

<b>Law &amp; regulations</b>	Compliance, Training & Supervision - Compliance	
	VERSION	4.0

## Aim

To ensure that all prerequisites have been completed prior to starting an APH project

## Requirements

Check which law and regulations apply to your research project. Consider at least the following items (further explained under How To):

1. Registration with the Centraal Meldpunt Gegevensverwerking;
2. Algemene Verordening Gegevensbescherming (AVG)/General Data Protection Regulation (GDPR)
3. Information to provide to study participants ([checklist AVG non-WMO research METc VUmc](#) ; [checklist AVG WMO research CCMO](#))
4. Review by the Medical Ethics Committee; or ERB (Ethics Review boards or committees) for non-medical research.
5. Confidentiality regulations and agreements (i.e. between research partners and service providers) need to be signed;
6. Trials need to be registered;
7. Population Screening Act (Wet op het bevolkingsonderzoek).

## Documentation

- Storing the documentation of the legal issues in the appropriate folder of the research project.

## Responsibilities

### Executing researcher:

- To register study details to the Centraal Meldpunt Gegevensverwerking, see CMG registration;
- To compile the research protocol to be submitted to the METc/ERB;
- To inform research participants about the study (including information about central insurance policy of the Amsterdam UMC) and receiving (written) consent from the participants;
- To ensure the confidential regulations are followed during the project;
- To register the study at the Netherlands trial register;

### Project leaders:

- The project leader should take care of important aspects at the beginning of the study:
- To instruct the executing researcher to register the study details to the Centraal Meldpunt Gegevensverwerking;
- To review the research protocol to be submitted to the METc/ERB;
- To make sure the research protocol is submitted to the METc/ERB;
- To ensure the executing researcher informs research participants about the study;
- To ensure the confidential regulations are followed during the project;
- To sign the associated confidentiality agreement;
- To ensure the executing researcher registers the trial;
- To initiate the application to the Population Screening Act (Wet op het Bevolkingsonderzoek);
- To notify the Centraal Meldpunt Gegevensverwerking of the finalization of the project.

### Research assistant:

- To sign the associated confidentiality agreement.

# Amsterdam Public Health



## A) Written consent of the participant

According to the Medical Research (Human Subjects) Act of February 1998 (Wet Medisch Onderzoek met mensen, WMO), conducting scientific research without written consent of the participant is a serious offence, which is punishable with a prison sentence up to 1 year. Undertaking research without insurance cover or in the absence of a protocol that has been approved by a recognised medical ethics committee is an offence punishable with a prison sentence of up to 6 months.

## B) General Data Protection Regulation (GDPR/AVG)

According to the General Data Protection Regulation (GDPR) (Algemene Verordening Gegevensbescherming (AVG), the Dutch Data Protection Authority may impose fines for non-compliance that can be as high as 10 or 20 million euros.

The data protection officer must be notified of the use of personal or privacy sensitive information in scientific research. Notification is done by registering the project with the Centraal Meldpunt Gegevensverwerking. For information about handling personal data we refer to the guideline Privacy. For background information click [here](#), which contains information about the Data Protection authority (Autoriteit persoonsgegevens) and the GDPR.

For specific questions:

- VUmc researchers: mail to [privacy@vumc.nl](mailto:privacy@vumc.nl)
- VU researchers: mail to [servicedesk.privacy@vu.nl](mailto:servicedesk.privacy@vu.nl)
- AMC researchers: mail to [fg@amc.nl](mailto:fg@amc.nl)

## C) Medical Ethics Committee and Ethics Review boards

The very first question is whether the research project falls under the Medical Research (Human Subjects) Act. Not every study falls under the WMO's remit, and therefore not every study needs to be assessed by METc. The assessment criteria to determine whether a study falls under the WMO remit can be found on the website of the [CCMO](#) or on the website of [METc VUmc/ AMC METc](#)

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 (<https://nethics.nl/Welkom-Welcome/> )

### Non-WMO research:

If you believe that your study does not fall under the WMO's remit. You must follow the [non-wmo procedure](#) (or this link [for AMC](#) ) on the METc website to notify the committee. Explain explicitly in your accompanying letter why you believe your proposal does not fall under the WMO remit.

Explain why your proposal is not medical scientific research in the definition of the METc or why participating in your project is not burdensome for the participants.

In case of non-WMO research, the METc still strongly advises to inform them about any changes in data collection, informed consent procedure, burden to participants and/or design of the study.

Please note: that most journals require an Institutional Review Board (IRB) or Ethical Committee Approval letter when an article is submitted. This letter can only be provided ex -ante by METc/ERB - so before you start your research, and not ex-post!

### WMO research:

Protocols should be accompanied by all the information leaflets and consent forms when sent for approval to the Medical Ethics Committee (Medisch-Ethische Toetsingscommissie, METc). The METc will consider the scientific significance of the study and weigh this against the burden on and risk to patients.

The research protocol sent to the METc of the Amsterdam UMC will be screened for completion. Only once the proposal is complete, both formally and contents-wise, it should be submitted to the METc; the assessment

# Amsterdam Public Health



period starts at this point. The committee makes a decision within 56 days. The study is not allowed to start before the executive board has issued an approval. Refer to the [METc VUmc website](#) / [AMC METc](#) for information about the Amsterdam University Medical Center's METc procedure (incl. an example of the insurance statement, information letter and consent form). Always look at the [checklist](#) before submitting research protocols. For AMC researchers, look at the intranetsite of [METC AMC](#).

## D) Participants (insurance and informed consent)

The Medical Research (Human Subjects) Act requires that participants are insured against any potential injury caused by the study. The Amsterdam University Medical Center has taken out a central insurance policy covering this eventuality. Study participants need to receive information about this in writing. You should contact METc when a participant makes a claim.

Another aspect of the METc procedure is that participants need to receive written information about the study and should have provided written consent to participate in the research. The METc provides a standard model participant information and informed consent form for both [WMO](#) and [non-WMO](#) research. For research involving participants who are unable to provide informed consent or under 16 years old, written consent will be required from their parents or representatives. More information can be found on the site of [CCMO](#)

## E) Privacy

A confidentiality agreement needs to be signed by all project team members with access to the confidential (paper or digital) study details. The project leader is responsible for ensuring that information about the confidentiality agreement is provided, and that the document is signed and archived on time. Access to confidential research data should only be extended to employees of the APH Research Institute who are registered to the project. (See also the guideline: Handling privacy sensitive data).

## F) Trials registration

The board of the APH Research Institute requires that all RCT's carried out in the Institute to be included in the trial register. All studies with interventions that are allocated by randomisation need to be considered for registration. This may involve registration at participants' level, as well as cluster randomisation (e.g. randomisation of treatment providers or departments). Registration may also be important to the project, given that a number of journals require that a trial has been registered for publication. Refer to [trial registration](#) for information about how and why.

## G) Population Screening Act (Wet Bevolkingsonderzoek)

The Public Screening Act (Wet Bevolkingsonderzoek, WBO) is intended to protect individuals against screening studies that may pose a danger to physical or mental health. Projects falling under the WMO's scope need to obtain a license from the Ministry of Health, Welfare and Sport (Volksgezondheid, Welzijn en Sport - VWS) prior to the study being carried out. This therefore does not fall under the METc auspices.

The definition of population screening, as laid down in the Population Screening Act, is: 'medical research in persons carried out on an entire population or a category thereof aimed at the detection of certain types of disease or certain risk indicators for the benefit of the participating subjects' (non-official translation). This definition contains a number of elements:

- It must concern a medical research within the population screening;
- The research must be carried out in the entire population, or a category thereof, that is it concerns screening. The investigator must be presented to the population or the population group through, for example, individual consultations, advertisements or other general communication, such as in the waiting room of the practice of the investigator.
- The screening should partly take place for the benefit of the participants, so that the individual results of the research can be offered to every participant as a health care benefit. With 'partly' is

# Amsterdam Public Health



meant that the research can possibly also be a 'trial population research' and may have a medical/scientific character.

- The term 'disease' is defined in the wider sense to include disorders, pain, injuries, deficiencies, or other physical or psychological conditions.
- Risk indicators are seen to be 'information on an individual containing details concerning the level of risk to that individual defined within a set time period and clinical manifestation. These increase the chance of contracting certain diseases' (non-official translation).

The study also needs to satisfy one of the criteria below in order to fall under the WBO scope:

- population screening whereby ionising radiation is used;
- population cancer screening;
- population screening of serious diseases or defects for which there is no treatment and prevention is not possible.

If your study satisfies all of the criteria, then it probably falls under the WBO scope. The national hearing test does not fall under the WBO's scope, as it does not satisfy the last three criteria. Contact Michel Paardekooper (VUmc) or Marleen Inge (AMC) if you have any doubts about this and/or consult the METC in order to determine whether the study falls under the WBO's scope.

Don't forget that the WBO licensing procedure may take a long time. The procedure may take as long as 3 to 4 months. The process may even take up to a year if there are any objections, or if information is incomplete.

## LINKS

	Link
Medisch-ethische toetsingscommissie	<a href="https://www.vumc.nl/research/overzicht/medisch-ethische-toetsingscommissie.htm">https://www.vumc.nl/research/overzicht/medisch-ethische-toetsingscommissie.htm</a> <a href="https://intranet.amc.nl/web/organisatie/clusters/commissies/medisch-ethische-toetsings-commissie/metc-startpagina.htm">https://intranet.amc.nl/web/organisatie/clusters/commissies/medisch-ethische-toetsings-commissie/metc-startpagina.htm</a>
CCMO	<a href="https://www.ccmo.nl/onderzoekers/standaardonderzoeksdossier">https://www.ccmo.nl/onderzoekers/standaardonderzoeksdossier</a> <a href="https://www.ccmo.nl/onderzoekers/standaardonderzoeksdossier/e-informatie-proefpersonen/e1-e2-informatiebrief-en-toestemmingsformulier-proefpersonen">https://www.ccmo.nl/onderzoekers/standaardonderzoeksdossier/e-informatie-proefpersonen/e1-e2-informatiebrief-en-toestemmingsformulier-proefpersonen</a> <a href="https://www.ccmo.nl/publicaties/publicaties/2017/02/01/toetsingskader-onderzoek-met-minderjarige-proefpersonen">https://www.ccmo.nl/publicaties/publicaties/2017/02/01/toetsingskader-onderzoek-met-minderjarige-proefpersonen</a>
Nethics	<a href="https://nethics.nl/Welkom-Welcome/">https://nethics.nl/Welkom-Welcome/</a>
Autoriteit Persoonsgegevens	<a href="https://autoriteitpersoonsgegevens.nl/">https://autoriteitpersoonsgegevens.nl/</a>
Netherlands Trial Register	<a href="https://www.trialregister.nl/trialreg/index.asp">https://www.trialregister.nl/trialreg/index.asp</a>
CCMO WHO Checklist	<a href="https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not">https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not</a>
WBO	<a href="https://wetten.overheid.nl/BWBR0005699/2019-04-02">https://wetten.overheid.nl/BWBR0005699/2019-04-02</a> <a href="https://wetten.overheid.nl/BWBR0007499/2020-10-01">https://wetten.overheid.nl/BWBR0007499/2020-10-01</a>

# Amsterdam Public Health



<https://www.ccmo.nl/onderzoekers/aanvullende-eisen-voor-bepaalde-soorten-onderzoek/overig-onderzoek/bevolkingsonderzoek/bescherming-proefpersonen>

## DOCUMENT HISTORY

Version	Status	Date	Name
1.1	Addition of trial registration and Population Screening Act (WBO)	SEPT2006	EMGO
1.2	TIP non WMO project	22JAN2009	EMGO
1.3	Translation into English and update	01JAN2009	EMGO
1.4	Name change from Ready to Go to Law and Regulations and update	28JAN2013	EMGO
2.0	Revision format	12JUN2015	EMGO
2.1	Update details	22MAR2017	EMGO
3.0	Update EMGO+ to APH	08FEB2018	SQC
3.1	Update GDPR	31JUL2018	SQC
4.0	Revision	29APR2021	SQC

## DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	29APR2021