**Codes and document titles for PDF documents**

Use this overview list to assign the correct codes and titles to the PDF documents you submit to the UMC Utrecht MREC. This list of examples is based on the standard research file created by the Central Committee on Research Involving Human Subjects (CCMO) at The Hague (see [www.ccmo.nl](http://www.ccmo.nl)). The options in blue are supplementary to the standard research file, and are listed here to enable you to name those documents correctly as well.

Where parts are highlighted in yellow, you must include the requested information in the document titles. Italicised text between brackets is a brief explanation.

**A. Correspondence**

A1. Cover letter from the applicant dated dd-mm-yy (*Templates for cover letters which must be submitted on paper along with the CD-ROM can be downloaded from the MREC website under Research file, A1. Cover letter*)

A1. Response to MREC questions dated dd-mm-yy (*Item-by-item response to questions from the MREC*)

A1. WMO / Non-WMO form dated dd-mm-yy (*This form can be downloaded from the MREC website*)

A2. Authorisation from sponsor dated dd-mm-yy (*Required if the sponsor is not the applicant*)

A3. Confirmation of receipt of EudraCT number dated dd-mm-yy (*This is an automatic e-mail message*)

**B. Forms**

B1. ABR form version … (*See https://www.toetsingonline.ccmo.nl*)

B3. EudraCT application form dated dd-mm-yy

B5. EudraCT notification of amendment form dated dd-mm-yy

B5. Notification of addition of participating centre [centre name] dated dd-mm-yy

B7. EudraCT end of trial form dated dd-mm-yy

**C. Research protocol and any protocol amendments**

C1. Research protocol NLxxxxx.xxx.xx, version …

C2. Protocol amendment version …

**D. Product information**

D1. IB for [product name] version …

D1. SUSAR line listing dated dd-mm-yy (*Only for SUSARs after the IB date*)

D2. IMPD for [product name] version …

D2. SPC for [product name]

D2. List of relevant trials

D3. Example labels version …

D4. TSE statement dated dd-mm-yy

D4. GMP declaration dated dd-mm-yy

D4. CE certificate for [product name] dated dd-mm-yy (*For research with a medical device)*

D4. CE Declaration of Conformity of [product name] dated dd-mm-yy (*For research with a medical device)*

D4. Other statements/licenses (*State type of document*)

D5. Hospital pharmacist product details

D6. Additional product details (*State type of document*)

D6. Report from the Medical Technology & Clinical Physics Cluster on [product name] dated dd-mm-yy (*For research with a medical device without a CE marking*)

**E. Information for subjects**

E1. Information sheet version …

E2. Informed consent form version …

E3. Promotional materials version … (*State type of document*)

E4. Other information materials version … (*State type of document*)

E5. Newsletter dated dd-mm-yy

E5. Letter with study results dated dd-mm-yy

**F. Questionnaires, patient diary, patient card, etc.**

F1. Questionnaire version …

F1. Interview script version …

F2. Patient diary version …

F3. Patient card version …

F4. Other documents (*State type of document*)

**G. Insurance information**

G1. Insurance certificate for WMO research dated dd-mm-yy

G2. Proof of liability coverage dated dd-mm-yy

**H. CVs**

H1. CV of independent expert [expert name] dated dd-mm-yy

H2. CV of coordinating investigator [investigator name] dated dd-mm-yy

**I. Information for each participating centre in the Netherlands**

I1. List of participating centres with their principal investigators dd-mm-yy

I2. Research declaration of [centre name] dated dd-mm-yy

I3. CV of principal investigator [investigator name] of [centre name] dated dd-mm-yy

I3. CV of independent expert [expert name] dated dd-mm-yy (*If this is not the same person as under H1*)

I4. Other centre information (*State type of document*)

**J. Additional information on financial compensation** (*If not included in the ABR form*)

J1. For research subjects dated dd-mm-yy

J2. For investigators and participating centres dated dd-mm-yy

**K: Other relevant documents**

K1. Decision/recommendation from [institution name] dated dd-mm-yy (*subsidy provider, EMA recommendation, FDA recommendation, etc.*)

K2. List of decisions from MRECs and/or competent authorities in other countries (including VHP) dated dd-mm-yy

K3. Clinical trial agreement dated dd-mm-yy

K3. Subsidy granting decision dated dd-mm-yy

K3. Statement that the clinical trial agreements concluded are the same as the version reviewed by the MREC dated dd-mm-yy

K4. Scientific publication in [journal name] dated [publication date]

K5. Data Safety Monitoring Board charter version …

K5. Composition of the DSMB

K6. Other documents (*State type of document, e.g. letter to GP, letter to treating medical specialist, recommendation from radiation committee, etc.*)

K6. Monitoring plan version …

**L: Safety information**

L1. SUSAR reference dated dd-mm-yy

L1. SADR reference ………. dated dd-mm-yy

L2. Periodic SUSAR line listing for [product name] dated dd-mm-yy

L3. Annual Development Safety Update Report for [product name] dated dd-mm-yy

L4. SAE reference dated dd-mm-yy

L5. Advice from the Data Safety Monitoring Board dated dd-mm-yy

L6. Other relevant safety information (*State type of document*)

**M: Progress reports and study results**

M1. Progress report dated dd-mm-yy

M1. Interim analysis dated dd-mm-yy

M2. Summary of study results dated dd-mm-yy

M2. Scientific publication dated dd-mm-yy

M3. Clinical study report dated dd-mm-yy