

WMO / Non-WMO Form as of January 2019



WMO / Non-WMO Form:

- Tool for investigators and the MREC: Is the WMO or the Medical Devices Decree applicable?
- Not to be used for review of the proposal's substance.
- Collects information to determine which of these legislative instruments applies: please consult the CCMO website via the hyperlinks provided in the form!
- Applicability only determined based on the completed form.
- How the privacy of subjects is assured is not relevant here.
- If the WMO does not apply: other legislation may apply, such as privacy law (GDPR) and the Dutch Medical Treatment Contracts Act (WGBO); investigator/institution is responsible for compliance.

Article 1 of the WMO:

In this Act and the provisions based on it, the following definitions apply:

b. scientific research:

medical scientific research in which persons are subjected to procedures or are required to follow rules of behaviour;

Your research: Is it subject to the WMO or not?

If a study is subject to the [Medical Research Involving Human Subjects Act \(WMO\)](#), it must undergo a review by an accredited MREC or the CCMO.

Research is subject to the WMO if the following criteria are met:

2 steps:

1. It concerns medical scientific research and
2. Participants are subject to procedures or are required to follow rules of behaviour.

1. It concerns medical scientific research

The WMO does not offer a definition of the term medical-scientific research. As a result, it is not always clear if the research protocol must be submitted for review by law. A comparable matter is the case with studies with (leftover) embryos and the [Embryo Act](#). The CCMO assists in this by offering the following definition:

'Medical/scientific research is research which is carried out with the aim of finding answers to a question in the field of illness and health (etiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by systematically collecting and analysing data. The research is carried out with the intention of contributing to medical knowledge which can also be applied to populations outside of the direct research population.' (Unofficial translation)

Step 1 (Form part A): Definition of medical scientific research

I) Goal? Research question?

'Medical/scientific research is research which is carried out with the aim of finding answers to a question in the field of illness and health (etiology, pathogenesis, signs/symptoms, diagnosis, prevention, outcome or treatment of illness), by systematically collecting and analysing data. The research is carried out with the intention of contributing to medical knowledge which can also be applied to populations outside of the direct research population.' (Unofficial translation)

II) Scientific research?

III) New insights in the field of medicine? Publication?

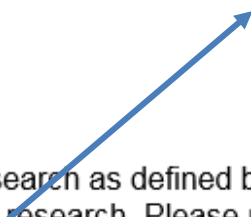
Note: Procedures / rules of behaviour are not taken into account here.

WMO / Non-WMO Form, part A

A. Study

1. Study title:
2. a) Study objective(s):
b) Aim of the study:
c) Study design:
3. Does it concern medical scientific research as defined by the CCMO? Click [here](#) to see the CCMO definition of medical scientific research. Please note that subjecting participants to procedures / requiring them to follow rules of behaviour is not part of this definition. The considerations in this regard are discussed under B below.
 - Yes
 - Unsure: please indicate which aspects of the definition (study itself, objectives, general applicability) you are unsure about:
 - No (If your answer is 'no', a decision from the MREC on the scope of the WMO is not necessary as the proposed research is by definition not subject to the WMO. Other laws, regulations and policies may still apply, however. For this you need to consult the contact person of the institution where the proposed research will be conducted, or check this institution's information. You do not need to complete the rest of the form and you do not need to submit the form to the MREC.)

Research with patient files can also fall under the scope of the definition



[Examples of non-medical-scientific research:](#)
customer satisfaction surveys, educational
research, HCP career surveys

Step 2

2. Participants are subjected to procedures or are required to follow rules of behaviour

In general, research with human subjects is only subject to 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 be subject to the WMO. Therefore retrospective research/file research is not subject to the WMO. In that case the data are already available and not collected specifically for a medical-scientific research. The subject does not have to do or abstain from something on behalf of the research.

[More information on Step 2:](#)

<https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not>

WMO / Non-WMO Form, part B

B. Subjects

1. Will the subjects themselves be physically involved in this study? Link to [Explanation on procedures / rules of behaviour](#)

Yes

No (Subjects do not need to do anything or refrain from doing anything, e.g. retrospective research / research with patient files (link to explanation on [file research](#) on the CCMO website);

➤ Move on to part C)

B1: If the answer is ‘yes’, complete the rest of part B and, if applicable, enclose the relevant documents:

- Diary
- Script for structured or semi-structured interview
- Questionnaire(s)

More information:

- Examples of how to determine WMO applicability: [Onderzoekswijs.nl](https://onderzoekswijs.nl) > when is review required?
- Explanation on WMO / Non-WMO research and the GDPR:



The screenshot shows the website www.ntvg.nl. The logo for ntv.g is displayed, with the text "NEDERLANDS TIJDSCHRIFT VOOR GENEESKUNDE" underneath. A navigation menu includes "Artikelen", "Academie", "Auteurs", "Banenbank", "Over NTvG", "Service", and "Contact". A breadcrumb trail reads "HOME > ARTIKELEN > TER DISCUSSIE". The main heading of the article is "Algemene Verordening Gegevensbescherming" (General Data Protection Regulation), with the subtitle "VRIEND OF VIJAND VAN ONDERZOEKERS?". The article is dated "22-10-2018" and is by "W. Antoinette Groenewegen en Elise M. van de Putte".

<https://www.ntvg.nl/artikelen/algemene-verordening-gegevensbescherming>