**(non)WMO-form**

(to determine whether or not research is subject to the WMO)

*This form:*

* is a tool to determine whether the WMO (Medical Research Involving Human Subjects Act; in short: WMO) applies.
* is not intended for a substantive assessment of the research proposal.
* consists of two parts: A (Research) and B (Subjects).

*When completing this form, please consult:*

* the instructions about this form on the website of the Medical Research Ethics Committee NedMec (MREC NedMec) ([Is review required?](https://www.nedmec.nl/en/is-review-required)).
* the website of the Central Committee on Research Involving Human Subjects (in short: CCMO) via the hyperlinks in this form.

*Also note that:*

* the assessment of whether or not a research proposal is subject to the WMO will only be based on the information provided in this form.
* no information is required in this form on how subjects’ privacy is guaranteed, as this is not relevant to the assessment whether or not the WMO applies.
* if a research proposal is not subject to the WMO, the researcher and the institute where the research will take place remain responsible for carrying out the research in accordance with applicable laws and regulations, including (but not limited to) the GDPR, the Dutch WGBO and the institute’s local policies.
* a non-WMO declaration issued by the MREC is not a permission to conduct the research.
* **UMC Utrecht researchers**: this form should be submitted only **after the quality check by the Research Quality Coordinator** of your division has been performed. For contact details, click [here](https://umcutrecht.sharepoint.com/sites/DMN_Onderzoek/SitePages/Contact-Details.aspx).

*Submission*:

Please submit the completed form, including relevant attachments to Part B, in PDF‑format to the MREC NedMec via email: metc@nedmec.nl.

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1. **Contact details**

Investigator with final responsibility:

Institute :

Division :

Department :

Telephone :

Email :

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact person :

Institute :

Division :

Department :

Telephone :

Email :

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Details for invoicing**

Please complete the following for **external or sponsored** research:

Contact person : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Company/Organization : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Postal/City : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Functional email address : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

VAT/BTW number : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PO number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please complete the following for **internal (AvL, PMC, UMCU)** non-sponsored research:

Company/Organization : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Purchase order number(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| *To be completed by MREC secretariat for Financial Administration purposes* |
| Protocol number |  |
| Fee | €  |
| PO number |  |
| Beneficiary PO number | R114 | General ledger account 8393149 |

1. **Research**
	1. Study title:
	2. a) Study purpose:

b) Study objective(s):

c) Study design:

* 1. Does the research proposal concern medical-scientific research as defined by the CCMO? Link: [CCMO definition - medical scientific research](https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/your-research-is-it-subject-to-the-wmo-or-not).

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.

1. **Subjects**
	1. Will subjects be physically involved in this research? Link: [Explanation on procedures and rules of behaviour](https://www.ccmo.nl/onderzoekers/wet-en-regelgeving-voor-medisch-wetenschappelijk-onderzoek/uw-onderzoek-wmo-plichtig-of-niet)

Yes

No (Subjects do not need to do anything or refrain from doing anything, e.g., retrospective research/file research). Link: [Explanation file research](https://www.ccmo.nl/onderzoekers/aanvullende-informatie-over-bepaalde-soorten-onderzoek/niet-wmo-onderzoek/dossieronderzoek)

* Please proceed to **Note** at the end of this form.
	1. Research assessments: what procedures will subjects undergo and/or what rules of behavior will they have to follow (e.g., completion of questionnaires, sampling of bodily material, other measurements, …)?
	2. In case of repeated measurements/procedures, please specify which measurements/procedures this concerns and at which timepoints they will be performed (e.g., timeline and time burden in hours or days, …).
	3. Please describe the characteristics of the research population (e.g., condition or illness, main inclusion and exclusion criteria, age, target group, [temporarily] incapacitated, …).
	4. A) What is, in your view, the burden on subjects when participating in this research?

B) Does the burden infringe on subjects’ physical and/or psychological integrity?

C) To what extent can the burden be considered minimal? Please provide a justification.

* 1. Are there any risks associated with participation? If yes, please describe.

**Note: Non-WMO clinical research involving a medical device (MD) or investigating in vitro diagnostics (IVD) may be subject to the EU Medical Device Regulation (MDR) or EU In Vitro Diagnostic Regulation (IVDR)** if the research is to investigate the safety or the performance of the device **(which may include software or apps). For more information, refer to the CCMO website:** [MDR](https://english.ccmo.nl/investigators/clinical-investigations-with-medical-devices) **or** [IVDR](https://english.ccmo.nl/investigators/performance-studies-using-in-vitro-diagnostics-ivdr).

Attachment(s) to Part B (Subjects):

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

 Questionnaire(s)

*(\* tick the document[s] that apply)*

*Note: These attachments are not assessed substantively, but only serve for the considerations of Part B (Subjects). Please do not include any other attachments.*