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

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

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

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

**B. Forms**

B1. ABR form version … dd dd-mm-yy

B1a. Eudamed form dd dd-mm-yy (*MDR*)

B2. Local addendum ABR-form

B2. Registrationform biobank dd dd-mm-yy

B3. EudraCT application form dated dd-mm-yy

B4. Gene therapy / GMO form dd 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 … dd dd-mm-yy

C1. Biobankprotocol version ... dd dd-mm-yy

C2. Protocol amendment version … dd dd-mm-yy

**D. Product information**

D1. IB for [product name] version … dd dd-mm-yy

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

D2. IMPD [product name] version … dd dd-mm-yy

D2: IMDD [product name] version … dd dd-mm-yy

D2. SPC [product name]

D2. List of relevant trials dd dd-mm-yy

D3. Example labels version … dd dd-mm-yy

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. Statement manufacturer on safety and performance of medical device dd dd-mm-yy (*MDR*)

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] dd dd-mm-yy (*For research with a medical device without a CE marking*)

**E. Information for subjects**

E1/E2. Information and informed consent form version … dd dd-mm-yy

E1. Information sheet for biobank research version ... dd dd-mm-yy

E2. Withdrawal from for subject information sheet version … dd dd-mm-yy

E3. Promotional materials version … dd dd-mm-yy (*State type of document*)

E4. Information materials version … dd dd-mm-yy (*State type of document*)

E5. Newsletter dd dd-mm-yy

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

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

F1. Questionnaire version … dd dd-mm-yy

F1. Interview script version … dd dd-mm-yy

F2. Patient diary version … dd dd-mm-yy

F3. Patient card version … dd dd-mm-yy

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

**G. Insurance information**

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

G1. Statement insurance certificate for WMO research dd dd-mm-yy

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

**H. CVs**

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

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

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

I3. CV of independent expert [expert name] [centre name] dd 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. Information on financial compensation for research subjects dd dd-mm-yy

J2. Information on financial compensation for investigators and participating centres dd dd-mm-yy

**K: Other relevant documents**

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

K1. Advise other institutions dd dd-mm-yy (*MDR*)

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

K3. Clinical trial agreement dd dd-mm-yy

K3. Subsidy granting decision dd dd-mm-yy

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

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

K5. Data Safety Monitoring Board [composition, charter] version … dd dd-mm-yy

K6. Description of procedures to comply with GDPR tile dd dd-mm-yy (*MDR*)

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 … dd dd-mm-yy

K6. Agreements central Biobank UMC Utrecht dd dd-mm-yy

K7. Clinical evaluation plan dd dd-mm-yy (*MDR*)

**L: Safety information**

L1. SUSAR reference ……… dd dd-mm-yy

L1. SADR reference ………. dd dd-mm-yy

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

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

L4. SAE reference ………. dd dd-mm-yy

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

L6. Other relevant safety information [Type of document] dd dd-mm-yy

**M: Progress reports and study results**

M1. Progress report dd dd-mm-yy

M1. Interim analysis dd dd-mm-yy

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

M2. Scientific publication dd dd-mm-yy

M3. Clinical study report dd dd-mm-yy