MREC Stichting BEBO

Weiersstraat 1C

9401 ET ASSEN

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

Ref.: Request for declaration of research not subject to the WMO - \*study code\*

Dear members of the MREC,

Hereby a request to the members of the MREC Foundation BEBO to review the research entitled *‘\*study title\*’* whether it is subject to the WMO or not with the request to issue a non-WMO statement.

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

**Explanation of research not subject to the WMO**

*\*[Please explain in detail why the research is not subject to the WMO. Please also pay attention to the actions, burden and time investment (on top of standard care) for participants.]\**

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.

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 |  |  |
| C. Protocol  |  |
| C1 | Research Protocol | C1. Research\_Protocol\_[*NLXXXXX.056.20*]\_[*version (V)*]\_ddMmmyy |  |  |
| 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 |  |  |  |

**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 documents are not applicable, remove them from the overview.
* Keep the table in landscape orientation.
* Remove this text before submitting.