Erasmus MC
University Medical Center Rotterdam

ERASMUS MC RESEARCH CODE

Version 2

Adoption date: **May 2021**

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PREFACE

Acting with integrity must be at the centre of everything we do at Erasmus MC. The Erasmus MC Research Code sets the framework for conducting honest research. It is also the Executive Board's starting point for continuous dialogue with – and between – researchers and research groups about sound science and its associated dilemmas.

This Research Code is not a law book. Instead, it sets a framework for how we should conduct ourselves in research. The VSNU's Netherlands Code of Conduct for Research Integrity is taken as the starting point. The Erasmus MC Research Code contains a description of an ethical scientific climate and an overview of relevant laws and regulations at national, European and global levels, supplemented by Erasmus MC-specific information about our policies and guidelines.

The code as presented here (online) is a dynamic document that is tested at least once a year to keep it up-to-date. We amend and supplement it when necessary. The Erasmus MC-specific components are part of our quality assurance system.

The code is aimed at everyone involved in scientific research.

Prof. Dr. Hans van Leeuwen
Dean and member of the Erasmus MC Executive Board

LIST OF ABBREVIATIONS

BROK	Introductory Course in Regulation and Organisation for Clinical Researchers (Basiscursus Regelgeving en Organisatie voor Klinische onderzoekers)
BSO	Biological Safety Officer
CCD	Central Animal Testing Committee (Centrale Commissie Dierproeven)
CCMO	Central Committee on Research Involving Human Subjects (Centrale Commissie Mensgebonden Onderzoek)
CGR	Code for Pharmaceutical Advertising (Code Geneesmiddelen Reclame)
CIOMS	Council for International Organisations of Medical Sciences
CPO	Consultation Centre for Patient-Oriented Research (Consultatiecentrum voor Patiëntgebonden Onderzoek)
CSB	Centre Specific Meeting (Centrum Specifieke Bijeenkomst)
DEC	Animal Experiments Committee (Dierexperimentele Commissie)
DRE	Digital Research Environment
ECB	Erasmus MC Central Biobank
EDC	Experimental Animal Centre (Erasmus Dierexperimenteel Centrum)
ELN	Electronic Laboratory Notebook
FCOI	Financial Conflict of Interest
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HDP	Health Data Platform
ICH	International Conference Harmonisation
ICMJE	International Committee of Medical Journal Editors
KNAW	The Royal Netherlands Academy of Arts and Sciences (Koninklijke Nederlandse Akademie van Wetenschappers)
LOWI	National Board for Research Integrity (Landelijk Orgaan voor Wetenschappelijke Integriteit)
MDR	Medical Devices Regulation
METC	Medical Ethical Committee (Medische Ethische Toetsingscommissie)
MVF	Environmental Safety Officer (Milieuveiligheidsfunctionaris)
NFU	The Netherlands Federation of University Medical Centres (Nederlandse Federatie van Universitaire Medische Centra)
NRIN	Netherlands Research Integrity Network
NWO	Dutch Research Council (Nederlandse organisatie voor Wetenschappelijk Onderzoek
NVWA	Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit)
PKO	Privacy Knowledge Office
PSI	The Parelsnoer Institute
TTO	Technology Transfer Office
VSNU	Association of Universities in the Netherlands (Vereniging van Samenwerkende Nederlandse Universiteiten)
WGBO	Medical Treatment Contracts Act (Wet op de Geneeskundige Behandelingsovereenkomst)
WHO	World Health Organisation

WMA	World Medical Association
WMO	Medical Treatment Involving Human Subjects Act (Wet medisch wetenschappelijk onderzoek met mensen)

1. SCIENTIFIC RESEARCH INTEGRITY

1.1 Reading Guide

The Erasmus MC Research Code is primarily a dynamic online document. Its current version can be found on the Erasmus MC website. The code serves as a tool and guide for Erasmus MC employees.

- Chapter 1 contains the most important principles for medical-scientific research in the form of a profile of an honest researcher:
    - We provide a brief overview of the development of the Netherlands Code of Conduct for Research Integrity
    - We describe the core values of an honest Erasmus MC employee
    - We emphasise the importance of integrity management

- Chapter 2 provides an overview of national and international laws and regulations. Material in the blue boxes describes how Erasmus MC helps employees conduct sound scientific research. Additional information can be found through hyperlinks (underlined text).
    - We provide information about various forms of research (such as research with test subjects, body materials or animals)
    - We provide an overview of Erasmus MC policies in areas such as data management, intellectual property, inducements and publishing

- Chapter 3 contains an overview of all relevant links mentioned in this document.

- Chapter 4 has an overview of amendments from previous versions.

1.2 Why have an Erasmus MC Code of Conduct?

The Erasmus MC Executive Board is responsible for promoting an honest science climate with our available resources. The Research Code plays an important role in this area. All Erasmus MC employees who conduct research within, or on behalf of, the Erasmus MC have the responsibility and the obligation to do so in an ethical manner according to applicable standards. They also have a responsibility to prevent and signal behaviour that does not demonstrate scientific integrity. The code offers researchers a guideline for promoting ethical conduct. To this end, a framework has been developed to indicate how they should act in different situations in accordance with the standards for scientific integrity and applicable laws and regulations. The code also provides a framework for intervention in the event of suspected scientific misconduct.

1.3 The scope of the Research Code

This code applies to all persons involved in research within the Erasmus MC. Employees of the Erasmus MC who are involved in scientific research elsewhere in the world, as well as students and fellows who have no employment relationship with the Erasmus MC, are also expected to carry out their research activities in accordance with this code. In addition, the code is intended for third parties, such as clients, sponsors, politicians, social and patient organisations, to acquaint them with the principles used by the Erasmus MC when conducting scientific research.

1.4 An ethical science climate

History

The Memorandum on Scientific Integrity was drawn up in 2001 by the Association of Universities in the Netherlands (VSNU), the Dutch Research Council (NWO) and the Royal Netherlands Academy of Arts and Sciences (KNAW). The memorandum provided a suggestion for procedures that have now been introduced at universities, NWO and KNAW. The memorandum described undesirable scientist behaviour, and introduced the National Board for Research Integrity (LOWI). The LOWI is the central professional body for decentralised complaints procedures in the event of a suspected violation of scientific integrity. Following this memorandum, the VSNU prepared a second document: the Netherlands Code of Conduct for Academic Practice (2004, revision 2012, 2014).

Netherlands Code of Conduct for Research Integrity

In 2018, at the initiative of VSNU, KNAW, NFU, NWO, the TO2 Federation (a collaboration between institutes of applied research) and the Netherlands Association of Universities of Applied Sciences, the Code of Conduct was revised by the Committee for the revision of the Netherlands Code of Conduct for Research Integrity and renamed the Netherlands Code of Conduct for Research Integrity. In this code of conduct, the emphasis is on desired behaviour, focusing on a number of moral qualifications. Five principles are defined: honesty, scrupulousness, transparency, independence and responsibility.

It also sets standards for good research practices, followed by duties of care for institutions to create a working environment in which these practices are promoted and guaranteed. The Code of Conduct formulates a number of duties of care for the institutions that subscribe to the code. These include commitment in areas such as training and supervision, research culture, data management, disclosure and dissemination, and ethical standards and procedures. The new Code of Conduct can apply to both public and public-private scientific research in the Netherlands. It also explicitly encompasses cooperation and multidiscipline approaches.

The last part of the new Code of Conduct describes how to deal with potential violations of scientific integrity by using weighting criteria to arrive at a balanced judgment. The Erasmus MC, like all other Dutch universities, endorses this Code of Conduct. The Research Code is an Erasmus MC-specific elaboration and supplement to this Code of Conduct.

More information about Research Integrity can be found on the KNAW website (under the theme Research Integrity), and the website of the Netherlands Research Integrity Network.

1.5 Profile of an ethical Erasmus MC researcher

Honest, careful and transparent
A qualified and competent scientist works carefully and conscientiously when conducting research. The scientific value of research results depends on research originality, as well as on the care taken in design, implementation, data and material management, processing and reporting. The steps of the research process are planned and accurate, and are documented in such a way that the research is reproducible and findings are verifiable and accessible.

Data is handled and stored with integrity, in compliance with the General Data Protection Regulation, and in such a way that it can be viewed by third parties if required. When publishing results, the scientist shows respect for fellow scientists and students through careful acknowledgment of the source, honest mention of everyone who has made an original and substantial contribution, and careful disclosure of relevant interests. Human research also emphasises an awareness that findings can lead to new treatments and changes to existing guidelines.

Communication about research findings (including non-scientific expressions and public appearances) is fair and careful, and does not raise expectations that cannot be met. Above all, the ethical handling of research data applies, as described in the KNAW recommendation "Responsible research data management and the prevention of scientific misconduct" (2012).

Independent and impartial
During the investigation process, justice is displayed to all interests and interested parties. The knowledge transfer of research results is unbiased, and is based on the current state of science. Objectivity of substantive knowledge is not damaged by personal preferences or (financial) interests. When considering different interests, the scientist may sometimes encounter moral dilemmas, with different values coming into conflict with each other. If doubts about impartiality and objectivity arise, the researcher consults experts and seeks dialogue, maintaining openness about facts, motives and their own interests.

Responsible and reliable
The scientist can fully account for their scientific work with valid arguments. This way, they can justify their own work while contributing to an honest and fruitful research climate. Taking and giving scientific responsibility requires a high level of knowledge and skills, along with insight into the limits of one's own expertise.

Anyone suspecting or observing a violation of scientific integrity – within or outside of their own research group – is obliged to take action. If possible, the person involved in undesirable behaviour is directly addressed. If this has insufficient results, or is not possible or desirable, the behaviour is raised via hierarchical lines. The scientist can speak to an Erasmus MC confidential counsellor at any time.

Respectful
The researcher must treat patients/test subjects and test animals with respect. A respectful attitude of basic appreciation is also self-evident towards colleagues, subordinates and managers. The doctor or scientist remains aware at all times of the interests of the patient/ test subject or test animal. The

senior scientist takes responsibility for the junior researcher, student researcher or doctoral student through good mentorship, and does not abuse the
hierarchical dependency relationship. The junior researcher is aware of their responsibility and does not behave in a way that exceeds their powers and abilities.

1.6 Managing within an ethical research and education environment

As a (bio) medical scientific research organisation, the Erasmus MC is more than the sum of its individual researchers. Mutual trust is the basis on which joint research projects are established. Managers, in particular, determine a climate in which ethical scientific practice can flourish. They are expected to maintain the preconditions set out in the Research Code and to fulfill an exemplary role in this regard.

Managers are aware of potential pitfalls when concluding agreements for conducting (bio) medical scientific research, and when valorising (the economic and/ or social 'marketing' of) research results. After all, there is always the chance of a conflict of interest or the appearance thereof. Good agreements, transparency and ongoing dialogue about inevitable dilemmas that will arise in this context are therefore essential.

Special attention and care are required when it comes to the education and training of researchers. Within the Bachelor's and Master's programs, attention is paid to the responsible practice of scientific research. In the courses offered to PhD students, academic integrity is part of the curriculum at both the university and faculty levels. This obligation also applies to researchers-in-training as they follow courses in areas such as the design and implementation of human-related research, animal testing and basic statistics.

Managers are aware of their example-setting role, as well as the importance of their role as mentors, influencers, and discussion partners for prospective researchers and research staff, especially in the areas of scientific integrity. The Erasmus MC encourages and facilitates them to shape research in accordance with applicable laws and regulations.

2. LEGISLATION AND REGULATIONS, THE ERASMUS MC POLICIES AND GUIDELINES

2.1 General

This chapter provides a description of (inter)national laws and regulations in the field of scientific integrity in relation to (bio) medical scientific research. Every researcher in the Netherlands is expected to act in accordance with these regulations. Erasmus MC applies all these laws and regulations or has its own policies and / or guidelines based on these laws. The additional policy rules and guidelines specific to the Erasmus MC are provided in separate boxes, and sometimes supplemented with practical information. The following areas of application are distinguished:

- Research with patients and other test subjects
- Research with body materials and patient data
- Research with laboratory animals
- Data management
- Publishing
- Relationships with third parties
- Intellectual property

The Erasmus MC general rules and guidelines

Scientific integrity is part of integrity in a broader sense. In other words, acting with integrity is not just limited to specific activities. It is a matter of mentality and awareness, and is therefore always present. Integrity affects the Erasmus MC's 'corporate identity'. The integrity of an organisation stands or falls with the integrity of its individual employees. The Erasmus MC has rules and guidelines in all areas to promote ethical behaviour among all employees. You can find the following topics on the intranet:

- The Integrity is part of the Erasmus MC brochure (Dutch)
- An explanation of ancillary activities (Dutch)
- The Conflict Resolution Directive (Dutch)
- Media protocols (Dutch)
- The Information security policy (Dutch)
- The Whistleblower procedure (Dutch)

Suspected scientific misconduct

All people within the Erasmus MC take their own responsibility for maintaining scientific integrity. To this end, the general principles of professional scientific conduct must be observed at all times. The Dutch Code of Conduct for Scientific Research Integrity elaborates on these principles, which are also endorsed by the Erasmus MC.

One of the ways we test academic integrity is to provide the right to submit a report if anybody suspects that a former or current employee and / or student of the Erasmus

MC has violated scientific integrity. Of course, the Board of Directors can also decide to initiate or arrange for investigation in the event of a possible violation of scientific integrity. This regulation is based on the National Scientific Integrity Complaints Procedure Model (VSNU, 2019, Dutch) from the Association of Universities in the Netherlands. A description of the implementation of this reporting right can be found in the Erasmus MC Scientific Integrity Complaints Procedure.

2.2 Research with patients or other test subjects

In research, the role of the scientist can be twofold: as a researcher and a practitioner. This dual role entails specific tasks and responsibilities. The researcher knows that tension can arise between their research and the interests of patients and other test subjects. For contract research, tension can also arise between these interests and the financier of the research. The researcher always guarantees the interests of patients and other test subjects. This protection of the interests of test subjects is laid down in legislation and regulations. The sources on which the regulations are based are discussed below.

Declaration of Helsinki (1964, last update in Fortaleza, Brazil, 2013)
This statement is the basic document for the protection of test subjects in medical scientific research. The statement is available on the website of the World Medical Association (WMA).

Guideline for Good Clinical Practice-ICH (2001/20/EG, last update in November 2016)
In the Netherlands, drug research must comply with the International Conference Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. In addition, study medication must comply with Good Manufacturing Practice (GMP) guidelines.

Laboratory research takes place in laboratories that work with a quality system, such as Good Laboratory Practice (GLP), ISO standard 17025 (for test laboratories), or 15189 (for medical laboratories). The ICH-GCP directive can be downloaded from the ICH website.

Medical Devices Regulation (MDR, 2017/745 and 2017/746)
Medical devices and medical devices for in vitro diagnostics make an important contribution to the quality of life and the health of patients. They include a varied group of products – from bandages, artificial hips and pacemakers to laboratory and self-testing equipment.

In May of 2017, the European Parliament and the Council on Medical Devices and In Vitro Diagnostic Medical Devices published Regulation (EU) No 2017/745 and Regulation (EU) No 2017/746.

International Ethical Guidelines for Health-related Research Involving Humans (Council for International Organisations of Medical Sciences, 2002, last update 2016)
The CIOMS, which operates under the auspices of the WHO, has the task of operationalising ethical principles of good scientific research with test subjects for research practice.

The guidelines issued by the CIOMS try to make clear how ethical principles can be applied effectively in practice.

Medical Research Involving Human Subjects Act (WMO 1998, last update in August 2018)

The Medical Research Involving Human Subjects Act (WMO) relates to scientific research in which people are subjected to actions or rules of conduct imposed upon them. The requirements that the WMO sets for research can be found on the site of the Central Committee on Research Involving Human Subjects (CCMO): Legal framework for medical scientific research. The WMO's purpose is to offer test subjects good legal protection and to legitimise bona fide research. For research with minors and incapacitated test subjects, we refer to the following CCMO memorandum: Therapeutic vs non-therapeutic research on minors and incapacitated test subjects (January 2017, Dutch). For information about the assessment of resistance during participation, see: Codes of conduct with regard to the resistance of persons unable to act.

Medical Devices Act (last update July 2020)

The Medical Devices Act implements Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

The regulations aim to ensure the safety of medical devices in several ways: through stricter rules on the marketing of medical devices and stricter supervision of manufacturers and the products they make available to the market.

Ethical Review of research with patients/subjects

Every research project with patients/test subjects must be submitted to an accredited Medical Research Ethics Committee (MREC) in advance. The MREC first performs an initial assessment as to whether the project falls within the scope of the WMO. If the project does fall within the scope of (and is therefore subject to) the WMO, the research protocol is assessed by the MREC against the WMO.

If the project is not subject to the WMO, it must be assessed by a non-WMO review committee. Only approved projects may be implemented in accordance with the approved protocol.

> ***The Erasmus MC MREC***
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> The Erasmus MC MREC (Medical Research Ethics Committee) is a committee recognised by the CCMO on the basis of Article 16 from the WMO. It acts as an independent administrative body, and derives its tasks from the WMO. Please note that the MREC does not perform 'retroactive reviews'. This means that research protocols must be submitted to the MREC in advance so that it can implement its WMO review. The MREC procedures are described on the Erasmus MC website.

Quality assurance for human research (NFU, December 2020)

The Guideline on Quality Assurance for Human-Related Research is aimed at quality assurance for research that is subject to the WMO, but it can also be used for other medical- scientific research with test subjects. The safety of test subjects and the quality of the scientific results are central. The aim is to minimise any participation risks and disadvantages for test subjects. Such risks must always outweigh the added value that can be expected from conducting the research. Topics covered include risk classification, monitoring, reporting to the client and archiving, as well as training and auditing.

Erasmus MC as the provider of research subject to WMO

In 2020, the Erasmus MC renewed the policy measures for clinical research. These policy measures include a mandatory monitoring plan, the decision to deploy a Data Safety Monitoring Board, and the mandatory use of an automated Clinical Data Management System.

Research Suite

To better facilitate both organisation and researcher in the field of IT and data, the Board of Directors initiated the Research Suite programme in 2018.

The Research Suite develops a cohesive ecosystem around IT infrastructure, the (re)use of data and the researcher's digital workplace.

Digital Research Environment (DRE)

Research should not be bound by walls or boundaries. A digital workplace based on cloud technology is therefore being developed in which the researcher can collaborate securely across those walls and boundaries.

Electronic Data Capture

In 2020, Castor was chosen as the Electronic Data Capture system for Erasmus MC to be used for collecting data for research involving human subjects.

Electronic Lab Notebook (ELN)

The ELN (Electronic Lab Notebook) is a web-based programme for keeping track of data. You can use it to structurally organise and recover all the data from your experiments.

The ELN system can store all kinds of data, including protocols, images and raw data, and it has an advanced search facility which can find the precise data you need. There is also a registration system for samples, which means that each sample can be separately tracked and traced.

Health Data Platform (HDP)

The Research Suite is developing a data platform in collaboration with Data & Analytics to make it possible to reuse (healthcare) data for research. The HDP's aim is to enable the researcher to obtain as much necessary data as possible, while still staying within legislation and regulations. The focus will be on data from HiX (EPD) and Labtrain (LIMS).

PaNaMa

The PaNaMa guides researchers in the process of starting up and carrying out research involving human subjects by means of workflows, templates, procedures, actions and tasks. It also offers both insight and an overview of the research already being done in Erasmus MC.

Any new research must be registered in the PaNaMa when it begins. Each department has one or more Super User(s) who can help with the initial registration process.

Storage and Compute

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BROK

The e-learning module Introductory Course in Regulation and Organisation for Clinical Researchers (eBROK) was developed by the Netherlands Federation of University Medical Centres (NFU). It teaches researchers the laws and regulations that apply to people-related research. Information on how to take the BROK course is described in the BROK course's Training and Exam Regulations.

The BROK® consists of an e-learning programme (eBROK®) in Dutch or English and a Centre Specific Meeting. It is designed so that you can process the material at your own pace. The BROK® offers a customised course, tailored to the type of research being conducted and appropriate to the needs of the individual researcher. This course is completed with a digital exam. You are BROK® certified if you have completed the e-learning programme, attended the Centre Specific Meeting and passed the exam.

BROK at the Erasmus MC

Clinical researchers conducting research covered by the WMO within the Erasmus MC are required by the Board of Directors and the MREC to obtain a BROK® certificate before or within 6 months of starting the study. Clinical researchers are understood to mean scientific researchers with the daily responsibility for conducting the research with patients and other participants. The principal investigators are also required to obtain a BROK® certificate. The BROK® obligation does not yet apply to researchers who only conduct non-WMO research.

Centre Specific Meeting

To meet the requirements for obtaining the certificate, you must attend a Centre Specific Meeting (CSB). You can register for a CSB after registering for the eBROK®. During a CSB, information is provided by in-house experts.

Trial register

The Vancouver Group, a joint venture of major medical science journals, decided in 2004 to only accept clinical trials for publication if they are officially registered with a recognised trial register. The purpose of this condition is to identify potential publication bias and reduce any related adverse effects.

Researchers must register their clinical trials in advance with a recognised Trial Register, such as the Dutch Trial Register (www.trialregister.nl) from The Dutch Cochrane Center – a collaboration including, the Ministry of Health, Welfare and Sport, Nefarma (now the Association Innovative Medicines) and the CCMO. Other recognised trial registers are the ISRCTN registry (UK), ClinicalTrials.gov (USA), the EU Clinical Trials Register and the WHO International Clinical Trials Registry Platform (IC TRP).

The registration of clinical trials conducted by the Erasmus MC

All principal investigators employed by the Erasmus MC must register their clinical trials in the Dutch Trial Register. Researchers must register prospective comparative human-related medical examinations prior to the start of the study. The registration of experimental intervention research is mandatory. It is not mandatory for observational research. Research that is subject to the WMO must always be registered in the Dutch Trial Register.

Codes of conduct with regard to resistance from the incapacitated

Researchers conducting scientific research with the participation of incapacitated test subjects must adhere to the following codes of conduct. It is essential to interpret signals that the test subject no longer wants to participate in the study.

The concept of 'resistance' in the context of the Medical Research involving Human Subjects Act (WMO) is further elaborated in three codes of conduct: resistance from incapacitated geriatric and psychogeriatric patients, resistance from minors participating in medical research and resistance from people with mental disabilities.

General Data Protection Regulation (GDPR, May 2018)

The General Data Protection Regulation (GDPR) is the privacy legislation for the entire European Union. The GDPR strengthens and expands privacy rights, gives organisations more responsibilities when it comes to the collection and processing of personal data, and gives the same powers to all European privacy regulators. This also has consequences for the collection, storage and processing of personal data in medical research. The General Data Protection Regulation Implementation Act (UAVG) carries out the GDPR in the Netherlands which has replaced the Personal Data Protection Act since May 2018.

Support services within the Erasmus MC

Consultation Centre for Patient-related Research (CPO)

The mission of the CPO is to stimulate and maintain the Erasmus MC's top position in clinical research. The consultants advise Erasmus MC researchers, from junior to senior, in many aspects of research.

Researchers can contact the consultants directly or first make an appointment to discuss the specific question with the CPO coordinator.

Clinical Trial Agreement

The Erasmus MC's Technology Transfer Office (TTO) answers questions about drawing up and concluding a Clinical Trial Agreement. This also applies to the use of a model agreement between the NFU and members of the Association Innovative Medicines.

Privacy Knowledge Office (PKO)

The Privacy Knowledge Office (PKO) is the knowledge center and source of information for everything in the field of GDPR. Questions can be directed to pko@erasmusmc.nl.

Research Support Office

The Research Support Office supports all products and services that the Research Suite offers, such as the relevant practical guidelines for managing regular research data in accordance with the FAIR principles. A team of experts can be consulted for questions relating to data management in all types of research, such as WMO or non-WMO research, and fundamental and translational medical research. These experts can offer researchers support on the following subjects:

- Data management planning
- PaNaMa registration
- Finding extra space or computing power to process your data
- Digital Research Environment (DRE)
- Electronic Lab Notebook and Castor

2.3 Research with human tissue and patient data

Biobank materials are collected prospectively (de novo), so that they can be used later for new research questions. Possibilities for scientific research with human tissue and associated medical, genetic and other data from patients are increasing, partly due to the emergence of prospective biobanks such as the Parelsnoer Biobank.

Parelsnoer is a facilitating infrastructure within Health-RI (Health Research Infrastructure Initiative) and has partnerships with other (inter)national biobank initiatives such as BBMRI, Lifelines and TraIT.

This type of prospective research does not fall within the scope of the WMO (it is non-WMO research). However, this does not alter the fact that non- WMO research is also subject to clear rules and must be tested in advance. Legislation is currently being prepared in this area – in particular for body tissue. Researchers who use body tissue or patient data must take into account the following laws and rules of conduct:

Code of conduct for health research with body tissue (Code of Conduct for responsible use, Federation of Medical Scientific Associations, 2011, with postscript in 2015)

These rules of conduct are intended for scientific researchers who want to use anonymous or coded human tissue. They also apply to the further use of biobank body tissue that was initially purchased for a different purpose, such as diagnostics.

In addition, they apply to prospective (de novo) biobanks, where biomaterials are collected for future scientific researchthat is not further defined. The design and implementation of these biobanks must follow theguidelines of the Code of Proper Use.

Declaration of Taipei (2002, latest changes in Taipei, Taiwan, 2016)

The "Declaration of Taipei on ethical considerations regarding health databases and biobanks"is a supplement to the Declaration of Helsinki regarding the rights of individuals who provide their tissue or data for research and other purposes based on confidentiality and privacy rules. The English-language statement is available on the World Medical Association (WMA) website.

Control at the Erasmus MC

The following principles apply to the ownership of biomaterial for prospective biobanks at the Erasmus MC:

Partial control over biomaterials and associated data is obtained on the basis of permission given by the Donor. A person who has handed over body tissue to the Erasmus MC has control over the material and can partially transfer it to the Erasmus MC via Informed Consent. The specific type of transfer control is determined by written patient/subject information and Informed Consent.

The Erasmus MC delegates provide control to the scientists employed by the Erasmus MC, who thereby acquire the right to use this material for a specific purpose and for a specific period.

The Donor may withdraw Consent at any time, in part or in its entirety, free of charge and without stating reasons. Instructions for this are described in the information given to the patient when they sign Informed Consent. After permission withdrawal, no new body tissue or data will be collected from the Donor for medical scientific research.

Biomaterials that have only been collected for scientific purposes and have not yet been released from the biobank for that research will be destroyed. Any residual material still available, primarily collected for diagnostics, will be marked in such a way that the biomaterials will no longer be issued for scientific research, but will remain available for diagnostics.

Data and images that have been made available for specific research by the biobank prior to consent withdrawal will remain available in the same form for the purposes of that research and within applicable laws and regulations.

The written information through which the Donor has granted earlier permission must include a section stating that, when withdrawing permission, bodily material that is already under investigation cannot be destroyed.

For further use of biobanks, a specific no objection system applies as described in the Code of Proper Use.

Available infrastructure for the collection of biomaterials and associated data

The Erasmus MC-wide Biobank

The Erasmus MC Central Biobank (ECB) is one, centrally-directed, Erasmus MC-wide biobank consisting of different structured collections of human-derived materials (including cell lines, organoids and xenografts) and / or images linked to related clinical and / or epidemiological data, available for scientific research.

In order to guarantee the quality of the samples and to promote the reproducibility of results, biomaterials can be collected via the Erasmus MC Central Biobank collection points, such as Clinical Chemistry and Pathology. Work can also be done before and after saving the samples.

Centralised and standardised storage can also be arranged via this service platform.

Erasmus MC has established central Biobank regulations (version 2, April 2019). This regulation applies to the collection, storage, publishing and use of all human tissue and associated data for medical scientific research at the Erasmus MC. These collections are managed and documented by the ECB.

This regulation does not include:

- The use of human embryonic or foetal tissue for scientific research, regardless of how it was obtained. Requests must be submitted to the CCMO in accordance with the Embryo Act.
- Collections of body tissue primarily intended for therapeutic purposes or any other reuse in or on the patient.
- The storage of tissue that originates from a human body and has been made available to science.

Laws regulating germ cells and embryos (Embryo Act 2002, last change September 2013)

The Embryo Act (Dutch) stipulates that research with (residual) embryos must be assessed in advance by the Central Committee on Research Involving Human Subjects (CCMO). Research on reproductive cells made available specifically for this purpose must also be assessed in advance by the CCMO. The Ministry of Health, Welfare and Sport has drawn up a manual for the practical application of the Embryo Act.

Code of conduct for the use of personal data in scientific research (2005, consultation version 2017)

The Association of Universities in the Netherlands (VSNU) has drawn up a Code of Conduct (Dutch) for the use of personal data in scientific research. The Code of Conduct states that data that could be traced back to persons must be destroyed after research, unless there are compelling arguments that make it necessary to keep the data for longer.

Code of conduct for health research with patient information (Code of Conduct for the Use of Data in Health Research, Federation of Medical Scientific Associations, 2003, status 2019)

The code of conduct for health research is intended for care providers and / or scientific researchers who want to make use of anonymous or coded patient data. The code of conduct contains rules for protecting the rights of participants in data research.

For the purposes of this code of conduct, research is defined as: medical research (such as patient-related research, epidemiological or health care research) using data that is already available or can be collected for that purpose, and to which professional secrecy applies as defined in Article 88 of the Individual Healthcare Professions Act.

Health research within the meaning of this Code of Conduct does not include scientific research as referred to in the Medical/Scientific Research involving Human Subjects Act (WMO) and as described in Article 1b of that Act. Work is currently underway on a revision of this code of conduct.

Research with patient data at the Erasmus MC

For information about the use of personal data in scientific research, please contact the Privacy Knowledge Office at pko@erasmusmc.nl.

2.4 Research with laboratory animals

The law states that the use of animals for research and education is not permitted unless justified by the importance of the goal, and unless the results cannot be obtained otherwise. A recognition of the intrinsic value of the animal comes first.

The Experiments on Animals Act (last revision in January 2019)

The Experiments on Animals Act, the Experiments on Animals Decree and the Animal Testing Regulation (all Dutch) help to implement Directive 2010/63/EU. They focus on the responsible use of laboratory animals and limiting animal testing as much as possible according to the 3R principle: Replacement, Reduction and Refinement.

New elements also include transparency (inter alia the publication of non-technical summaries of granted project permits) and the specific competences of employees who work with animals (care, handling, and killing) or who determine the design of the research.

Ethical assessment of research with laboratory animals

Animal testing may only be conducted in the context of a project for which a project permit has been granted. Project permits are issued for a maximum of 5 years by the national Central Animal Testing Committee (CCD, Dutch), an independent administrative body. The project permits must be applied for by the institution's permit holder.

The permits are issued to the institution's license holder. The responsible researcher is primarily responsible for implementation in accordance with the permit.

Each license holder must establish an Animal Welfare Authority (IvD) for:

- advice on animal welfare and best practices, including outside the implementation of projects;

- supervising the implementation of projects and checking compliance with the permit;
- assessing and advising on test designs and proposed methods;
- advising on 3R alternatives and evaluating animal tests with a view to this.
- The development and implementation of alternatives must always have the attention of every researcher who works with laboratory animals.

The license holder must designate named persons for:

- monitoring compliance with the law;
- promoting and monitoring the competence (expertise and ability) of employees for their work, including the availability of information in that context;
- responsibility for the care and welfare of the animals;
- expert veterinary supervision of animal welfare.

These functions are embedded in the IvD, including the implementation of the institution's various registration and reporting obligations.

The IvD advises on the preparation of project proposals before they are submitted to the CCD for testing. New project applications are only offered by article 9 group leaders / principal investigators (PIs) and are supervised by the IvD in order to ensure high-quality application.

The CCD determines whether a project permit is granted, partly on the basis of the advice of the Animal Experiments Committee (DEC). Institutional license holders may express their preference for a specific DEC when submitting a project license application to the CCD. The CCD generally follows that preference, but can also submit the request for advice to another DEC.

Based on the project permit application, a DEC tests whether the importance of the animal test outweighs the degree of discomfort the test animal will experience. It must also be clear that no real alternatives are available. If the use of laboratory animals is unavoidable, their welfare must be guaranteed as far as possible, and the number of laboratory animals must be limited to what is necessary to achieve the objective.

The Erasmus Experimental Animal Center

The Erasmus Experimental Animal Center (EDC) is the centralised facility for animal experimental research at the Erasmus MC. The EDC supports the organisation and the researchers in complying with the specific laws and regulations concerning the keeping and use of (test) animals. It provides the acquisition, accommodation and care of laboratory animals and support in the conduct of animal testing in a broad sense, including the care of animal health and welfare, and the environment.

It offers facilities and support for conducting animal experiments, the targeted education and training of practitioners, professional assistance, and the use of equipment. The Responsible use of animals, human and animal safety and the quality of research are paramount.

Animal Experiments Committee

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The Erasmus MC employs a recognised Animal Experimental Committee (DEC) when applying for permits.

The Article 9 officer within the Erasmus MC

A researcher who wishes to conduct animal experiments must meet the requirements for expertise set out in Article 9 of the Animal Testing Act. The researcher must be an expert in the field (holding at least a relevant Masters degree) and must have successfully completed a course in laboratory animal science. The course focuses on the careful and responsible use of laboratory animals in research, and results in the official designation as an Article 9 officer.

Masters degrees within the European economic area are accepted without additional assessment. An additional assessment is necessary for recognition in all other situations.

Animal-specific knowledge is also required in the setting up of animal tests and to carry out actions on animals. In addition, the specific competency (expertise and ability) must be demonstrated or acquired. Employees who care for, treat or euthanise animals must be qualified to do so – that is, they must be holders of a legally-recognised diploma, supplemented by demonstrable practical competence (expertise and ability). There is no automatic recognition of international qualifications. Foreign qualifications must be assessed, and exemptions possible only in selected cases for the performance of specifically-mentioned activities.

2.5 Research with GMOs and infectious agents

Research with GMOs has various applications. This doesn't just concern in vitro research, but also research with laboratory animals (in vivo). GMOs are also increasingly being used in patients (gene therapy). The legislation and regulations for work with GMOs consist of the Decree on Genetically Modified Organisms in the Environment 2013 (Decree on GMO / Regulations on GMO).

Information about working with GMOs, legislation and regulations and the permit database can also be found on the website of the National Office for GMOs. In addition, information can be found on the website of the National information Point for Access and Distribution of Benefits.

Nagoya Protocol (EU Regulation 511, 2014)

The Nagoya Protocol describes the rights and obligations for countries that have signed it. As of October 2014, the protocol gives countries that possess genetic resources the opportunity to request compensation from citizens and companies that obtain and use these resources. This compensation must be reasonable and equitable, and countries may not refuse access to these resources. The countries in which users are located have an obligation to monitor users for the correct use of these resources.

Nagoya Protocol Implementation Act (2016, last change January 2019)

The Netherlands adopted the Nagoya Protocol Implementation Act (Dutch) on 16 April 2016. As a result, there is now supervision of the careful use of genetic material in the Netherlands. The NVWA (Netherlands Food and Consumer Product Safety Authority) carries out this supervision. More information can be found on the website of the National Contact Point.

Scientific research with GMOs at the Erasmus MC

The Erasmus MC has appointed Biosafety Officers (BVFs, Dutch). The Board of Directors has mandated duties to these BVFs. This means that they provide information and advice on behalf of the Board of Directors, and monitor and supervise work with GMOs that takes place under restricted use. The Biosafety Officers report directly to the Board of Directors; the latter is ultimately responsible.

Similar restrictions based on the Working Conditions Act also apply to working with classified infectious agents. The BVFs are also responsible for supervising the application of these restrictions in the context of research.

The Erasmus MC also has Environmental Safety Officers (MVFs) who are responsible for working with GMOs that do not take place under stringent physical restrictions, such as clinical gene therapy. The Environmental Safety Officers are comparable to Biosafety Officers. On behalf of the Board of Directors, they coordinate work with GMOs that are introduced into the environment and supervise implementation of this work.

Compliance with the Nagoya Protocol within the Erasmus MC

Researchers at the Erasmus MC are responsible for the careful use of genetic resources falling under the Nagoya Protocol. Documentation demonstrating compliance with this legislation should be kept for 20 years. This documentation should consist of at least prior informed consent (PIC) and mutually agreed terms (MAT).

If researchers receive a grant for research using genetic material that falls under the Nagoya Protocol or if researchers want to market a product based on such material, a Due Diligence Statement must be submitted via the IT system 'DECLARE' which was made available through the EU. You can find further information through the BVF and/or TTO.

Biosecurity Code of Conduct (2008)

The Netherlands is one of the first countries in the world to have a Biosecurity Code of Conduct (Dutch). The aim of this code of conduct for researchers is to raise awareness of the potential risks of misuse of life science knowledge.

The code was drawn up by the Biosecurity Work Group – a body set up for this purpose by the Royal Netherlands Academy of Arts and Sciences (KNAW) – and is intended for knowledge and research institutions. The code of conduct lays down rules for how they carry out their responsibilities and provides starting points for management and sanctions.

2.6 Data management

As an employer, the Erasmus MC is designated by Dutch Copyright Law as the economic owner of all works and new inventions by a researcher. This includes research data (see the Intellectual Property section below). Researchers are expected to collect, process and store research data in accordance

with applicable guidelines. The Netherlands Code of Conduct for Research Integrity emphasises the importance of the verifiability of research results.

For more information about handling research data, we refer to the KNAW publication Responsible research data management and the prevention of scientific misconduct. In addition, we saw the launch of Health-RI, a collaboration between private and public partners. Its goal is to lay the foundation for the future of personalised health through the creation of a sustainable, effective infrastructure for medical research in the Netherlands.

The first result of this initiative is a 'living' document called HANDS (Handbook for Adequate Natural Data Stewardship), a digital handbook for good data stewardship. The associated FAIR data principle (Findable, Accessible, Interoperable, Reusable) is widely recognised in the Netherlands.

Retention and storage periods

There is still no clear legal framework for the retention and storage periods for data (and human tissue) for scientific research. If the research is subject WMO, the Erasmus MC position is to retain all documentation and data for 15 years after the research has been completed / published. However, data from studies with cell or tissue products are retained for 30 years.

For all non-WMO research (including basic and pre-clinical research), a retention period of at least 10 years applies unless there are other agreements to keep it for a shorter or longer period.

Personal research data

Agreements for handling personal research data within the Erasmus MC are laid down in the Erasmus MC Data Protection Policy (2018). Further information can be found on the Legal Affairs Care for Data website.

Sustainable data storage

International guidelines are available for sustainable long-term archiving. The simplest set of criteria is that of the international CoreTrustSeal. These criteria and the associated quality seal are independent of the given field of expertise. An archive that stores data in a sustainable way has a 'trusted digital repository' certificate. In the Netherlands, CentERdata, DANS and 4TU.ResearchData all have this certificate.

Research Data management at the Erasmus MC

Research grant organisations are increasingly making structural data management compulsory. Horizon2020, ZonMw, NWO and other organisations have good reasons for this. After all, good data management promotes scientific integrity and increases the impact of research. At the same time, 'open data' and the sustainable availability of research data funded by public funds for reuse are also increasingly mandatory.

The main requirements are as follows:

- A research request must be provided with a data management section describing how people will handle the data.
- After the application has been approved, the researcher must develop the data section into a data management plan within 4-6 months. This section must describe in more detail how they will deal with data.

Data systems in the Erasmus MC

The Erasmus MC offers researchers a variety of data management and storage solutions:

- CastorEDC is used to collect, validate, clean and manage clinical research data in an approved environment.
- LimeSurvey is a system for the development of digital questionnaires.
- GemsTracker is used when distributing questionnaires/forms/CRFs to a group of persons/patients/care providers/relations with a set of questionnaires/forms and measurement points with complex logistics.
- Digital storage: archive and online storage services.

2.7 Publications

General

A scientific publication formally informs other researchers about the results of research, and offers third parties the opportunity to test the quality of that research. The starting point is that all research results should be available for publication in scientific or professional literature, independently of funding and regardless of the outcome. Publishing is of great importance for science, the career of the individual employee and the institution.

Clinical and biomedical research is increasingly becoming multidisciplinary or multicentre. As a result, publications almost always have several authors. In addition to the fact that a researcher is an author, the order of authorship also plays a role. This position says something about the nature and weight of the contribution they have made to the research.

Although scientific journals sometimes provide guidelines for describing author contributions, in most cases there is no conclusive regulation that defines which contribution justifies which author's position.

General principles for publication are laid down in national legislation (in particular in the Dutch Copyright Law, last update January 2021).

High-quality scientific publications and peer reviews meet certain due diligence requirements laid down in guidelines drawn up by international committees, as shown in the overview below.

International Committees and the ethics of scientific publishing (last update December 2019)

The International Committee of Medical Journal Editors (ICMJE), formerly the Vancouver Group, provides information and consensus guidelines on ethical issues related to publishing

in biomedical journals, such as authorship requirements, potential 'conflicts of interest', and duplicate publications.

The Committee on Publication Ethics (COPE) is concerned with the integrity of the peer review process for scientific publications, in particular within the biomedical sciences. The Guidelines on Good Publication Practice can be found under Code of Conduct at http://www.publicationethics.org/.

Open Access, Plan S

Open Access is a broad international academic movement that strives to make scientific information free and accessible online. The principles of Open Access were laid down in 2003 in the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities. This statement has been signed by all Dutch universities and research organisations.

EQUATOR network: Enhancing the QUAlity of Transparency Of health Research

EQUATOR is an international initiative with guidelines for reporting on various types ofresearch. This includes:

Guidelines for reporting on the main forms of research		
Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	
Quality improvement studies	SQUIRE	
Economic evaluations	CHEERS	

CCMO statement on publication policy, March 2002

When assessing a protocol, medical ethics review committees must take into account the agreements made by those who conduct and perform WMO research. In this statement, the CCMO has laid down its principles regarding the disclosure of research data. This concerns, for example, the rights of different parties involved in an investigation, and the requirement that unforeseen or negative investigation results also be published.

Quality and Predatory Journals

Open Access journals are not by definition of lesser quality than traditional journals. However, there are publishers who abuse the open access model to make money. They charge fees for making publications accessible without organising editorial services and peer reviews.
Information about journals can be found on the websites below:

- DOAJ (Directory of Open Access Journals). All the journals included here have been screened for quality procedures.
- Listof Predatory Publishers. This list contains the names of publishers and journals that may abuse the open access model.

CRediT

Since 2014, the contributor taxonomy – otherwise known as CRediT (Contributor Roles Taxonomy) has been widely adopted across a range of publishers. CRediT is a new approach to authorship which aims to capture the various contributions that go into a scholarly work by providing 14 defined roles.

The roles are intended to provide greater recognition for the work of each author, reduce authorship disputes, and facilitate collaboration. Not all roles may apply to every paper and each author is likely to have contributed in multiple roles.

Publishing guidelines at the Erasmus MC

The starting point for the Erasmus MC is that all results from research carried out at the Erasmus MC must be published. Furthermore, it is not acceptable for industry or other financiers or sponsors to influence the content of scientific publications.

On the other hand, the Erasmus MC is prepared to make agreements about a reasonable period for publication postponement (up to a maximum of 60 days), so that patent applications can be filed in time and the research partner can become acquainted with the content and possibly comment on it.
Information that comes entirely from a research partner (and is therefore not generated by the Erasmus MC) remains the property of the research partner and cannot be published.

The department head has the responsibility within their department to create an environment in which authorship and order of authorship fits as much as possible within the principles of this guideline.

Preconditions for authorship at the Erasmus MC

The starting point for publishing is the ICMJE consensus guidelines, supplemented with the following preconditions:

- Each author must make a substantial contribution to the creative idea, design or execution of the research described in the article and / or to the analysis or interpretation of the data.
- Each employee who makes a substantial (intellectual) contribution to the research, such as drafting or critically commenting on at least a part of the intellectual concepts, is an author of the article.
- Each author has approved the latest version of the entire manuscript, in particular their own contribution. Journals usually demand that all authors sign a statement confirming authorship, sometimes describing the nature and extent of each author's contributions.

- One of the authors takes responsibility for the total article (in principle, this is also the author to whom correspondence is addressed).
- The routine provision of data or material or the provision of financial resources does not justify co-authorship. Mentioning 'acknowledgments' or an overview of contributing persons can do justice to the intended contribution.
- 'Gift authorships' are undesirable.
- Authors are obliged to state potential conflicts of interest, ranging from sponsorship by third parties to the financial interests of each of the authors (disclosure).
- Clinical research must be registered prior to publication in (inter) national databases in conformity to the requirements of clinical journals.
- A non-exhaustive list of possible contributions from authors:

- Initiating the research
- Designing the research
- Designing questionnaires
- Contributing to new reagents or analysis methods
- Conducting research
- Collecting data in combination with another contribution
- Administrative, technical and material support in combination with another contribution
- Data analysis
- Writing important parts of the article
- Writing and approving the final manuscript
- Providing commentary on drafts
- Contributing academic expertise from an Erasmus MC Core Facility

Author position

- Author order must be established through a joint decision by all authors. Agreements about authorships are preferably made in advance.
- The first author is the researcher who has contributed the most to the project, including implementation (for example, a PhD student or a post-doc).
- The last author has often generated the creative idea for the research and has supported it. The last author is generally the group leader.

Auteur affiliation

- An author indicates affiliation to the Erasmus MC if the research is largely carried out under the responsibility of the Erasmus MC, using the research infrastructure and expertise available there.
- A new researcher appointed at the Erasmus MC can still indicate their old institution as an affiliation for publications for research that has been carried out (for the most part) at the old institution. The researcher can, of course, indicate that the corresponding address has changed. Conversely, an Erasmus MC researcher who is going to work elsewhere can also indicate the Erasmus MC in publications about research that was carried out (for the most part) during their appointment at the Erasmus MC. In view of the above principles, it is ultimately up to the researcher, in

consultation with the department head, to make an assessment of the extent of the contribution to an article from the various institutions to which they have been appointed.

- The Erasmus MC maintains, just like other University Medical Centres in the Netherlands, that only publications that actually state affiliation to their own institution are counted as their own production.

Open Access within the Erasmus MC

All authors from the Erasmus MC and Erasmus University Rotterdam (EUR) are obliged to offer their publications in Open Access via the repository of the EUR: RePub.

The latest author's version can be placed in RePub immediately, or after an embargo period, if the journal publisher's policy allows this.

Prevention of publication bias

The Erasmus MC attaches importance to the publication of all data, including data that does not confirm a research hypothesis. This can be published, for example, in specialised journals, so that these publications can be cited, making the data available to a broad (scientific) audience.

Reference checks for dissertations

Since September 2015, PhD regulations have included a stipulation that a supervisor must perform analysis through a plagiarism scan (reference check) during the assessment period within which the doctoral thesis is definitively approved. At the Erasmus MC, this reference check is carried out by the Medical Library.

Assessment of scientific publications and research proposals

The assessment of scientific publications and research proposals from 'peers' is an important part of a researcher's work. These assessments by reviewers for articles and research proposals have serious consequences for the researchers involved. It is therefore important that the assessment is always characterised by high quality, respect and impartiality.

The reviewer must also guarantee the ownership of ideas and confidentiality at all times. It is of great importance that a reviewer does not
respond to a request to review a scientific article or research proposal if the reviewer cannot comply with the above.
The starting points here are:

- The reviewer has no interest in a positive or negative assessment.
- There is no (apparent) conflict of interest: no involvement with the document to be assessed and no involvement with the applicant or co-applicants.
- The content of the document does not exceed the expertise of the reviewer.

Points of attention for the assessment

- A reviewer starts the assessment with a description, in their own words, of the structure and content of the document being assessed.
- A reviewer always provides constructive feedback.
- A reviewer provides a good foundation for points of criticism, with references and suggestions for improvement where possible.
- A reviewer distinguishes between personal preference and scientific inaccuracies.

If fraud is suspected, it is in the interest of science to inform the editor of the journal in question, or the scientific advisory board of the relevant subsidy provider, along with stated arguments and reasons.

2.8 Codes of conduct in relationships with third parties

Guidelines of the Foundation for the Code for Pharmaceutical Advertising (CGR) and the Code of Conduct Advertising for Medicinal Products (2014, latest changes July 2019)

The CGR, established in 1998, is responsible for the design and implementation of self-regulation in the field of pharmaceutical advertising aimed at professionals. The CGR has set up an assessment framework to formulate a code of conduct that is elaborated in guidelines and guiding principles. Some of these also relate to clinical scientific research.

Chapter 6 of this code of conduct states, among other things, the permitted conditions for the sponsorship of scientific research. Chapter 7 discusses openness about financial relationships. For more information, see the CGR website Code of Conduct Pharmaceutical Advertising for Medicinal Products and the Policy Rules for the Medicines Act.

Code of Conduct Medical Devices (2014, last update January 2018)

The Code of Conduct Medical Devices aims to give further substance to careful, transparent and responsible interaction between suppliers of medical devices and the parties involved in decision-making regarding the purchase and / or application thereof, regardless of the setting in which they operate.

Inducements

Since 2018, new rules have come into effect on inducements in both the medical device sector and under the Medicines Act. The purpose of these rules is to regulate the (financial) relationships between suppliers of medical devices or medicines and the people who purchase, apply or prescribe them.

The patient's needs should determine the choice of a specific aid or medicine, not a healthcare professional's personal benefit, and these rules are designed to prevent any deviation from that policy.

The rules prohibit medical device manufacturers and pharmaceutical companies from offering money, gifts or services to their customers. A list of exceptions has been drawn up, but they are all subject to strict terms and conditions. This prohibition applies to both the provider and the recipient. What a provider may not offer or supply, a recipient may not request or accept.

The Health and Youth Care Inspectorate (IGJ) monitors compliance with the prohibition on inducements in the medical device sector. You can find more information on the IGJ website.

Inducements within the Erasmus MC

When balancing the various interests, the employee's (scientific), independence, reliability, care and impartiality – and by extension the Erasmus MC – must always prevail. Even the appearance of dependence, unreliability, carelessness or bias should be avoided.

Balancing interests is not always easy. If in doubt, employees can present the case to their supervisor. In this context, their program director acts as a supervisor for students.

In addition, if employees or managers have any doubt, they can submit the case to a confidential adviser for advice.

Starting point for company inducements

The starting point within the Erasmus MC with regard to dealing with companies can be described as follows: society must be able to count on the sound choices of the Erasmus MC when it comes to knowledge transfer and scientific research activities.

The importance of the Erasmus MC's public tasks must be paramount. In practice, this means that no concessions can be made with regard to the quality, reliability, independence and accuracy of scientific research and knowledge transfer.

Receiving gifts

Receiving gifts in person is permitted, as long as the gift is of limited value and is significant for carrying out work in the field of scientific research and knowledge transfer. No conditions may be attached to the receipt of such a gift.

Employees must realise that the act of giving and receiving gifts can create expectations. A gift can be given as a thank you for cooperation, but it could also be given as inducement for a service or assignment.

In principle, small gifts up to the value of €50 may be accepted, but more expensive gifts may not. If you are in any doubt as to whether or not to accept a gift or an invitation, you should discuss this with a manager.

Inducements and academic education & training tasks

Inducements could potentially lead to activities with and by students, assistants, doctor's assistants and PhD students. Therefore, to prevent conflicts of interest, the following principles should apply:

- During teaching, supervision or training, teachers, supervisors and trainers of medical students, interns, doctor's assistants, researchers and PhD students should not be guided by anything other than purely academic motives in the field of education, training and scientific research.
- Assignments to medical students, interns, doctor's assistants, researchers and PhD students must be aimed at and serve the academic development needs of the person involved.
- The teacher, supervisor and/or trainer must be transparent in any dealings with the student, assistant, doctor's assistant, researcher and/or PhD student with regard to any personal interest they may have on a matter.
- The student, assistant, doctor's assistant, researcher or doctoral candidate must publish the results that arise from their work in the context of the training or research that they carry out.

The above principles also apply to all situations in which employees advise, guide and supervise colleagues.

Giving assignments to companies

Employees of the Erasmus MC may not be involved in giving assignments to companies in which they themselves have an interest. This prevents unwanted conflicts of interest when it comes to valorisation.

Financial Conflicts of Interest (FCOI, January 2020)

Conflicts of interest occur when an employee, or the department/part of the organisation for which they work, has financial or personal ties with other persons or organisations that could possibly influence research or other activities taking place within the Erasmus MC.

Such situations could include accepting so-called ancillary activities such as political, administrative, advisory, shareholder or supervisory positions. The influence of third parties can be extensive or limited.

Financial interests (such as financial claims, advisor fees, shareholder positions, donations and royalties) can be easily identified as potential sources of conflicts of interest. There is a strong chance that such an interest can undermine scientific independence. However, a conflict of interest can also exist without the employee being aware of it.

Conflicts of interest are often associated with the interests of (pharmaceutical) companies, but they can also arise from personal relationships. Sponsored research by the government or other investors can also give rise to conflicts of interest.

The Erasmus MC's general policy in this area complies with the rules and guidelines as described in the Public Health Service's regulation CFR50 Subpart F "Promoting objectivity in research" and describes potential conflicts of interest, as well as the Erasmus MC policy.

Erasmus MC researchers and dealing with the media

Media attention for scientific (bio) medical research is important. Researchers can keep society informed on scientific developments and show how public funds are being spent. Positive reporting can also facilitate fundraising and give research institutions a reputation for solid expertise.

However, there are also risks. It can be difficult to present researcher messages in a nuanced way, which may result in a misleading public view of research results and their application in healthcare. Commercial and political interests can also create undesirable influence. Careful and responsible action is therefore required.

There are rules and guidelines which apply to contact with journalists within the Erasmus MC. The most important rule is: all press contact must go through press officers.

You should never speak to the media without prior consultation with the press officer and only authorised employees or designated experts may speak on behalf of the Erasmus MC. If an employee speaks about the Erasmus MC in a personal capacity, they must identify themselves as an employee and say that they are not speaking on behalf of the Erasmus MC.

When it comes to social media, you are permitted to use your personal title. However, remember that you are the organisation's calling card. Employees can be held legally responsible for what they say and do online.

2.9 Intellectual property

Ownership and protection of research results

As an employer, the Erasmus MC is designated by Dutch Copyright Law as the economic owner of all works and new inventions by a researcher. This means that the researcher may not monetise these products, or use them for purposes other than the performance of their position at the Erasmus MC, without the permission of the Erasmus MC.

A scientific researcher falls under legislation in the field of intellectual property with regard to the results of their research. For example: copyrights on publications and software; patent law on new products or methods.

Intellectual property at the Erasmus MC

The Erasmus MC has an active policy when it comes to the protection and valorisation of knowledge. The scientific departments are supported in this area by business developers and lawyers from the Technology Transfer Office (TTO).

Some important principles of the Erasmus MC's policy when it comes to the valorisation of research results are:

a. The financial benefits of research that is (partially) funded by community funds must be returned to the Erasmus MC in a manner proportionate to supporting further research.
b. The Dutch Patent Act stipulates that the intellectual property (such as an invention) of people employed by a university, college or research institution is the property of the university, college or research institution involved.
c. Scientific freedom, and in particular the possibility of publishing and further using all results for scientific research, must be guaranteed at all times.

There are different forms of legal protection:

Patents

Patent law offers protection for new products or methods. The patent holder has the exclusiveright to market the invention for a period of 20 years.

To ensure that an invention retains its commercial potential, it is important that the invention is protected in time, through the timely application for patent or design protection. The adequate protection of inventions stimulates the transfer of knowledge to business and therefore to society.

To be eligible for patent protection, an invention must meet the following requirements:

Novelty:

The product or method may not be publicly known anywhere else in the world before the dateof filing the patent application, not even by the inventor themselves (for example through inclusion in a dissertation, a public business discussion or a presentation at a trade fair).

Inventiveness:

The inventiveness of an invention is assessed by the relevant authorities. In short, aninvention should not be obvious to a person skilled in that area.

Industrial applicability:

The invention must be a technically-demonstrable, functioning product or production process. Services, natural science theories, calculation methods, medical procedures, or ideas without concrete effect and aesthetic design cannot be protected by a patent. Otherforms of protection may apply, such as copyright, design law or trademark law.

Patent policy and financial aspects at the Erasmus MC

At the Erasmus MC, knowledge exploitation is a means of carrying out one of our core tasks: making the knowledge we develop available to society. Industry will notwant to invest in the further development of inventions that are not protected.
The Erasmus MC applies for patent protection for patentable knowledge that is expected to be of interest to the business community.

Subsequently, TTO, in collaboration with the relevant department, seeks a market player that is able tobring the invention to the market. In 2020, the TTO renewed its patent policy.

Participation Regulation within the Erasmus MC

When researchers get involved in the activities of third parties – particularly with businesses – it should in no way give (or be) cause to doubt the independence of the research conducted at the Erasmus MC.

The Erasmus MC therefore applies rules for the co-participation of researchers, as laid down in the Participation Regulation (January 2020).

Copyright

Anybody who creates a literary, scientific or artistic work can immediately claim copyright protection. Examples of works that are subject to copyright protection include: texts, software, artworks, films, photos, scale models, and construction works. The copyright notice '©' (in combination with the name of the rights-holder and the year of first publication) can be used to state that there is a copyright on a certain work.

The use of this sign is not an obligation in the Netherlands. There are no costs associated with copyright, and protection is based on the Berne Convention almost everywhere in the world.

Copyright at the Erasmus MC

According to Dutch Copyright Law, copyrights on works performed by the employer belong to the employer. An exception to this rule for scientific work currently applies at the Erasmus MC based on case law and literature (the Doctrine of Verkade).

Scientific work must be produced freely. The copyright on a scientific article prepared by an independent researcher therefore belongs to the relevant researcher. If more than one researcher works on a research project and publishes results from it, then the copyright is shared.

This exception does not apply to research reports, textbooks, software or designs, for which the Erasmus MC owns copyright. This also includes educational materials such as syllabi.

Database law and data control

A database is any collection of items or data that is organised systematically or methodically by the creator, and that is also accessible as such. A database does not necessarily have to be electronic, only text-based, or containing works that are protected by copyright.

A database is not automatically protected by database law. To be able to claim protection, there must be a substantial investment in its composition and/or maintenance. This does not just mean a financial investment. Database law was derived from the EU Database Directive, which was worked into national legislation, resulting in the Database Act.

The owner of the database is the institution or person who has compiled it. This does not mean that the individual data becomes the property of this person or institution. The owner of the database can, just like with other intellectual property (IP), license use for a fee. If an external party orders the creation of a database, it may have stipulated that it is the owner of the database.

Databanks at the Erasmus MC

At the Erasmus MC, it is important to guarantee freedom of scientific publication. If a database falling under the definition of database law is mainly established with resources from the Erasmus MC, then the Erasmus MC owns the database.

The Erasmus MC has control over data from research at the Erasmus MC. Case Report Forms (CRFs), lab journals (digital or otherwise) and other written or digitally recorded

research findings are the property of the Erasmus MC. Control over the data has been formally placed with the department heads involved.
However, different agreements can be made through proper consultation.

The Erasmus MC supports the idea of data sharing. Agreements must be made about the use of research data for both internal and external cooperation.

Inventions in use at the Erasmus MC

Pursuant to the Patents Act, the Erasmus MC – as the employer – owns all patentable inventions. This also applies to inventions that have come about “under the shower” – in other words, inventions that may have been thought of while outside of the Erasmus MC – provided that the invention relates to the work of the Erasmus MC scientist involved.

The inventor is entitled to equitable remuneration, and further rules in this regard are laid down in the Patent Policy of the Erasmus MC. All first patent applications (called ‘premier depôts’) submitted for inventions made within the Erasmus MC must be in the name of "Erasmus University Medical Center Rotterdam".

This ensures that the Erasmus MC and the names of the inventors involved become visible in the international patent registers. This also applies to subsidized collaborations and collaborations with industry (see "Inventions in collaborative projects").

Attribution of inventions

In short, the inventor of a patentable invention is the person who has taken the inventive step. Inventive activity occurs when what has been invented is not obvious to a person skilled in the area. It does not matter how the inventor created the invention. It is therefore irrelevant whether the finding was made by accident or as a result of systematic research.

An inventor as described above is not the same as an author of a scientific publication: in most cases there is only one person who has made the substantially inventive contribution and can be listed as an inventor in a patent on that basis.

If there are more inventors, they will of course be mentioned. Determining inventorship when applying for a patent is not optional, and the legal criteria for inventorship must be met. Inventing is not the same as authorship in the publication of a new development. An incorrect listing of inventors, particularly in the US, can lead to the patent being invalid.

Attribution at the Erasmus MC

The inventor within the meaning of patent legislation is entitled to have their name added to the patent application, and ultimately to the patent granted. That is, the inventor can be mentioned as such alongside the owner of the patent: the Erasmus MC.

If employees of the Erasmus MC have contributed to the research project in question without being an inventor within the meaning of the patent legislation, their department head can make further arrangements in the form of a reward or scientific recognition.

Inventions in collaborative projects

Collaborative projects between the business community and the Erasmus MC are common. If such a project results in a new product or process, it is important that the parties make agreements at the outset about the rights to the invention in question. For the knowledge institution, such a project is often part of a broader research program.

To guarantee continuity, IP agreements with cooperative partners must not impede further investigation. TTO's lawyers can provide advice about drafting good cooperative contracts with industry, tailored to the specific circumstances of the case.

Patent applications for inventions made by the Erasmus MC researchers during sponsored collaborative projects should, in principle, be in the name of the Erasmus MC. This will ensure that the Erasmus MC as a research institute becomes visible in the official patent registers. Furthermore, it is particularly important for visibility that the scientists involved be mentioned as inventors in the patent applications.

TTO acts as a central ‘desk’ where a scientist can go first with any questions in the areas of intellectual property, contracts and knowledge valorisation. All agreements involving rights to research results or intellectual property must be submitted to TTO for advice. Patent applications must always be submitted via TTO; the patent portfolio of the Erasmus MC is managed by TTO.

3. REFERENCES

Erasmus MC internet

Medical Research Ethics Committee	https://www.erasmusmc.nl/commissies/metc/
Ancillary activities	https://www.erasmusmc.nl/-/media/ErasmusMC/PDF/2-Themaoverstijgend/Overzicht-Nevenfuncties-wetenschappelijk-personeel-en-hoogleraren.pdf?la=nl-NL
Open Access Publishing	https://medbib.erasmusmc.nl/publiceren/open-access/
Reference check	https://medbib.erasmusmc.nl/publiceren/referentiecheck/
RePub	https://repub.eur.nl/
Technology Transfer Office	http://www.erasmusmc-tto.nl/

Intranet/Topdesk

Financial Conflict of Interest Policy	https://intranet-cdn.prod.erasmusmc.nl/wp-content/uploads/2019/12/12143142/financial-conflict-of-interest-NED.pdf
Brochure: Integrity in the Erasmus MC	https://intranet-cdn.prod.erasmusmc.nl/wp-content/uploads/2020/12/17134712/Integriteit-in-het-Erasmus-MC-2020.pdf
BROK	https://intranet.erasmusmc.nl/servicebedrijf/onderzoeksbeleid-en-advies/research-integrity/brok/?searched=true
Care for Data	https://intranet.erasmusmc.nl/servicebedrijf/control-compliance/juridische-zaken/privacy-knowledge-office-pko/?searched=true
Castor	https://intranet.erasmusmc.nl/programma/research-suite/electronic-data-capture/?searched=true
Consultation Centre for Patient-Oriented Research	https://topdesk.erasmusmc.nl/tas/public/ssp/content/detail/service?unid=7e0c8733a2e44397b7fd99488bbc7037&from=192dd138-2373-4680-8850-362eedca6f2e
Course in laboratory animal science	https://intranet.erasmusmc.nl/corefacility/edc/cursus-proefdierkunde/?searched=true
Data management and storage	http://intranet.erasmusmc.nl/onderzoeksbeleid/researchfac/datamanagementopslag/
Data management plan	https://topdesk.erasmusmc.nl/tas/public/ssp/content/detail/service?unid=cec9f361f26c41f4bdabe8af3ef3e6a1
Digital Research Environment	https://intranet.erasmusmc.nl/programma/research-suite/producten-en-diensten/digital-research-environment-dre/
Animal testing	https://intranet.erasmusmc.nl/corefacility/edc/?searched=true
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Data protection	https://intranet.erasmusmc.nl/carefordata/algemeen/beleid-gegevensbescherming/
Health Data Platform	https://intranet.erasmusmc.nl/programma/research-suite/producten-en-diensten/research-data-platform/
Information Security Policy	https://intranet.erasmusmc.nl/carefordata/informatiebeveiliging/
Management Development	https://intranet.erasmusmc.nl/servicebedrijf/management-development/
Scientific Integrity Complaints Procedure - Erasmus MC	https://intranet-cdn.prod.erasmusmc.nl/wp-content/uploads/sites/2/2020/03/24072147/Scientific-Integrity-Complaints-Procedure-Erasmus-MC-NL.pdf
Patents Policy	https://intranet-cdn.prod.erasmusmc.nl/wp-content/uploads/2020/12/15100603/23-11-2020-Octrooibeleid-Erasmus-MC_FINAL-RvB.pdf
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Participation Regulation	https://intranet-cdn.prod.erasmusmc.nl/wp-content/uploads/2020/12/15100613/23-11-2020-Participatieregeling-Erasmus-MC-FINAL-RVB.pdf
Privacy Knowledge Organisation	https://intranet.erasmusmc.nl/servicebedrijf/control-compliance/juridische-zaken/privacy-knowledge-office-pko/contact/privacy-kennis-organisatie/
Research Suite	https://intranet.erasmusmc.nl/programma/research-suite/?searched=true
Research Support Office	https://intranet.erasmusmc.nl/programma/research-suite/producten-en-diensten/support
Storage and Compute	https://intranet.erasmusmc.nl/programma/research-suite/producten-en-diensten/storage-compute/
Technology Transfer Office	https://intranet.erasmusmc.nl/servicebedrijf/technology-transfer-office-tto
Confidential Counsellor for Research Integrity	https://topdesk.erasmusmc.nl/tas/public/ssp/content/detail/service?unid=cb43ec5ce4c34af89c9a56d8caa632e8&from=9f7bcc72-cbfb-42a9-af57-a53729541311

KMS

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Whistleblower procedure	https://kms.erasmusmc.nl/iDocument/Viewers/Frameworks/ViewDocument.aspx?DocumentID=fd6e05d2-b54d-402a-8eb6-bd00bb840a30&NavigationHistoryID=18635767&PortalID=250&Query=klokkenluidersregeling
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Conflict Resolution Directive	https://kms.erasmusmc.nl/iDocument/Viewers/Frameworks/ViewDocument.aspx?documentid=bbded0bb-fb06-4509-b620-d6ca15b9d518&customcss=&HyperlinkID=b91b45ff-932b-4f5d-bc8c-255aabf2965c
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GDPR Implementation Act	https://wetten.overheid.nl/BWBR0040940/
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Scientific/Medical Research Involving Humans Act	https://wetten.overheid.nl/BWBR0009408/
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Experiments on Animals Act	http://wetten.overheid.nl/BWBR0003081/

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Note Publication Policy	https://www.ccmo.nl/publicaties/publicaties/2002/03/15/ccmo-notitie-publicatiebeleid
Therapeutic vs non-therapeutic research on underage and incapacitated subjects	https://www.ccmo.nl/onderzoekers/publicaties/publicaties/2017/01/01/ccmo-notitie-therapeutisch-vs-niet-therapeutisch-onderzoek
Collection, storage and processing of personal data in scientific/medical research	https://www.ccmo.nl/onderzoekers/wet-en-regelgeving-voor-medisch-wetenschappelijk-onderzoek/wetten/algemene-verordening-gegevensbescherming-avg
Expression of objections from people with mental disabilities	https://www.ccmo.nl/onderzoekers/publicaties/publicaties/1999/01/01/gedragscode-verzet-bij-mensen-met-een-verstandelijke-handicap
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Legislation and regulations for scientific/medical research	https://www.ccmo.nl/onderzoekers/wet-en-regelgeving-voor-medisch-wetenschappelijk-onderzoek

KNAW

Research Integrity	http://www.knaw.nl/nl/thematisch/ethiek/wetenschappelijke-integriteit
Care and integrity in the handling of scientific research data	http://www.knaw.nl/nl/actueel/publicaties/zorgvuldig-en-integer-omgaan-met-wetenschappelijke-onderzoeksgegevens

NFU

eBROK	https://nfu-ebrok.nl/
Quality Assurance for Human-Based Research	https://www.nfu.nl/sites/default/files/2021-01/21.00023_Richtlijn_Kwaliteitsborging_Mensgebonden_Onderzoek_2020.pdf
Ancillary activities in the CAO UMC	http://www.nfu.nl/publicaties/cao-universitair-medische-centra/cao-umc/hoofdstuk-9-overige-rechten-en-plichten/artikel-9-3-nevenwerkzaamheden
BROK training and exam regulations	https://www.nfu.nl/sites/default/files/2020-11/20.30509%20BROK%20Opleidings-%20en%20examenreglement%20OER%20eBROK%202020%20.pdf

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Code of Conduct for the use of personal data	https://www.vsnu.nl/files/documenten/Domeinen/Accountability/Codes/Gedragscode persoonsgegevens.pdf
National Scientific Integrity Complaints Procedure Model	http://vsnu.nl/files/documenten/Domeinen/Onderzoek/Landelijk_Model_Klachtenregeling_Wetenschappelijke_Integriteit_Universiteit_X.pdf
Netherlands Code of Conduct for Scientific Integrity	http://www.vsnu.nl/files/documenten/Nederlandse gedragscode wetenschappelijke integriteit 2018.pdf

Ancillary activity regulations for sector	http://www.vsnu.nl/files/VSNU 2017/Sector regeling nevenwerkzaamheden 2017.pdf

Federa

Code of Conduct for Responsible Use	https://www.federa.org/code-goed-gebruik
Code of Conduct for Behaviour	https://www.federa.org/code-goed-gedrag

Nationaal

4TU.ResearchData	https://researchdata.4tu.nl/
GDPR	https://autoriteitpersoonsgegevens.nl/nl/over-privacy/wetten/algemene-verordening-gegevensbescherming-avg
Biobank BBMRI	https://www.bbmri.nl/
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Biobank TraIT	https://trait.health-ri.nl/
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Code of Conduct for Biosecurity	https://www.knaw.nl/nl/actueel/publicaties/een-gedragscode-voor-biosecurity
Code of Conduct for Pharmaceutical Advertising	https://www.cgr.nl/nl-NL/Gedragscode-Geneesmiddelenreclame
Code of Conduct for Medical Devices	http://www.gmh.nu/index.php?option=com_content&view=category&id=35&Itemid=245
HANDS (Handbook for Adequate Natural Data Stewardship)	https://www.health-ri.nl/data-stewardship-handbook-hands
Health-RI	https://www.health-ri.nl/
National Organ for Scientific Integrity	https://lowi.nl/
National Focal Point (NFP) for Access and Benefit-Sharing	https://www.absfocalpoint.nl/nl/absfocalpoint.htm
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Parelsnoer Biobanks	https://www.health-ri.nl/parelsnoer
RePub	https://repub.eur.nl/
Association of Innovative Medicines	https://www.verenigginginnovatievegeneesmiddelen.nl/klinisch-onderzoek
Trial register	http://www.trialregister.nl/

Internationaal

Access and Benefit-Sharing Clearing House	https://absch.cbd.int/
General Data Protection Regulation	https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/verordening_2016_-_679_definitief.pdf
Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities	http://openaccess.mpg.de/Berlin-Declaration
CIOMS Ethical Guidelines	https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/
Clinical Trials	https://clinicaltrials.gov/
COPE	http://www.publicationethics.org/
CoreTrustSeal	https://www.coretrustseal.org/about/
CRediT	https://casrai.org/credit/
Database guidelines	https://eur-lex.europa.eu/legal-content/NL/TXT/HTML/?uri=CELEX:31996L0009&from=NL
DECLARE	https://ec.europa.eu/environment/nature/biodiversity/international/abs/material_en.htm
Declaration of Helsinki	https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
Directory of Open Access Journals	https://doaj.org/
EQUATOR	http://www.equator-network.org/
EU Clinical Trials Register	https://www.clinicaltrialsregister.eu/about.html
FAIR data	https://www.nature.com/articles/sdata201618#article-info
ICH-GCP	https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
ICMJE consensus: publishing guidelines	http://www.icmje.org/icmje-recommendations.pdf
ISRCTN registry	http://www.isrctn.com/
List of Predatory Publishers	https://predatoryjournals.com/publishers/
PHS regulation for promoting objectivity in research	https://www.federalregister.gov/documents/2011/08/25/2011-21633/responsibility-of-applicants-for-promoting-objectivity-in-research-for-which-public-health-service#h-34
Nagoya Protocol	http://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32014R0511&from=EN
Regulation of medical devices	https://eur-lex.europa.eu/legal-content/NL/TXT/HTML/?uri=CELEX:32017R0745&qid=1547726023835&from=EN

Regulation of medical devices for invitro diagnostics	https://eur-lex.europa.eu/legal-content/NL/TXT/HTML/?uri=CELEX:32017R0746&qid=1547725849889&from=EN
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4. AMENDMENTS IN VERSION 2

This second version of the Erasmus MC Research Code further elaborates on the Erasmus MC's duties of care, including the IT infrastructure developed in the Research Suite. In addition, it outlines new internal policies, such as those for research under WMO authority, but also policies for patents, financial conflicts of interest and the Participation Regulation. Finally, all hyperlinks were checked and replaced where necessary.

Erasmus MC
University Medical Center Rotterdam

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