**Addendum METC NedMec**

Addendum to cover letter for submission to METC NedMec

(version CCMO: WMO or MDR)

1. **Review by METC NedMec is necessary because the study is subject to:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **WMO** | **MDR** | | | | **IVDR** | |
|  | art. 62 | art. 74.1 | art. 74.2 | art. 82 | art. 58 | art. 70.1 |

1. **Please explain in a few sentences why this study is subject to this/these regulation(s). Only a reference to the protocol is not sufficient[[1]](#footnote-2):** Click to enter text
2. **Please explain in a few sentences why it is important that this study will be conducted:** Click to enter text
3. **Is there a relationship with other (overlapping) research protocols in the participating centres, and if so, which research in which centre?** Click to enter text
4. **Medical devices**
   1. Does the study concern research into medical devices?

Yes  No  
*When answered no, the questions 5b.and 5c.can be skipped.*

* 1. Do these medical devices bear a CE mark?

Yes  No

* 1. Will these medical devices be used within the scope of the CE mark?

Yes  No

1. **Human study subject information**
2. There is/are Click to enter a number (add number) subject information sheet(s) and informed consent form(s) (PIF) submitted (Note: pregnancy PIFs not included). In the case of more than 1 PIF, specify these PIFs and add an explanation of the reason for more PIFs and for which group of research subjects they are intended:
   * 1. Click to enter text
     2. There Choose an item Pregnancy PIFs submitted.
3. Is it possible for research subjects to give consent electronically?

Yes  No

*When answered yes, attach a completed* [*form “Checklist e-Consent”*](https://www.nedmec.nl/en/documents-forms#checklist-e-consent)*. The committee reviews the electronic consent based on this checklist.*

1. Indicate how the research subjects are informed about the scientific results of the study and/or about findings during the study (individually or at group level). If the subjects are not informed, please indicate why not: Click to enter text
2. **Studies in the AvL**: The recruitment text of the study will be published on [www.avl.nl](http://www.avl.nl). The text is hereby submitted for assessment and has been drawn up in accordance with the mandatory AVL format. See MyAntonet.
3. **Human biological samples**
4. Does this study involve a Biobank component (collection and/or, storage of human tissue) for use in research yet to be determined?

Yes  No

1. If so, this concerns[[2]](#footnote-3)

Extra sampling in addition to the WMO study

Residual material from the WMO study samples

1. **Has/have the principal investigator(s) completed an ICH-GCP and BROK course?**

Yes  No

1. **Is there a contract associated with the clinical study?**

Yes  No

*When answered yes, attach the contract and include a written statement regarding the reference clinical trial agreement[[3]](#footnote-4).*

1. **Risk classification**: In case of researcher-initiated research subject to WMO. Which risk classification is appropriate according to the sponsor?

Select risk classification

Please substantiate the classification and/or refer to the relevant pages in the protocol: Click to enter text

*Explanation for researchers: Risk classification for monitoring intensity*

|  |  |  |  |
| --- | --- | --- | --- |
| Degree of damage  Size  of probability | Slight damage | Moderate damage | Severe damage |
| Low probability | Negligible risk | Negligible risk | Moderate risk |
| Moderate probability | Negligible risk | Moderate risk | High risk |
| High probability | Moderate risk | High risk | High risk |

**Please do not forget to fill in and sign the invoice sheet on the next page.**

**Invoice sheet**

**Signature and invoicing**

The undersigned declares with regard to:

Research title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

• that all relevant documents from the aforementioned research file have been signed by the authorized persons. The original, signed documents are in possession of the sponsor.

• that she/he is aware of the possibility that the METC or the CCMO will charge a rate of up to €6000 excl. VAT, and that additional costs may be charged for the assessment of amendments. These costs are in accordance with the rates as published on the website.[[4]](#footnote-5)

Signature on behalf of the board/management of the institution 'enter name of institution'

Place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ date:      \_\_\_\_\_\_\_\_\_\_

Manager’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Manager’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Billing information**

In case of external or sponsored study, please fill in the invoice details below:

Mr/ Mrs: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

Zipcode/City:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Functional E-mail address:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone number:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

VAT / TAX number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

In case of internal (AvL, PMC, UMCU) study that is not sponsored, please fill in the invoice details:

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

Cost center number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| *to be completed by the MREC secretariat for the purpose of the Financial Administration* | | |
| Protocol number |  | |
| rate | € | |
| PO number |  | |
| beneficiary cost number | R114 | general ledger account 8393149 |

1. Please use the [CCMO Guideline MDR: Review of a clinical investigation with a medical device – guidance document for MRECs](https://www.ccmo.nl/onderzoekers/publicaties/publicaties/2021/05/17/leidraad-mdr-review-of-a-clinical-investigation-with-a-medical-device-–-guidance-document-for-mrecs), in particular the tables on pages 12 and 17 to substantiate whether this research falls under article 62, 74.1, 74.2 or 82 MDR or falls outside the scope of the MDR. [↑](#footnote-ref-2)
2. In case of extra sampling: The file will be checked by the METC against the WMO/MDR and the UMC Utrecht Biobank Regulations or the Biobank Regulations of the NKI-AVL. [↑](#footnote-ref-3)
3. <https://english.ccmo.nl/investigators/standard-research-file-for-research-subject-to-the-dutch-wmo-act/k-other-documents/k3-clinical-trial-agreements> [↑](#footnote-ref-4)
4. <https://www.nedmec.nl/nl/vergaderschema-tarieven> [↑](#footnote-ref-5)