. In this case, the author must be aware of the content of the original material.
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 entire sections have been copied almost verbatim. Even though extensive citation is not necessarily 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, e.g., a vested copyright.
5. When publishing their scientific papers, authors must always specify their interest (financially or other, possibly conflicting interests), in accordance with the appeal of the International Committee of Medical Journal Editors (ICMJE).

3 Good mentorship¹⁰

Research is often performed by PhD students. In addition to PhD students there are other junior researchers, e.g., polytechnic trainees, academic (master) students, analysts and post doc researchers. Their research takes place under the supervision of a more experienced (senior) researcher (principal investigator). The final responsibility lies with a professor, associate professor (UHD) or tutor. The adequate supervision and training of junior researchers is an important part of good academic practice, as a junior researcher often depends on the supervisor. Within the UMCG the relationship between the supervisor and the PhD student is regulated by the Graduate School of Medical Sciences (GSMS). Outside the scope of the school it is also important to lay down tasks and responsibilities, as described in this chapter.

3.1 Duties of the supervisor

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

- teaching the junior researcher;
- enthusing the junior researcher and showing a keen interest in his or her work;
- (helping to shape or) shaping the desired activities of the junior researcher in concrete terms;
- supervising the junior researcher with an appropriate degree of intensity and respect.

In order to realize these duties, a supervisor shall observe the following aspects:

1. The supervisor ensures that the activities the junior researcher is expected to perform are based on a clear plan. The plan may take different forms and depends on the stage the research project has reached. A plan could pertain to: the elaboration of an idea, drawing up a research protocol, performing literature research, performing experiments, collecting data, analyzing the collected data or preparing a publication or paper. For PhD students at the Graduate School of Medical Sciences this has been regulated by the Training and Supervision Plan, which is kept in the electronic PhD students' registration system Hora Finita.
2. The junior researcher and supervisor agree on the purpose of their collaboration and have specified this purpose in clear terms. The objective may be: the writing of a doctoral thesis (dissertation), paper, report or oral presentation. Sometimes the collaboration is confined to a single work package as part of a larger study.
3. The supervisor ensures that the junior researcher has access to shared facilities and is adequately supported in its use in compliance with relevant standards¹¹. This does not just concern the laboratory or clinical facilities but also access to people with specific expertise within and/or outside the department.
4. 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.

¹⁰ Source: AMC Research Code.

¹¹ E.g. GCP Directive 2005/28/EU, April 8 2005 of the European Parliament, good laboratory practice (GLP), good manufacturing practice (GMP); URL http://www.ccmo-online.nl/hipe/uploads/downloads_cati/EU-2005-28_NL.pdf

5. 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 student will be different from the support given to a PhD student in the final stages of the doctoral research. In the clinical setting the patient's interest should also be factored in where the support given to a junior researcher is concerned.
6. Regular consultations should take place¹² concerning the progress of the junior researcher. Such consultations 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 consultations. Finally, there must be sufficient consultations about how to achieve the final objective (see point 2.), e.g., the doctoral thesis. Preferably, the consultations lead to specific agreements on short-term and (if necessary) medium-term goals.
7. It should be easy for the junior researcher to contact the supervisor. The supervisors 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.
8. The junior researcher and the supervisor have a performance appraisal interview at least once a year¹³ in which the junior researcher and the supervisor exchange views on performance issues.
9. In case of doctoral research, the supervisor and junior researcher agree on a specific and phased educational plan, before the research starts, if possible. The educational plan is part of the Training and Supervision Plan, (see point 1). It allows the junior researcher to familiarize himself with the issues and cast a wider educational net than the research project alone. The educational plan factors in the junior researcher's specific desires.
10. The supervisor and junior researcher should have an open and critical attitude – irrespective of the situational hierarchy between them – towards the academic goals originally formulated. They should be aware that their original hypotheses may prove incorrect, given the research results of others or their own results. If this is the case, the original hypotheses, goals and work plans should be revised.
11. The supervisor shares his knowledge, experience and network with the junior researcher to guarantee the progress of the project. This allows the junior researcher to build his own network, in order to grow as an independent researcher.

3.2 Right to authorship

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

3.2.1 Authorship

Authorship is an explicit way in which accountability is assigned and credit is given for intellectual labor as reported in academic publications, papers and abstracts. Authorship is important for the reputation, academic promotion and appeal of the individual researcher. Authorship is also important for the

¹² The University of Groningen PhD regulations specify that the supervisor must support the PhD student and that he must ensure that there are regular consultations and that the proceedings concerning the thesis and the defense run properly. URL <http://www.rug.nl> search term *promotiereglement*.

¹³ UMC employees are subject to the rules of the UMC Collective Bargaining Agreement where the performance appraisal interviews are concerned.

strength and reputation of the UMCG and underlying parts of its organization, e.g., the departments, research institutes and research programs. Various institutes, academic societies and journals have developed guidelines for authorship. The UMCG endorses the ICMJE guidelines as a basis for authorship. Employees are obliged to follow these guidelines.

Authorship implies that these three criteria are met:

1. A substantial contribution is made to the intellectual concept and design;
2. Original writing or editing of written text;
3. A substantial involvement in the approval of the final version of the eventual manuscript.

In addition, the following ICMJE best practices are adopted:

- The persons 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 (guarantor).
- The mere fact that someone contributes to attracting funds, collecting data, and general supervising 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 superiors and – if there is reason to do so- to the confidential advisor (see chapter 5.2).

3.2.2 Types of authorship

The first, second, last and penultimate authors generally made a more significant contribution to the paper 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 to alternate the first and second author per article.

3.2.3 Responsibilities of those involved in the research

Here, the responsibilities of the various people involved in the research are listed. They are: the (junior) researcher performing the research, the (day-to-day) supervisor, the project leader, the promotor, and the director of the Graduate School of Medical Sciences.

A). The (junior) researcher is primarily responsible for:

- The careful conducting of the research;
- The careful handling of (rights and data of) patients or laboratory animals, and the observing of the legal guidelines and codes (of conduct);
- Correct reporting.

B). The (day-to-day) supervisor is primarily responsible for:

- The (day-to-day) supervision of the researcher, i.e., the supervisor is available almost on a daily basis;
- The practical check on the careful conducting of the research;
- The practical monitoring of the research's progress.

C). The research or project leader is primarily responsible for:

- The quality of the problem definition, design, analysis and reporting;
- A coherent research program of the research line;
- The supervision on progress made by the research line in question;
- Quality policies;
- The monitoring of educational and training activities (e.g., BROK¹⁴ and GSMS courses) and the researcher's career path.

D). The promotor is primarily responsible for:

- The quality of the doctoral thesis (dissertation) to the extent of the thesis being defensible.

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 track 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.

¹⁴ Basic training in the Regulation and Organization of Clinical Research

4 Respect for human subjects and animals involved in medical research

Respect for the privacy of human subjects is part of sound academic conduct. This implies that medical and personal data are properly protected, i.e., the protection and security of personal data for health care and medical research, as well as body material for further use, are ensured. Some examples:

1. Patient data¹⁵ and research data are strictly separated.
2. Wherever possible, the researcher uses anonymous or coded research data and body material. Data on patients that can be traced back to the individual are only collected and only used for research with the patient's consent. For this, the patient will receive written information about the nature of the research and the data needed. The researcher ensures 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 consent¹⁶.
3. Respect for the interest of patients is a prerequisite for motivating participants to take part in medical research, besides ethical and legal considerations. In medical research involving human subjects roughly three types of research can be distinguished:
 - Medical research that includes subjecting persons to interventions or imposing a particular course of conduct upon them, e.g., research into the effect of an experimental drug or product or taking blood samples for research purposes (see section 4.1).
 - Medical research on human body material (blood, tissue, DNA and so on) already available, e.g., because samples were taken in view of patient care (biobanking; see section 4.2).
 - Medical research on data already present in the patient file or yet to be collected (see section 4.3).

4.1 *Medical research involving human subjects*

The Medical Research including Human Subjects Act (WMO) applies to: 'medical research that includes subjecting persons 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 are medical studies in which: a new product/drug is tested, (additional) 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 committee acknowledged by the CCMO. In case of specific types of research the research protocol is assessed by the CCMO itself.

¹⁵ In chapter 4, the term 'patient' also includes donors, participants in medical studies and test subjects.

¹⁶ Art. 7:458 of the Netherlands Civil Code (*Medical Treatment Agreement, WGBO*)

The UMCG METc is a review committee that has been acknowledged by the CCMO. The organization and working method of the UMCG METc have been laid down in regulations¹⁷ and a large number of Standard Working Methods. The CCMO Guideline on External Review 2012¹⁸ applies to multicenter research and to the so called external review of monocenter research. Researchers are to comply with this guideline.

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 (functioarisgegevensbescherming@umcg.nl). See also section 4.3.

4.2 Medical research on human body material

As of November 2012 the UMCG Biobank Regulation¹⁹ became effective. All researchers and studies that fall within the scope of the UMCG Research Code are subject to this regulation. The UMCG Biobank Regulation defines the rules for taking body material to be included in a biobank and the data linked to this. The UMCG Biobank Regulation also pertains to the conditions under which body material taken for diagnostics or treatment can later be included in collections for medical research. The UMCG Biobank Regulation stipulates how such collections must be established, managed, used and ended. Furthermore, the UMCG Biobank Regulation sets the conditions for establishing a new biobank.

Actual research on body material and the data linked to this may only be performed in accordance with a research protocol. Actual research on body material that has been stored in a biobank may only commence after approval of the research protocol by the UMCG METc. Also, the study must have been reported to the Data Protection Official at UMCG.

4.3 Medical research on data

The Wbp and the Medical Treatment Agreement (WGBO) comprise rules on how to inform patients and how to collect, keep and use (medical) data.

In principle, data that can be traced back to an individual may only be used with the explicit permission of the person in question.

In order to be able to use data from a patient file for medical research, the researcher needs to get the patient's permission in writing. Permission is given on the basis of written information about the nature and the purpose of the research. Permission is also required if other researchers wish to use the patient data or want to consult the medical files.²⁰

In exceptional cases patient data may be used for medical research without the patient's permission²¹,. Important conditions for this are the fact that it is not reasonably possible to ask for permission and that in providing the data the patient's privacy is guaranteed. Also, the patient may not have objected to the use of his data for medical research in the past.

¹⁷ Regulations of the UMCG Medical Ethics Review Committee (METc UMCG), February 1 2005, UMCG document 183.491. See: http://www.ccmo-online.nl/hipe/uploads/downloads_cate/Reglement%20METC%20UMCG%20versie%20dd%2001-02-2005.PDF

¹⁸ Guideline on External Review 2012, CCMO, see <http://www.ccmo-online.nl>, search term 'externe toetsing'.

¹⁹ UMCG document 12.272.770

²⁰ Only in rare exceptions the consent requirement for providing patient data to third parties may be abandoned. The possible traceability of the data plays an important role in this respect.

²¹ Art. 7:458 NCC (WGBO)

For research using (medical) data that are already available and that are subject to physician-patient confidentiality, (e.g., data from medical files) the Dutch Federation of Biomedical Societies established a Code of Conduct for the Use of Data in Health Research, also known as the Research Code of Conduct. The Dutch Data Protection Authority (CBP) stated that the Code of Conduct for the Use of Data in Health Research (version 2004) is a correct interpretation of the Wbp and other statutory rules about the use of personal data²². Among other things, the Code of Conduct for the Use of Data in Health Research stipulates that the research protocol for medical research that uses data on identified or identifiable (natural) persons must first be cleared with a medical ethics review committee.

Medical research requires reliable data, which in turn require:

- **confidentiality:** only authorized users have access to the required data;
- **availability:** data is available at the right time and the right place;
- **integrity:** the data is substantially complete and correct.

This translates into requirements regarding data management for medical research in general. The UMCG information security officer can advise on the basis of a risk analysis. Further details are given on the UMCG intranet: <http://informatiebeveiliging.umcg.nl>.

4.4 Respect for laboratory animals

(Medical) research may also involve laboratory animals. Researchers are expected to treat laboratory animals with respect. Laboratory animals are only used for research (and training) if there are no suitable alternatives. The Animal Experiments Act²³ applies. The Act stipulates that animal experiments are only allowed if an acknowledged animal experiment committee has approved the research plan. The researcher must ask the University of Groningen Institutional Animal Care and Use Committee²⁴ (DEC-RUG) for its consent. The DEC-RUG is an acknowledged animal experiment committee that advises the University of Groningen and the UMCG on scientific experiments with animals.

4.5 Relationship of the researcher with external parties, including funding bodies

Traditionally, scientific research performed by academic medical institutes are financed with intramural funds as well as funds provided by external organizations, such as the Netherlands Organization 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 statement of independence of KNAW²⁵ 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 (RvB). Only the Board of Directors, or persons authorized by the Board of Directors may sign research contracts with external funding bodies. This is why every research project that receives (part of) its funding from external sources is first reported to and registered with the UMCG Third Party Funding Office. Among other things, the Office handles the compulsory review of the prospective agreements by Legal Affairs. Since

²² Order of CBP d.d. 19 april 2004. URL

http://www.cbpreweb.nl/downloads_gedragscodes/gedr_FMWW_gkvk.pdf?refer=true&theme=purple

²³ <http://wetten.overheid.nl>, search term: *wet op de dierproeven*.

²⁴ <http://www.rug.nl/fwn/faculteit/bestuur/dierenExperiment/dec/index>

²⁵ URL http://www.knaw.nl/Content/Internet_KNAW/publicaties/pdf/wetenschappelijke_onafhankelijkheid.pdf

January 1 2009, the assessment of research contracts involving patients or healthy test subjects is a statutory task of the METc.²⁶ The assessment is limited to the rules on premature termination of the research and the publication of research data.

4.6 Ancillary activities and conflict of interests

UMCG employees are expected to dedicate their knowledge and capabilities on behalf of UMCG. Any ancillary activities or jobs, whether paid or not, may lead to the presumption of a conflict of interest. This is prevented by a transparent practice and sound balancing process. The UMC Collective Bargaining Agreement contains clear guidelines pertaining to this matter.

4.6.1 Ancillary activities

The UMC Collective Bargaining Agreement²⁷ 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.

4.6.2 Conflict of interests

UMCG considers it to be important that the results of medical research performed within UMCG are published as soon as possible, e.g., via peer reviewed 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 be considered as well. This is where a conflict of interests 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. This is a list of situations that may cause a conflict of interests.

Situations that may lead to research bias:

- Research funded by third parties, if the researcher or his family have a financial interest in the funding party.
- Accepting favors from parties funding research.
- Consulting positions with funding bodies, e.g., companies, government funds and charities. Consulting positions must be transparent to all stakeholders, e.g. by publishing them on the employee 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.

²⁶ CCMO guidelines published in the Netherlands Government Gazette of November 25 2008. URL http://www.ccmo-online.nl/hipe/uploads/downloads_catp/Staatscourant%20CCMO-richtlijn%20onderzoekscontracten.pdf

²⁷ The Collective Bargaining Agreement is a public law legal status regulation (art 9.3) URL <http://www.nfu.nl> , search term: CAO.

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.

Situation in which the researcher deals with himself:

- 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.
- (Compulsory) prescription of textbooks that were (co)written by the staff member.

5 Violation 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 Organization for Scientific Research (NWO) jointly wrote the Memorandum on Academic Integrity²⁸. 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 (complaints on) violation of academic integrity.

5.1 Examples of fraud

This is a list of examples of violation of academic integrity. These examples are taken from the Memorandum on Academic Integrity mentioned above, the AMC Research Code²⁹ 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 data, particularly the omission of any unwanted data.
4. The presenting of fictitious data from 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. Forcing colleagues and subordinates to influence the outcomes of research.
11. Deliberate misrepresentation or biased representation of data and research reports of others. This means: presenting oneself as (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.

²⁸ Notitie Wetenschappelijke Integriteit, over de normen voor wetenschappelijk onderzoek en een landelijk orgaan voor Wetenschappelijke Integriteit. KNAW, NWO en Vereniging van Universiteiten (VSNU) ISBN 90-6984-335-8. URL www.knaw.nl/Content/Internet_KNAW/publicaties/pdf/20011082.pdf

²⁹ See www.amc.nl, tab sheet 'research', search term: research code.

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) 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. The ignoring of established codes of conduct for the handling of data on test subjects.
15. The copying of test designs or software without permission.
16. Unreported multiple submission or publication.
17. Unreported submissions or publications where the sample increases with every next publication and new data are added to data published earlier while the outcomes have not changed.
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 (Board of Directors, Heads of Department) has a duty of care towards science in general and toward the researchers in his immediate circle in particular.

5.2 How to handle complaints about alleged violation of academic integrity

The Board of the University of Groningen 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 the (suspected) violation of academic integrity. The procedure in place at the UMCG is complimentary to the University of Groningen Regulations.

5.2.1 Procedure

A description of how complaints about alleged violation of academic integrity are handled is given below. These rules were established on the basis of, and are complementary to, the University of Groningen Regulations. For complaints about academic integrity the UMCG uses the procedure of the Committee for Academic Integrity (CWI). This procedure is described in the Regulations for the Protection of Academic Integrity.

At the UMCG a confidential advisor on academic integrity has been appointed. The advisor is the first port of call in case of questions or complaints about academic integrity. The confidential advisor will try to mediate or settle the complaint amicably. The confidential advisor may also point the complainant to the possibility of filing a complaint with the University of Groningen CWI. The committee handles cases for the University of Groningen as well as the UMCG.

Anyone involved in academic research is personally responsible for preventing and drawing attention to the violation of academic integrity.

Anyone who suspects or finds that a person subject to the UMCG Research Code (see chapter 1) violates academic integrity may report this to the UMCG confidential advisor (vertrouwenspersoon.research@umcg.nl)³⁰. Complaints may also be lodged through the Dean or with the University of Groningen CWI directly (via email). When the CWI receives a complaint, the

³⁰ The (academic) background, position and practice of the confidential advisor will be laid down in separate regulations.

procedure as set out in the University of Groningen Regulations for the Protection of Academic Integrity will be followed.

Below a number of additional stipulations are given 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.

Exceptional situation: the accused is employed by both the University of Groningen and the UMCG, or the accused is involved in a University of Groningen/UMCG research project

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

- Within twelve weeks after the complaint has been lodged, the CWI advises 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 hears the Board of Directors on the matter and passes an initial ruling within four weeks following the CWI advice.
- The Board of the University informs the complainant and the accused person(s) and the Board of Directors of this initial ruling. Complainant and the accused person(s) 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 following the initial ruling. The Board of the University will consider the LOWI's advice (if given) in its final ruling on the violation of academic integrity.

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

If the complaint concerns a person or research where the accused person is only employed by UMCG and not by the University of Groningen, 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 after the complaint has been lodged, the CWI advises the UMCG Board of Directors about the validity of the complaint. The Board of Directors then informs the Board of the University of the advice.
- The Board of Directors passes an initial ruling within four weeks following the CWI advice and communicates this to the complainant and the accused person(s). Complainant and the accused person(s) also receive a copy of the CWI advice.
- 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 Directors within six weeks following said ruling. The Board of Directors will consider the LOWI's advice (if given) in its final ruling on the violation of academic integrity.

The UMCG wants to establish a safe climate for reporting and acknowledging a violation 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, confidential advisors or members of the committee.

6 Dealing with the media

At the UMCG a lot of good research is being performed that is relevant to the general public. Publicity brings this to the attention of the general public. It strengthens UMCG's reputation as a research institute and increases the acquaintance of researchers and research groups. Moreover, 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 led 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 therefore must 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'³¹ 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 officers³².

Furthermore, the University of Groningen and the UMCG made arrangements about joint communication on medical research.

6.1 *Due caution regarding media contacts*

Popularizing academic 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. One must therefore be cautious of making statements about the possible clinical applications of fundamental research. Many a 'medical breakthrough' reached the general public because the research was led by exciting theoretic vistas rather than the actual scope of the results. When presenting clinical research data, similar caution is required, e.g., concerning the question as to which patients will actually benefit from a new drug or the actual availability of a drug for patients. One must also be cautious when intermediate results appear to point at success. It is very tempting to publicize results prematurely.

6.2 *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 doubt as to the independence of the research, e.g., when the publicity is based on commercial motives. The institute always handles its own publicity. If necessary, the press officers may make arrangements with third parties about a particular allocation of tasks. Giving UMCG's sign of approval to publicity underpins the independence of the research. Clarity on the funding may prevent any doubts on this issue.

6.3 *Publicity about scientific publications*

In case of important scientific publications you are advised to contact one of the press officers at an early stage, especially if a lot of media attention is expected, if the outcomes of a study can easily be misinterpreted or if the research touches upon a controversial issue. You must also factor in the strict

³¹ Intranet UMCG, search path: UMC-staf, Communicatie, Diensten en Middelen, Persvoorlichting (ref. 276.766/RvB)

³² The UMCG press officers are available by telephone 24 hours a day, 7 days a week. During office hours via the secretariat of the UMC Communications Staff, tel. (050) 361 22 00, and outside of office hours the press officer who is on call can be contacted via the UMCG switchboard at tel. (050) 361 61 61.

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 suited, and they prepare the researcher for any interviews with journalists. For more information please refer to the brochure 'Media contacts for scientific staff' at the UMCG intranet under *UMC staf, Communicatie, Diensten en middelen van de afdeling Communicatie*.

Appendix



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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.

Violating 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): A committee appointed by the Board of the University to deal with complaints concerning violations of academic integrity.

Article 1. Academic Integrity Committee (CWI)

The Academic Integrity Committee (Commissie Wetenschappelijke Integriteit = CWI) is authorized to handle complaints about suspected violations of academic integrity. The complaints procedure is set out in Articles 2 to 16 of the present 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 the present Regulations.

Article 2. Right of complaint

1. Everyone has the right to submit a complaint to the CWI concerning 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 will consist of a Chair-member and two members.
2. Every member will have 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 will 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, the confidential advisor, the Deans of the faculties and the directors of the 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. because of unsatisfactory performance as a member or deputy member of the Academic Integrity Committee
 - c. because of 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. In so far 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 involved parties 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 Academic Integrity Committee (Landelijk Orgaan voor Wetenschappelijke Integriteit = LOWI).
3. If the advice of the LOWI 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 advice of the LOWI 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. 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

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.

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