

Research protocols	Set-up & Conduct- Study Preparation	
	VERSION	4.0

Aim

To write a clear research protocol and submit it to the METc (for medical research)/ERB (for non-medical research) for ethical approval.

- Please note that each faculty of the universities: VU and the UvA have their own ERB (Ethics Review boards or committees) for non-medical research. See for more information: [Nethics](#)

Requirements

- For research under the Medical Research involving Human Subjects Act (WMO-plichtig onderzoek), the model protocol of the CCMO is obligatory (<https://www.ccmo.nl/onderzoekers/standaardonderzoeksdossier/c-protocol>)
- For research not under the Medical Research involving Human Subjects Act (niet-WMO plichtig onderzoek), the model protocol of the METc is obligatory (<https://www.vumc.nl/research/overzicht/medisch-ethische-toetsingscommissie/niet-wmo/indienen.htm>) → METc: Model protocol Niet-WMO. Or see [AMC Intranet - METC startpagina](#).
- For other necessary documentation, see the website of the METc.

Documentation

- A clear research protocol containing:
- The names and qualifications of the researcher(s);
- The scientific grounds for the research (support);
- Which questions need to be answered (research questions);
- Which participants may or may not participate in the study (selection criteria);
- How the study will be implemented (procedure, methodology);
- To what extent this differs from standard treatment;
- What the participants will be asked to do (burden);
- What safeguards are going to be in place;
- How the participants will be approached to participate (recruitment and informed consent);
- The (medical) ethics justification.
- Responsibilities

Executing researcher:

- To write the research proposal which includes all statements described under Documentation;
- To write down any changes to the protocol in an amendment and to submit these to the METc/ERB.

Project leaders:

- To review the research protocol written by the executing researcher and discuss these points with him/her;
- To ensure the project is registered at the CMG (Centraal Meldpunt Gegevensverwerking) [VUmc](#) of [AMC](#); To register study details to the Centraal meldpunt gegevensverwerking of your organisation (VUmc: [follow this link](#); AMC: [follow this link](#); VU: servicedesk.privacy@vu.nl)

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- To ensure that the research proposal is submitted to the METc/ERB;
- To ensure that the study does not start before consent was given by the METc/ERB;
- To ensure that any changes to the protocol are sent to the METc/ERB using an amendment. This is an obligation for research under the remit of the Medical research involving human subjects act (WMO-plichtig onderzoek). For research not under this act (niet-WMO plichtig onderzoek), changes should only be submitted when there is reason to suspect that the change would cause the study to fall under the remit of the Medical research involving human subjects act, or when other important issues, for instance regarding privacy or informed consent change.

How To

Within the VU University Medical Center each scientific study involving humans needs to undergo an ethical assessment. The Medical Ethics Committee (METc) considers the research protocol of the planned study. Within other departments of the VU/UvA, non-medical research involving humans needs to be approved by the Ethics Review Board (ERB). Many of the procedures of METc and ERB are equal or similar. If research does not include the Medical Research Involving Human Subjects Act (WMO), the METc can be asked for a declaration of non-WMO. Medical researchers in VUmc are required to register their project to the central datahandling point (Centraal Meldpunt Gegevensverwerking, CMG) *before* they are able to submit their research protocol to the METc. [Here](#) all the information how to apply for medical ethical approval can be found. This [intranet page](#) provides additional information and leads to the CMG. More information can be found in the guideline CMG registration.

A study should contain research questions that have not yet been answered or not answered sufficiently, and which will be addressed by the methodology described in the research protocol. Therefore, a research protocol is an ordered description of a scientific study.

Researchers undertaking studies within one of the longitudinal studies (AGGO, LASA, HOORN study) do not have to submit a research protocol to the METc for approval, as in these instances all the data have already been collected and work is only being carried out on (blinded) data. Within longitudinal studies an analysis plan may be viewed as the research protocol. The items that should be found in the research protocol can be found under Documentation.

The study may start once approval has been obtained from the METc.

The researcher should not deviate from the research protocol approved by the METc. Any changes to a protocol should be re-submitted to the METc using an amendment for approval. In case of research not under the remit of the WMO (niet-WMO plichtig onderzoek), the METc advises to only submit amendments when there is any doubt as to whether the change will cause the study to fall under the remit of the WMO or when privacy issues may arise.

Submitting research protocols to the METc

VUmc researchers have to submit their protocol to the METc VUmc. Information on submitting different types of studies can be found on the internet ([Amsterdam UMC, Locatie VUmc - Medisch-ethische toetsingscommissie](#)). Submission should be done through the online portal Research Manager. The link to this portal, as well as guidelines on how to use it, are available on the website of METc VUmc.

Audit questions

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1. Was this study registered to the CMG? Without CMG number, the study cannot be submitted to the METc
2. If not, why not?
3. Did the METc approve the research protocol prior to data collection?
4. Are there any amendments in the research protocol which were approved by the METc?
5. Did all participants sign an informed consent?

LINKS

	Link
CCMO	https://www.ccmo.nl/onderzoekers/standaardonderzoeksdossier/c-protocol
METc - Vumc	https://www.vumc.nl/research/overzicht/medisch-ethische-toetsingscommissie/niet-wmo/indienen.htm https://www.vumc.nl/research/overzicht/medisch-ethische-toetsingscommissie.htm
METc-AMC	https://intranet.amc.nl/web/organisatie/clusters/commissies/medisch-ethische-toetsingscommissie/metc-startpagina.htm
CMG	https://intranet.vumc.nl/afdelingen-themas-1/privacybescherming-informatiebeveiliging-1/centraal-meldpunt-gegevensverwerking.htm https://intranet.amc.nl/web/organisatie/themas/overzicht-themas/privacywetgeving-en-gegevensbescherming.htm
NFU	https://www.nfu.nl/themas/randvoorwaarden-wetenschappelijk-onderzoek/klinisch-onderzoek
Nethics	https://nethics.nl/Welkom-Welcome/

DOCUMENT HISTORY

Version		Date	Name
1.0	Research covenant removed form text. Addition of corrections from Scientific Committee	11AUG2005	EMGO
1.1	Translation into English	01JAN2010	EMGO
2.0	Revision format	12MAY2015	EMGO
3.0	Revision guidelines	16DEC2016	EMGO
4.0	Revision guidelines	02APRILY2021	Dr. Miranda Bos-Pronk Jolanda Westera

DOCUMENT APPROVAL

	Name	Date
Project Leader	Dr. Seta Jahfari	29APRIL2021