MREC Stichting BEBO

Weiersstraat 1C

9401 ET ASSEN

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

Ref.: Substantial Amendment for the 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 substantial amendment for the study entitled *\*study title\** which is registered under number \*NL-number\*.

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

The change(s) in this amendment concern(s):

\*an essential change to the current research\*

\*the addition of a study site\*

\*change in the design\*

\*other (please specify)\*

The reason for this change is \*elaborate description\*.

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/)).
* That the financial details previously provided have remained the same.

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 |  |  |
| B. Forms |  |
| B1 | ABR-form | B1. ABR-Form\_[*NLXXXXX.056.20*]\_[*version (V)*]\_ddMmmyy |  |  |
| B3  | EudraCT application form  | B3. EudraCT-form\_ddMmmyy |  |  |
| B5 | EudraCT notification of amendment form | B5. EudraCT\_NoA\_form\_Amdt\_[*nr*]\_[*version (V)*]\_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)  | D1. IB\_[*medicine*]\_[*version (V)*]\_ddMmmyyy |  |  |
| 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 |  |  |  |
| 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.