Medical Research Ethics Committee Utrecht

Internal mail no. D01.343

Postbus 85500

3508 GA Utrecht  
The Netherlands

image

Date [Select date]

**RE: Submission of substantial amendment no. … (NLxxxxx.xxx.xx, MREC xx/xxx)**

Dear MREC members,

Via this letter I would like to ask the Medical Research Ethics Committee Utrecht to conduct a medical ethical review of substantial amendment no.… for the study entitled ‘**full study title**’, registered under number NLxxxxx.xxx.xx. *(Only studies submitted after 1 March 2006 have an NL number.)*

The changes in this amendment relate to (please tick the relevant box):

 an essential change to the present study;

 the addition of a participating centre;

 other, i.e.: ……….….

The reason for this change is ……….…*.*

*The enclosed CD/DVD-ROM*[[1]](#footnote-1) contains the documents relating to the amendment. For a list of documents submitted, please refer to the annex.

The undersigned, i.e. the applicant / principal investigator, certifies 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: Invoicing information (for sponsored research)

Annex III: Internal annex relating to amendment invoicing

Annex IV: Annex relating to amendment invoicing

**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 or the applicant can indicate in the ‘Comments’ column that the document is ‘not applicable’. The period for review will start when the MREC has received a complete research file. The lay-out of the list of documents submitted must be the same as below; see also

<https://metcutrecht.nl/nl/en/how-to-submit>

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 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 the head of the department, the healthcare group manager or a person in a similar position |  |  |
| 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: Additional details**

**(to be entered by UMC Utrecht’s principal investigator)**

1. Has the study already been reviewed by any of the following[[2]](#footnote-2)?
   1. Radiation Protection Department. YES / NO / N/A
   2. Medical Technology & Clinical Physics Cluster YES / NO / N/A
   3. Antibiotics Committee YES / NO / N/A
   4. Other committee, i.e.: ……
2. Please list the divisions/departments where the study is being performed and/or which you will collaborate with and/or whose facilities you will use: ……
3. If the subject population is also involved in any other studies which are already taking place (at UMC Utrecht), please state here which studies it concerns: ……
4. If it concerns investigator-initiated research subject to the WMO: What risk classification applies according to the sponsor?

|  |  |
| --- | --- |
|  | Negligible risk |
|  | Moderate risk |
|  | High risk |

Please substantiate the risk classification and/or refer to the relevant pages in the protocol: ……

**Annex III: Approval from the division’s management**

Study title: ‘full study title’

***Signature on behalf of division management***

The management of the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Division hereby declares that:

* They approve of the performance of the study at the division;
* The entire management team agrees with this approval;
* Arrangements have been made about the performance of the study with other institutions/divisions participating in or supporting the study.

Place:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Manager:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Annex IV: Annex relating to amendment invoicing**

Only applicable in case of sponsored research and if UMC Utrecht is not taking part in the study.

**Protocol number:**  \_\_\_\_\_\_\_\_\_\_

**Amendment number:** \_\_\_\_\_\_\_\_\_\_

**Study title**: \_\_\_\_\_\_\_\_\_\_ ‘full study title’

**Name of the investigator**: \_\_\_\_\_\_\_\_\_\_

The MREC may charge a fee for the review (see also www.umcutrecht.nl/metc). Please state the invoice address below:

Mr/Ms/Mrs :      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (contact person)

Company/Organisation :      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Postcode/Town :      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone no. :      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PO number (required)\*** :      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(or WBS element of UU)

*\*The PO number (Purchase Order number / WBS element in case of UU) can be requested from the institution’s Accounting Department. If the institution does not use PO numbers, a different reference number may be entered.*

Signature on behalf of the board/management of the institution or department ‘enter name of institution/department’

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

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

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

|  |  |  |
| --- | --- | --- |
| *To be entered by the MREC secretariat for the Accounting Department* | | |
| Protocol number |  | |
| Fee | € | |
| PO number |  | |
| Receiving cost centre | R114 | Ledger account 8393149 |

1. In accordance with submission instructions on <https://metcutrecht.nl/nl/en/how-to-submit> [↑](#footnote-ref-1)
2. A report on the findings of the committee in question must be included in the file submitted. [↑](#footnote-ref-2)