METC Stichting BEBO

Weiersstraat 1C

9401 ET ASSEN

\*City\*, Click or tap to enter a date.

Ref.: Submission of research file – \*study code\* (\*NL-number\*)

Dear members of the MREC,

I hereby request the members of the MREC of the BEBO Foundation for a medical-ethical assessment of the research entitled *\*study title\** which is registered under number \*NL-number\*.

You will find the documents digitally uploaded *[or via another medium]* (see Appendix I).

The study is a \*First-in-Human / Biological / Tracer / ADME / PK-PD / Drug-Drug interaction / other / study \*

**Submission explanation**

*\*[Free space for an explanation of, among other things, the research, describing a possible connection with other research, etc.]\**

*For drug research with unregistered substances, one of the following two texts must be included:*

* *Since the last update of the Investigator's Brochure [version date / version number], no new SUSARs have occurred.*

*OR*

* *The SUSARs that occurred after the last update of the Investigator's Brochure [version date / version number] have been added in a list including along with an assessment.*

**Financial settlement**

For a quick financial settlement, we would like to receive an invoice with the following information:

* \*Company name\* and \*Billing address\*
* \*Attn. the relevant department or person\*
* \*Email address which the invoice should be sent to\*
* \*Payment details that must be included on the invoice \*
* \*VAT number for foreign invoices\*
* \*Telephone number of the financial department\*

The undersigned declares:

* That all relevant documents from the aforementioned research file are signed by the authorized persons. The original, signed documents are in the possession of the sponsor.
* That she / he is aware that a rate will be charged for the review (Rates see [www.stbebo.nl](https://stbebo.nl/en/general/our-rates/)).

We look forward to receiving the review.

Yours sincerely,

\*Name\*

\*Signature\*

\*Submitter / contact person\*

E-Mail: \*E-mail\* and telephone number: \*telephone number\*

|  |
| --- |
| Appendix I |
|  | Document | Format document name | Version | Date |
| A. Correspondence |  |
| A1 | Cover Letter | A1. Cover\_Letter\_[*study code*]\_ddMmmyy |  |  |
| A2 | Letter of Authorization | A2. Letter\_of\_Authorization\_ddMmmyy |  |  |
| A3  | Confirmation EudraCT-number | A3. Conf\_EudraCT\_ddMmmyy |  |  |
| B. Forms |  |
| B1 | ABR-form | B1. ABR-Form\_[*NLXXXXX.056.20*]\_[*version (V)*]\_ddMmmyy |  |  |
| B3  | EudraCT application form  | B3. EudraCT-form\_ddMmmyy |  |  |
| C. Protocol  |  |
| C1 | Research Protocol | C1. Research\_Protocol\_[*NLXXXXX.056.20*]\_[*version (V)*]\_ddMmmyy |  |  |
| C2 | Protocol amendments | C2. Prot\_Amdt\_[*nr*]\_[*NLXXXXX.056.20*]\_ddMmmyy |  |  |
| D. Product information |  |
| D1  | Investigator’s Brochure (IB)(& LL SUSARs) | D1. IB\_[*medicine*]\_[*version (V)*]\_ddMmmyyyD1. SUSARLL\_[*start periode*]-[*eind periode*]\_ddMmmyy |  |  |
| D2  | Investigational Medical Product Dossier (IMPD)  | D2. IMPD\_[*medicine*]\_[*version (V)*]\_ddMmmyyyD2. SmpC\_[*medicine*]\_[*version (V)*]\_ddMmmyyy |  |  |
| D3  | Example labels (in Dutch) | D3. [*name label*]\_[*version (V)*]\_ddMmmyyy |  |  |
| D4  | Applicable statements and licenses  | D4. [*type*\*]\_[*Manufacturer*]\_[*City*]\_[*Country letter code*]\_ddMmmyy\* = MIA/QP/GMP/GLP/TSE |  |  |
| E. Information research subjects  |  |
| E1/2 | Subject information sheet and informed consent form subjects | E1/E2. ICF\_[*name*]\_[*version (V)*]\_ddMmmyy |  |  |
| E3 | Promotional materials research subjects | E3. Advertisement\_[*version (V)*]\_ddMmmyy |  |  |
| E4 | Other informational materials  |  |  |  |
| F. Questionnaires etc. |  |
| F1 | Questionnaires | F1. Q\_[*Title*]\_[*version (V)*]\_ddMmmyy |  |  |
| F2 | Patient diaries | F2. PD\_[*Title*]\_[*version (V)*]\_ddMmmyy |  |  |
| F3 | Patient cards | F3. PC\_[*Title*]\_[*version (V)*]\_ddMmmyy |  |  |
| F4 | Other |  |  |  |
| G. Insurances |  |
| G1 | Insurance certificate for WMO research | G1. Insurance\_WMO\_ddMmmyy |  |  |
| G2 | Proof of coverage  | G2. Liability\_Insurance\_ddMmmyy |  |  |
| H. CVs |  |
| H1 | CV independent expert | H1. CV\_[*initials and last name*]\_[*titles (MD/PhD)*]\_ddMmmyy |  |  |
| H2 | CV coordinating investigator | H2. CV\_[*initials and last name*]\_[*titles (MD/PhD)*]\_ddMmmyy |  |  |
| H2 | CV principle investigator (in monocenter research) | H2. CV\_[*initials and last name*]\_[*titles (MD/PhD)*]\_ddMmmyy |  |  |
| I. Participating centers  |  |
| I1 | List of participating centers | I1. List\_Research\_Centers\_ddMmmyy |  |  |
| I2 | Research Declaration | I1. RD\_[*research center*]\_ddMmmyy |  |  |
| I3 | CVs principle investigator | I3. CV\_[*initials and last name*]\_[*titles (MD/PhD)*]*\_*ddMmmyy |  |  |
| I4 | Other information per participating center |  |  |  |
| J. Financial compensation  |  |
| J2 | Financial compensation for investigators and participating centers |  |  |  |
| K. Other documents  |  |
| K1 | Reviews by other institutions  | K1. Reviews\_[*from*]\_ddMmmyy |  |  |
| K2  | Overview list of competent authorities | K2. List\_comp\_authorities\_ddMmmyy |  |  |
| K3 | Clinical trial agreements  |  |  |  |
| K4 | Scientific publications  | K4. [*last name*]\_et\_al.\_[*year*]\_[*publication date*] |  |  |
| K5 | Data Safety Monitoring Board (DSMB) | K5. DSMB/IDMC\_[*draft/final*]\_[*version (V)*]\_ddMmmyy |  |  |
| K6 | Other information | K6. GP\_Letter\_[*version (V)*]\_ddMmmyy |  |  |

 **Instructions for completing the submission overview:**

* Fill out the table and match documents in terms of names. The submitted documents must correspond in terms of names to the file names in the overview.
* Is the type of document not in the table? Then add it manually. Keep the same style.
* Keep the length of the file name as short as possible, specific and including the version number and date (in the style ddMmmyy). The date is the date of the file or the date of the last signature.
* Multiple documents? Place these below the other in the same cell in the third column. The information in the first two columns does not need to be repeated.
* If there are several D4 documents with the same manufacturer, city name and country code, please complete the file name with the street name.
* If documents are not applicable, remove them from the overview.
* Keep the table in landscape orientation.
* Remove this text before submitting.