

# (Non-)WMO form

*A brief explanation of how to complete the (non-)WMO form*

# General explanation & instructions (I)

The (non-)WMO form:

- Is a tool to determine whether the WMO applies.
  - Is not intended for a substantive assessment of the research proposal.
  - Consists of two parts: Part A (Research) and Part B (Subjects).
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- When completing the form, consult the CCMO-website via hyperlinks in the form.
  - The assessment of whether the WMO applies is only based on the completed form.
  - Subjects' privacy is not part of the assessment whether the WMO applies.

## General explanation & instructions (II)

Note:

- A non-WMO declaration is not a permission to conduct the research.
- In case of non-WMO research: researcher and institute remain responsible for compliance with applicable laws and regulations (GDPR, WGBO, ...) and local policies.

# Article 1 WMO

1. 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;

Source: translated from:

[wetten.nl](https://wetten.nl) - Regeling - Wet medisch-wetenschappelijk onderzoek met mensen - BWBR0009408 ([overheid.nl](https://overheid.nl))

# Assessment whether WMO applies: two steps

## 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:

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

Source: CCMO website:  
[Your research: Is it subject to the WMO or not? | Investigators | The Central Committee on Research Involving Human Subjects \(ccmo.nl\)](#)

### Step 1:

**First, it must be established that it concerns medical-scientific research. This is done via the questions in (non-)WMO form Part A.**

### Step 2:

**Does the research proposal indeed concern medical-scientific research? Then it must be determined whether the research involves persons who are subjected to procedures/rules of behaviour, and if so, what this entails. This is done via the questions in (non-)WMO form Part B.**

# Step 1: Does it concern medical-scientific research?

The WMO does not offer a definition of the term medical-scientific research. The CCMO assists in this by offering the following definition:

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*‘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)*

**I) Goal, research question: illness and health?**

**II) Scientific research?**

**III) New medical-scientific insights? Publication?**

[Source: CCMO website:  
Your research: Is it subject to the WMO or not? |  
Investigators | The Central Committee on Research  
Involving Human Subjects \(ccmo.nl\)](#)

# Step 1: (Non-)WMO form Part A

## A. Research

1. Study title:
2. a) Study purpose:  
b) Study objective(s):  
c) Study design:

3. Does the research proposal concern medical-scientific research as defined by the CCMO?

Link: [CCMO definition - medical scientific research](#).

Note: Subjecting study participants to procedures and/or requiring them to follow rules of behavior is not part of this definition. Considerations in this regard (e.g., risks and burden) are discussed in Part B (Subjects).

Yes

Unsure – please indicate which part(s) of the CCMO definition you are not sure about (medical-scientific purpose, research question, generalizability):

No – if the answer is “No”, an assessment of WMO applicability is not in order. You do not need to complete the remainder of this form and the form does not need to be submitted to the MREC. If you do submit the form, you will not receive a non-WMO declaration, but an email stating the above that no assessment has been performed. In addition, the usual costs will be charged.

Note: Other laws and regulations (e.g., GDPR, Dutch WGBO) and (local) policies may apply. Please consult the contact person or information of the institution where the research will be conducted.

Procedures/rules of behavior are not part of the assessment whether it concerns medical-scientific research.

No medical-scientific research?  
An assessment of WMO applicability is not in order.

# Step 2: Procedures and rules of behaviour

## 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.

Source: CCMO website:

Your research: Is it subject to the WMO or not? | Investigators | The Central Committee on Research Involving Human Subjects (ccmo.nl)



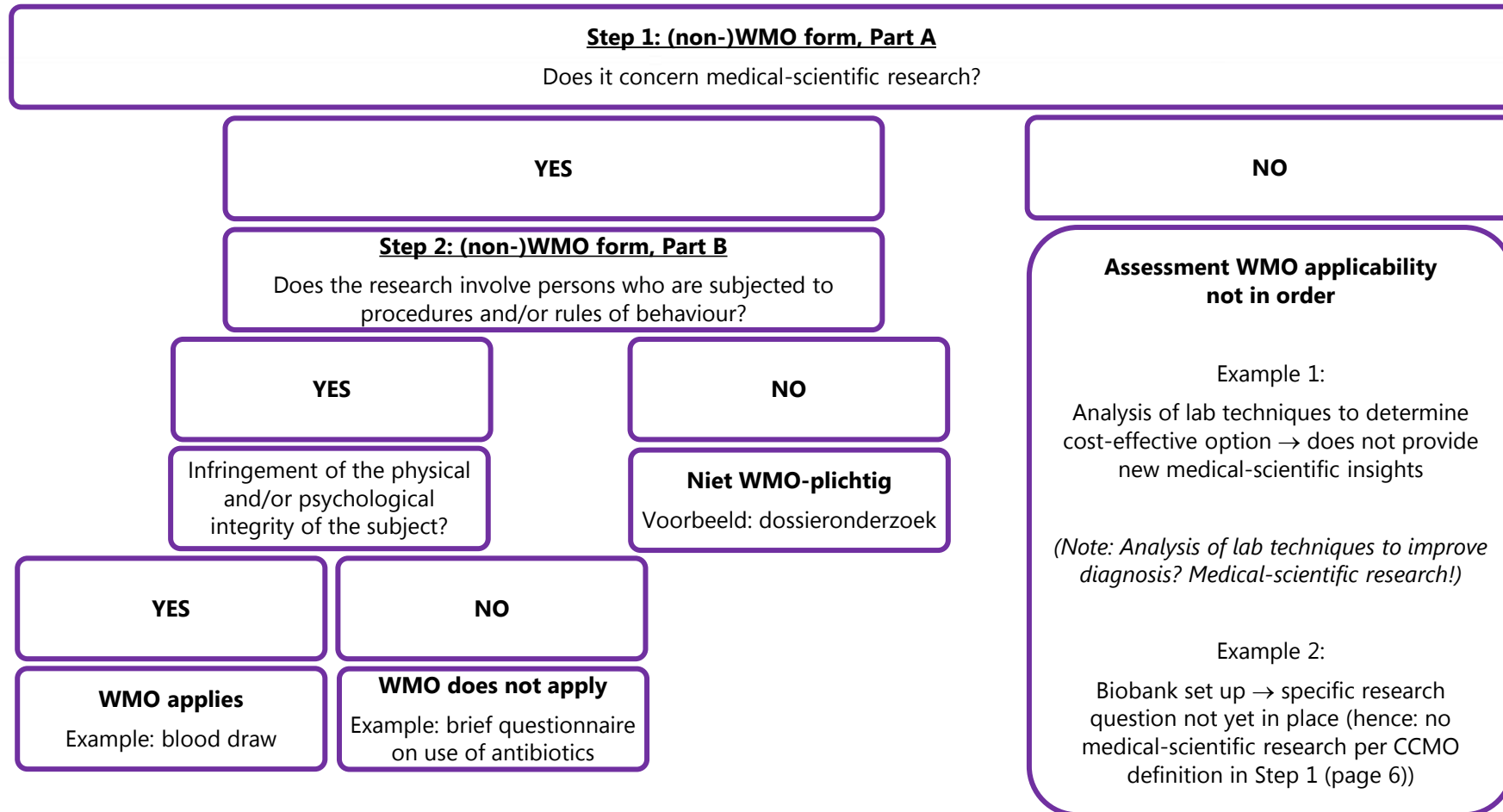
## Step 2: (Non-)WMO form Part B

### B. Subjects

1. Will subjects be physically involved in this research? Link: [Explanation on procedures and rules of behaviour](#)
  - Yes
  - No (Subjects do not need to do anything or refrain from doing anything, e.g., retrospective research/file research). Link: [Explanation file research](#)
    - Please proceed to **Note** at the end of this form.

**B1: Is the answer 'Yes'?**  
Then complete Part B and, if applicable, provide relevant appendices (e.g., diary, (semi)-structured interview script, questionnaires).

# Assessment whether WMO applies: overview



## More information?

- [Is review required? - NedMec](#)
- [Your research: Is it subject to the WMO or not? | Investigators | The Central Committee on Research Involving Human Subjects \(ccmo.nl\)](#)
- (In Dutch only) Explanation (non)WMO research and the GDPR:  
<https://www.ntvg.nl/artikelen/algemene-verordening-gegevensbescherming>