Medical Research Ethics Committee NedMec
metc@nedmec.nl



Date [Select date]

**RE: Response to questions from the MREC dated (NLxxxxx.xxx.xx, MREC xx/xxx)**

Dear MREC members,

You are hereby receiving my response to your questions and comments dated dd-mm-yyyy, relating to the study entitled ‘*full study title*’, registered under NLxxxxx.xxx.xx.

*(Only studies submitted after 1 March 2006 have an NL number.)*

*[Free space for possible explanation on the most important changes and/or any enclosed additional documentation. The item-by-item response to the MREC’s questions can be added in Annex II.]*

Enclosed are the documents related to the amendment. For a list of documents submitted, please refer to annex I.

With this submission, I declare that all relevant documents from the research file referred to above have been signed by the relevant authorised persons. The original, signed documents are held by the sponsor.

Yours sincerely,

*Name and signature*

***Applicant / contact person*** *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Institution*

*Address*

*Division, Department*

*Internal mail no.*

*Telephone no.*

*E-mail address*

*Name and signature*

***Principal investigator*** *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Institution*

*Address*

*Division, Department*

*Internal mail no.*

*Telephone no.*

*E-mail address*

* Annex I: List of documents submitted to the MREC
* Annex II: Item-by-item response to the MREC’s questions and comments dated dd-mm-yyyy

**Annex I: List of documents submitted to the MREC**

In the table below you can indicate which documents are contained on the CD/DVD-ROM, including version numbers and/or dates. If a document is not applicable, the line concerned can be removed from the table. The period for review will start when the MREC has received a complete response. The lay-out of the list of documents submitted must be the same as below; see also <https://www.nedmec.nl/en/method-of-submission>

If the study concerns research with a medicinal product or research with a medical device, you will need to submit more documents. The extra documents are marked as follows in the table below:

***\**** *for research with a medicinal product and cell therapy*

***\*\**** *for research with a medical device*

| **Section** | **Document** | **Version/date** | **Comments** |
| --- | --- | --- | --- |
| **A. Correspondence** |
| A1 | Cover letter |  |  |
| A2 | Authorisation from the sponsor if the submitting party is not the sponsor |  |  |
| A3 \* | Confirmation of receipt of EudraCT number |  |  |
| **B. Forms** |
| B1 | ABR form |  |  |
| B3 \* | EudraCT application form |  |  |
| **C. Research protocol and protocol amendments** |
| C1 | Research protocol |  |  |
| C2 | Protocol amendments |  |  |
| **D. Product information** |
| D1 \* | Investigator’s Brochure (release date: < 1 year ago) and list of SUSARs not yet included in the IB (including summary with review) |  |  |
| D2 \* | IMPD (or SPC if applicable), including list of relevant trials with the medicinal product being researched |  |  |
| D2 \*\* | IMDD (Investigational Medical Device Dossier) |  |  |
| D3 \* | Example labels in Dutch |  |  |
| D3 \*\* | IFU (Instructions for Use) |  |  |
| D4 \* | Applicable statements and licenses for the medicinal product being researched |  |  |
| D4 \*\* | CE marking for the medical device |  |  |
| D4 \*\* | Report from the Medical Technology & Clinical Physics Cluster, UMC Utrecht (e.g. acceptance test, sterilisation report for implants: stents, etc.) |  |  |
| D5 \* | Hospital pharmacist product details |  |  |
| D5 \* | Copy of arrangements agreed on with UMC Utrecht trial pharmacy |  |  |
| D6 \* | Additional product details, e.g. for gene therapy: digital nucleotide sequence of the vector (if applicable) |  |  |
| **E. Information for research subjects**  |
| E1/E2 | Information sheet(s) and informed consent form(s) for research subjects / representatives |  |  |
| E3 | Promotional materials for research subjects (if applicable) |  |  |
| E4 | Any other information materials |  |  |
| **F. Questionnaires, patient diary, patient card** |
| F1 | Questionnaires |  |  |
| F2 | Patient diary |  |  |
| F3 | Patient card |  |  |
| F4 | Other documents |  |  |
| **G. Insurance certificates** |
| G1 | Insurance certificate for WMO research |  |  |
| G2 | Proof of liability coverage  |  |  |
| **H. CVs of independent expert and coordinating investigator** |
| H1 | CV(s) of independent expert(s) |  |  |
| H2 | CV of coordinating investigator (for multicentre research) |  |  |
| H2 | CV of principal investigator (for monocentre research) |  |  |
| **I. Information on participating centres (including CVs of principal investigators)**  |
| I1 | List of participating centres with their principal investigators |  |  |
| I2 | Research Declaration signed by head of the department, the healthcare group manager or a person in a similar position (for multicentre research) |  |  |
| I3 | CV of the principal investigator of each centre (for multicentre research) |  |  |
| I3 | CV(s) of the independent expert(s) of each centre (for multicentre research) |  |  |
| I4 | Other information per participating centre |  |  |
| **J. Additional information on financial compensation**  |
| J1 | Additional information on financial compensation for research subjects |  |  |
| J2 | Additional information on financial compensation for investigators and participating centres |  |  |
| **K. Other relevant documents** |
| K1 | Copies of reviews by other institutions (peer review), e.g. review by subsidy provider, recommendation made by a regulatory authority |  |  |
| K1 | Approval from Central Biobank / Central Freezer facility of UMC Utrecht |  |  |
| K2 \* | List of competent authorities in other countries (for international research) & copies of reviews by other MRECs / competent authorities (including VHP) |  |  |
| K3 | Clinical trial agreement concluded between the sponsor and the investigator and/or institution |  |  |
| K3 | Statement from the sponsor that the clinical trial agreements concluded with other centres do not differ from the reference clinical trial agreement for which the reviewing committee has issued a positive decision |  |  |
| K4 | Scientific publications submitted |  |  |
| K5 | Data Safety Monitoring Board (DSMB) – composition and charter |  |  |
| K6 | Monitoring plan (if this is not part of the research protocol) |  |  |
| K6 | Recommendation from UMC Utrecht’s Radiation Protection Department |  |  |
| K6 | Other documents |  |  |

**Annex II: Item-by-item response to the MREC’s questions dated dd-mm-yyyy**

The item-by-item response can be entered below.