CAPHRI

Care and Public Health Research Institute

THE CAPHRI QUALITY ASSURANCE FRAMEWORK

"The CAPHRI Quality Assurance system helps foster greater trust in research"

Maastricht University | Maastricht UMC+

Content

Quality assurance

CAPHRI values the quality of its research and has therefore established a quality assurance system, with a quality officer and guidelines for research conduct and reviewing. This quality assurance system serves to help researchers at CAPHRI to do their research according to the existing rules and regulations.

Often it is difficult to find out exactly which regulations apply to your research, especially when your research is non-WMO. This framework document gives an overview of the key information, and you can use the embedded hyperlinks to navigate the framework and to find out more about each topic.

If you have questions, comments or suggestions regarding quality assurance please send your email to caphri-quality@maastrichtuniversity.nl, or contact one of the members of the CAPHRI Quality Assurance Committee.

Scientific integrity is also an extremely important aspect of research, but does not fall under the CAPHRI quality assurance system as UM has its own regulation and guidance on integrity, as well as a Platform for Research Ethics & Integrity.

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Ethics approval

Every study that is carried out at CAPHRI and that falls under the WMO law should be approved by an accredited ethics committee. If your study is not subject to WMO you should seek ethics approval from the FHML ethics committee.

The researcher is responsible for obtaining ethical approval before data collection. Most journals also ask for ethical/research approvals once you submit your manuscript (please note that you cannot ask for ethical approval retrospectively). Dutch law requires ethical approval from a medical ethics committee if your research falls under the WMO law.

The first step is to decide whether your research falls under the WMO or not.

WMO or not?

The study falls under WMO if it concerns medical/scientific research. Research with a medicinal product is also categorised as medical-scientific research. And behavioural-scientific research can in certain cases also be deemed medical-scientific. Furthermore, nursing, physiotherapy and psychology research can in some cases fall under the WMO.

Participants are subject to procedures or are required to follow rules of behaviour. In general, research with human subjects only falls under the WMO if there is an infringement of the physical and/or psychological integrity of the subject. The subject himself/herself must be physically involved in the research for the research to fall under the WMO. In a randomized clinical trial subjects are being assigned at random to one of the treatment or control groups. By doing so the subjects are required to follow certain rules of behaviour. It depends on the nature of this rule whether the research will or will not fall under the WMO – assuming the study meets the first criterion of medical-scientific research.

What to do if your study falls under WMO

If you think your research falls under the WMO, then submit it to an accredited ethical review committee. Be aware that regulations may depend on local requirements. For example, if the study is performed in MUMC+, it needs to be approved by the ethical committee of the MUMC+.

In case of doubt this website helps you to decide.

Also do not hesitate to contact the ethical review committee of MUMC+ or the CCMO.

Clinical Trial Center Maastricht has a useful webpage if you have questions about WMO research.

What to do if your study does not fall under WMO

If your study is not subject to WMO you should seek ethics approval from the FHML Research Ethics Committee.

If you are not sure if your study falls under the WMO, you could also consider to go to the ethical review committee of FHML (contact person: David Shaw). The committee will give

advice whether indeed the proposed study falls under the WMO or not. If so, they will redirect you to an accredited ethical review committee. If not, they will review it themselves.

Please note that the exact forms that you have to complete differ per committee. The ethical review committee of FHML requires less information. However, if they redirect you to another ethical review committee, then you still have to provide that other committee with all information according to their procedures. So, the ethical review committee of FHML should not be seen as a simple procedure (because they are not allowed to judge research that falls under the WMO law, and they require different information anyway).

Applications to the FHML-REC should be made using specific forms (which contain details of how to submit the forms). You can find these forms here.

Sensitive Partnerships

As part of the ethical evaluation process of research, you can **voluntarily** request input from the Sensitive Partnership Unit to help evaluate potential partners or partnerships in terms of Knowledge Security; Human Rights and un pursuit of a Fossi-free Society. You can find the information for each evaluation unit here.

Participant information and informed consent

Every person who is asked to participate in a study should be informed about the study, before he/she decides whether to participate or not (participant information). Every person who is asked to participate in a study should give informed consent before study enrolment (informed consent).

WMO templates for participant information and consent

In case of WMO research the information letter and informed consent form should be written according to a specific format. The format of the MUMC+ ethical review committee is the same as the National CCMO format, and can be found here:

- https://www.ccmo.nl/onderzoekers/standaardonderzoeksdossier
- https://english.ccmo.nl/investigators/standard-research-file (in English)
- https://metc.mumc.nl/nl/formulieren

Note that specific rules apply to research that is done among children or among people who are not able to give consent. If this is the case, the informed consent procedure should always be approved by an METC.

Informing and consenting subjects in non-WMO research

There is no specific format for participant information and informed consent forms in case the research does not fall under the WMO. However, it is CAPHRI policy that all potential subjects should be informed about the study and should give informed consent. The researcher should adhere as much as possible to the formats of participant information and informed consent mentioned above. We suggest starting with the complete format, to consider all elements mentioned, and to keep all elements that are relevant to the study.

In most cases, the FHL-REC will request an example of participant information documents and well as informed consent forms are part of their evaluation procedure.

Studies involving use of data from non-enrolled subjects (non-WMO data studies)

Generally, if you want to use data from persons, they need to give their explicit consent to use their data.

However, if getting informed consent from each individual would require an unreasonable effort from the researcher, the use of (anonymous) data is allowed. This could be the case for example, if the researcher wants to use data from medical records databases. There are some additional requirements for the usage of such data, so if you consider using such data read these laws carefully.

- Gedragscode Gezondheidsonderzoek
- Wet bescherming persoonsgegevens

Insurance for participants

For research that falls under WMO, the researcher should take out insurance. For research that does not fall under WMO, it is not necessary to take out insurance.

The first step is to decide whether insurance for participants is required. In general, for studies involving human subjects (WMO) the researcher should take out insurance for the participants. The insurance is taken out in order to cover any damage to the research subjects. This is the so-called direct damage insurance or WMO subject insurance. In addition, liability insurance must be taken out. For research that falls under the scope of the WMO, two insurance policies must be provided, namely the WMO subject insurance and liability insurance.

WMO insurance

Participants must be insured against any potential damages incurred as a result of participating in research. Maastricht University covers WMO subject insurance with continuous coverage. This means that the included respondents do not need to be signed in per person by the insurance company. Before the end of the year correct numbers of included participants need to be provided to the insurance coordinator at Maastricht University. The principal investigator is responsible for providing this information, which is needed to calculate the premium of the continuous coverage. An overview of costs will be calculated once a year based on the total number of participants and will be administered by the order number of the project (cost € 10,-- excl. 21% BTW per participants).

There is a contact person available at the University. To contact the UM coordinator for queries about the insurances, call (043 38) 82047 or email mailto:UM-Verzekeringen@maastrichtuniversity.nl.

WMO subject insurance and exemptions

The insurance must comply with specific regulations stated in the Compulsory Insurance Decree on Medical Research Involving Human Subjects (dd 1-7-2015). The new Insurance Decree does not apply to research issued a positive decision by an accredited ethical committee or the CCMO before the 1st of July 2015, regardless of any amendments to the research reviewed after this date. Exemption from this insurance obligation is possible under certain conditions. In this case, a request must be included in the submitted application.

A request for exception from subject insurance can be submitted if:

- there are no risks to the research subjects as a result of participating in the research
- in the case of a comparative study of two regular treatment methods if, as a result of the comparative character of the study, the risks are deemed negligible;
- if the research is carried out by a ministerially appointed institution, service or governmental organization, such as those which fall under the Ministry of Health, Welfare and Sport, or the Ministry of Defence.

Liability insurance

In principle liability insurance is mandatory. “Even if exemption from the WMO insurance obligation is granted, the liability insurance must still be covered. The WMO does not state specific requirements to the liability insurance. In general, a common liability insurance policy is sufficient. The insurance must cover the whole research. (quote drawn from the CCMO website)”

Protocol registration

Every clinical trial that is carried out at CAPHRI must be registered at an official registry. It is strongly recommended to register observational (hypothesis testing) studies.

Trial registration

Since a few years almost all scientific journals require pre-registration of clinical trials at official trial registries. If trials are not registered, publication of the results is often not possible. At CAPHRI we recommend registering at the following trial registry:

- www.clinicaltrials.gov

Registration of observational research (hypothesis testing)

Considering the trustworthiness of observational research and the often described bias as a result of posthoc hypotheses and analyses, it is expected that pre-registration will become a requirement for publication of increasing amounts of types of research. The above-mentioned registries also offer the possibility to register observational research. For systematic reviews and meta-analyses there are specific registries such as The Cochrane Database and the Prospero Database.

Data protection and storage

Researchers at CAPHRI are required to design and conduct their research that deals with sensitive personal (medical) information in a way that privacy is respected. UM has several different providers of advice and solutions on data storage and management.

European, Dutch and local laws, regulations and guidelines share a commitment to the protection of research subjects' privacy and require researchers to produce and handle personal data carefully, refrain from sharing it beyond the research team and store and retain the data safely. At the same time, norms prescribing responsible research invite researchers to share data to allow reproduction and verification, and to store data for extended periods, to allow reanalysis or reuse.

Maastricht University's Data Management Code of Conduct explains how long you need to store data and where, whose property research data is and who can be granted access under which conditions. As a general rule, retain your data 10 years after the last publication and store it safely on UM servers. Researchers are free to grant other researchers access to their data, provided this does not breach other contractual or ethical obligations. Read the full text here. Practically, this means that members of the research team need to live up to a series of requirements. All projects involving data use should have a data management plan, and Datahub provides a template that researchers can use to create one. Some funders, including ZonMw and NWO, require use of this template and approval of plans by a data management specialist.

Responsibilities

All researchers (including students and supporting staff):

- Stimulate awareness among peers and research assistants;
- Remain vigilant. This means:
    - Never share access to accounts (UM or MUMC+), not to new peers or students, etc.;
    - Never leave your computer unlocked when leaving your office (locking your computer can be done by pressing 'windows button-L');
    - At the end of the day, put all sensitive info in secure storage;
    - Store all data on UM servers. Do not use local drives, flash drives or non-sanctioned cloud storage

Project leaders:

- Document relevant decisions made regarding sensitive data;
- Ensure compliance to these requirements from peers and research assistants;
- Remain vigilant.

Data permissions

Non-sensitive/anonymous data can be used without any restriction or permissions. Privacy is not a serious concern in this situation. Examples include statistical data from the CBS or

number of patients who visited an institution or hospital. Anonymised data is considered anonymous only when identification of a person requires application of unreasonable means or disproportionate time and effort. Anonymous data, however, can be confidential because of agreements in the context of data collection, research prior to filing a patent or for (other) competitive reasons.

Data that contains personal information, data that is not completely anonymised or data that cannot be anonymised (e.g. qualitative research data) is always considered sensitive and needs to be treated accordingly. Collecting personal (medical) data requires informed consent to use or collect data. If consent cannot in all fairness be required or achieved, contact the METC or non-WMO IRB.

Data handling and encryption

- If possible, de-identify data during collection or directly after collection;
- Collect only the variables required to answer your research question;
- Store and process data always on UM/MUMC+ servers. Use data encryption when working outside the network. For info on encryption, see below.
- Data incidents (data loss, hacks, etc.) need to be reported to the Caphri Quality Committee;
- Outsourcing of data handling to third party services require those services to agree (in writing) on secrecy and security issues, incident handling and the destruction of data afterwards. Contracts are often required when sharing data outside UM, and advice on this can be sought from the CAPHRI Management Office.
- To encrypt sensitive data, we advise the open source platform 7zip. Use 265-AES encryption and a long password (recommendation of 12 characters or more). Do not send encrypted files and passwords using the same medium. Online instructions for how to encrypt using 7zip, can be found here.

Storing and transporting data

Retain your data in accordance with Maastricht University Data Management Guidelines:

Storage and transport	Non-sensitive data	Sensitive data
Cabinet	No restrictions	Locked cabinet in a locked room
Digital	No restrictions	In a secured project directory, only accessible to the research team
Email	No restrictions	Not allowed. Exceptions can be made for encrypted data, if project leader provides written permission

Storage and transport	Non-sensitive data	Sensitive data
Encrypted transport on mobile device	No restrictions	Only allowed when strictly required and data is encrypted
Cloud	Only ICTS offered and/or approved cloud services	Only ICTS offered and/or approved cloud services

Logging processes

Every WMO study at CAPHRI should keep a logbook. For non-WMO studies we strongly recommend keeping a logbook or other record of research decisions, such as minutes of meetings.

To ensure that essential decisions, queries and solutions are registered in a legible, durable and retrievable way at the time they are made, a logbook is required that is kept from the start until the end of the research. A logbook records the steps and activities you take to complete a project. However, it also records changes and what you did to overcome any unexpected results.

If you are not keeping a formal logbook for a non-WMO project, ensure that all important decisions and events at project meetings are recorded in minutes. These minutes should be stored during the project and archived at the end of a project to ensure a record of project decisions. Minutes should not contain any personal information (for example regarding PhD students).

Note that we make a distinction between a logbook and a syntax; a logbook is to record the general processes of the study and the syntax is for all steps in the statistical analysis process (see Analyses and syntaxes).

About the Logbook

The logbook is like a scientific journal (diary) and should be compiled and updated on a regular basis by the responsible researcher(s). This enables you to monitor the progress and decision-making processes during the study performed. The principal investigator will review regularly if the logbook is kept up to date and meets the minimal requirements. The logbook is stored on the UM/MUMC+ server, possibly with access for the study team.

Logbook entry

A minimum requirement includes the entry of the following data: date, description of important moments, decisions and solutions / actions undertaken by who.

Example of logbook data entry table

The example of the logbook data entry table provided below is not a complete logbook and should be taken as a demonstration of possibilities.

Date	Description of moment	Decision	Action	Who
01-10-2018	Preparation study	Ask for ethical approval	Protoocol submitted to the ethical committee	PI

Date	Description of moment	Decision	Action	Who
15-11-2018	Data collection	CEO approved participation of the organization		PhD
01-01-2019	Data entry	Enter data in SPSS	Create SPSS file	PhD
02-02-2019	Data analysis	Consult expert	Call statistician to make an appointment	PhD
06-05-2019	Publication	Submission approved by supervisor	Electronic submission in Journal XXX	PhD

Analyses and syntaxes

For each publication, the final data (on which the reported analyses are based) should be stored. Syntaxes should be available for all results reported in the publication.

All co-authors should be able to see the original data and syntaxes on which a study manuscript is based.

Recommendations in line with full disclosure (see here for example).

- Raw data should be stored.
- For each publication, also the final data (on which the reported analyses are based) should be stored.
- Syntaxes should be made available as part of a replication package that allows others to replicate the steps you made in the analyses.

How syntax files can be made available differs per software package. For example, when using R, the syntax files (i.e., having the file name extension .r or .rd) provide an overview of all the steps taken during analyses. It is highly recommended to document these steps (e.g., by using comments) so both yourself and others understand decisions/steps that were made during analyses. When using SPSS, the syntax files can also be saved separately (i.e., having the file name extension .sps). Also here you can add comments to document the decisions/steps taken during analyses. Moreover, syntax commands can also be automatically added to the output files (.spv-files) in SPSS (tick the box 'Display commands in the log' under Options > Viewer).

Besides data files in their original format, it is warranted to also supply them in non-proprietary format, such as plain text, Open Document Format (ODF), Portable Document Format (PDF), or Hyper Text Markup Language files (HTML), or, for images, Portable Network Graphics (PNG) or Scalable Vector Graphics (SVG). This is important because opening proprietary formats require the purchase of specific software, which other researchers may not have. Syntaxes (e.g. for SPSS, SAS, or R) are provided in their original format, because these generally already are in plain text format.

In the context of qualitative research, the structure of analysis is not usually referred to as a syntax, but in line with the suggestions above, we advise the storage of coding lists or trees alongside the original data.

Reporting

All research results should be reported to ensure transparency, ensure the evidence base is not distorted and avoid wasteful duplication of research, regardless of the nature of the results. This framework provides useful resources regarding best practices in reporting results.

The quality of reporting will **not** be evaluated as part of research reviews but whether research has been reported will be assessed.

The EQUATOR network provides reporting guidelines for several types of studies:
https://www.equator-network.org

For qualitative research the COREQ checklist is recommended:
https://www.equator-network.org/reporting-guidelines/coreq/

The US National Library of Medicine provides links to many other useful resources:
https://www.nlm.nih.gov/services/research_report_guide.html

Statistics

Using the right statistical methodology is very important. Here we provide a statistics checklist to help researchers. This checklist is limited to quantitative empirical studies and it does not provide any guidelines for studies involving small-scale in-depth interviews, systematic reviews, or philosophical studies. Further, this checklist serves as an aid in the design and analysis of quantitative studies, not as a mandatory tool. The recommendations in this list are based on decades of broad experience in statistical consultancy and analysis, but can be discussed with a member of the Methodology & Statistics dept.. Note that statistical methods will not be evaluated in reviews.

Open science

Open science is a very important aspect of research quality. Although open science practices are **not actively reviewed** by the Quality Assurance Committee, CAPHRI encourages researchers to share their results and data openly whenever possible, so that the scientific community can benefit maximally from their work. The section below offers a synthesis of the CAPHRI Quality Assurance Framework through the open science lens, supplemented with non-quality related resources.

Preregistration

Registering studies before the actual research is carried out promotes transparency by enabling a distinction between confirmatory and exploratory analyses. Regardless of the study type, the Open Science Framework offers researchers a free platform to enable these aims by registering studies, storing data during and after a project, and sharing it with other researchers. Specific platforms exist for systematic reviews and clinical trials. Your data steward can inform you about alternatives, based upon your needs.

Data and syntaxes

Data management should follow FAIR principles to the extent possible. Generally, for each project or publication, the final data (on which the reported analyses are based) should be stored. When applicable, syntaxes should be available for all results reported and co-authors should be able to access original data and syntaxes on which a study manuscript is based. Syntaxes can be made available as part of a replication package that allows others to replicate the steps you made in the analyses. An example of more detailed recommendations in line with full disclosure can be found here). GitHub is a popular collaborative platform to share, develop, publish and maintain analysis code and documentation.

Reporting

As part of adherence to open science principles, all research results should be reported to ensure transparency, accurate representation of collective evidence, and avoid wasteful duplication of research, regardless of the nature of the results.

- The EQUATOR network provides reporting guidelines for several types of study.
- For qualitative research, we recommend the COREQ checklist.
- The US National Library of Medicine provides links to many other useful resources.

Note that specific publication choices can and will have consequences for which guidelines apply.

Publishing

Open access publishing is an important part of open science; whenever possible, research should be published *open access*, ensuring that research results are available to all. Some projects will not have funding for open access publication fees, in which case institutional repositories should be used to store a freely available version. We recommend using the UM

Library service *Taverne – You share, we care!* (free, and opt-in only) to automatically share paywalled publications in accordance with Dutch copyright law.

Researchers should be wary of the risk of "predatory journals" which offer easy publication for a fee but are not reputable or respected. Read more about this.

Outreach/Engagement

The openness of open science is not only about sharing materials or outcomes but also refers to the attitude of scientists relative to other societal partners: stakeholders, citizens, policymakers and others. The potential for this kind of openness is very diverse, connected to subject matter, community and methods used. Societal stakeholders can be informed and involved to varying degrees in all stages of research. They can be involved in setting research agendas, gathering data and conducting research, and in science communication. Public engagement: a practical guide: A five-step approach to public engagement by the NHS National Institute for Health Research. This is a practical guide for researchers on involving the public in working out how to communicate findings - from the earliest stages of projects, and on the most challenging of subjects.

For more information on open science, please visit the Open Science-information page of Maastricht University.