Medical Research Ethics Committee Utrecht

Internal mail no. D01.343

Postbus 85500

3508 GA Utrecht
The Netherlands



Date [Select date]

**RE: Submission of research file NLxxxxx.xxx.xx**

Dear MREC members,

Via this letter I would like to ask the Medical Research Ethics Committee Utrecht to conduct a medical ethical review of the study entitled ‘***full study title***’, registered under number **NLxxxxx.xxx.xx.**

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

For this study a clinical trial agreement is / is not being concluded.

*[Free space for a short explanation on the study, any connection with another study, reasons to request an exemption from the insurance obligation, etc.]*

***Research with a medicinal product***

*For research with a medicinal product* ***which involves the use of unregistered medicinal products*** *one of the following two sentences must be included:*

1. No new SUSARs have occurred since the most recent update to the Investigator’s Brochure [version date/number].

**OR**

1. The annex includes an overview list of the SUSARs which have occurred since the most recent update to the Investigator’s Brochure [version date/number], including a summary review.

***Blinded study*** (*please delete if not applicable*)

It concerns a blinded study. To avoid unblinding, it is important to **not send the investigator** any information from the MREC on any Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs) or other safety issues. **All information and questions from the MREC on SAEs, SUSARs and other safety issues can be sent to:** [email.address@sponsor.nl]

***Bodily material*** (*please delete if not applicable*)

In this study, bodily material of UMC Utrecht subjects is being stored while the specific research question is as yet unknown. The file must be reviewed based on the Medical Research Involving Human Subjects Act (WMO) and UMC Utrecht’s Biobank Regulations.

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;
* He/she knows that the MREC may charge a fee of up to €3500 excluding VAT for the review, and that in addition costs may be charged for the review of amendments and for an annual subscription until the last patient has been included. These costs correspond with the rates published on the website[[2]](#footnote-2);
* He/she agrees that (if UMC Utrecht is taking part in the study) UMC Utrecht’s Accounting Department will automatically pass on the fee. The fee will be charged to the main cost centre of his/her division or to a specific cost centre designated by him/her (e.g. a project-specific cost centre).[[3]](#footnote-3)

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: Additional details
* Annex III: Invoicing annex

**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://www.metc-utrecht.nl/nl/wijze-van-indienen>

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 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**

1. Please indicate how subjects will be informed about the scientific results of the study and/or about any findings during the study (individually or on a group level). If subjects will not be informed, please explain why not: ……

**Questions 2, 3, 4 and 5 should only be answered if UMC Utrecht is involved in the study in the role of sponsor and/or executing party.**

1. Has the study already been reviewed by any of the following[[4]](#footnote-4)?
	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: Internal annex**

If UMC Utrecht is taking part in the study, a representative of the division’s management must sign this annex.

Study title: ‘full study title’

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

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

The management of the **…………… Division** 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Cost centre (for sponsored research): \_\_\_\_\_\_**

|  |
| --- |
| *To be entered by the MREC secretariat for the Accounting Department* |
| Protocol number |   |
| Fee |  €  |
| Cost centre to be charged |   |
| Receiving cost centre |  R114 | Ledger account 4599180 / 4599181 |

**Annex III: External annex relating to invoicing**

Only applicable if UMC Utrecht is not taking part in the study.

Study title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

The MREC may charge a fee for the review (see also [https://metcutrecht.nl/nl/en/meeting-schedule-fees](https://metcutrecht.nl/nl/vergaderschema-tarieven) ). 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 the MREC’s submission instructions on <https://metcutrecht.nl/nl/en/how-to-submit> [↑](#footnote-ref-1)
2. <https://www.metc-utrecht.nl/nl/en/meeting-schedule-fees> [↑](#footnote-ref-2)
3. External applicants will receive the invoice at the invoice address provided by him/her. [↑](#footnote-ref-3)
4. A report on the findings of the committee in question must be included in the file submitted. [↑](#footnote-ref-4)