Standard research file

for the submission of a research proposal to a WMO reviewing committee and/or the competent authority

A. Correspondence

A1: Covering letter to the reviewing committee and competent authority

A2: Authorisation letter from the sponsor if the submitting party is not the sponsor

A3: Confirmation EudraCT number 

B. Forms

B1: ABR form including a summary (online, including date and signature)

B2: Local addendum to the ABR form (at the request of the reviewing accredited MREC)

B3: EudraCT application form: (online, signed and dated) 

B4: Gene therapy/GMO form (if applicable)

B5: EudraCT form notification of amendment 

B6: CCMO form end of trial

B7: EudraCT end of trial form 

C. Protocol and amendments

C1: Research protocol

C2: Protocol amendments, in chronological order

D. Product information

D1: Investigator's Brochure (publication date: < 1 year old) and overview of SUSARs not yet mentioned in IB (including summary and assessment) 

D2: IMPD, (or SPC when applicable), including list with relevant trials with the medicinal product being researched 

D2: IMDD (if applicable)

D3: Example lables in Dutch 

D4: Applicable declarations/licenses 

D5: Product information hospital pharmacist (if applicable) 

D6: Additional product information, e.g., for gene therapy: digital nucleotide sequence of the vector (if applicable) 

E. Information for the research subjects

E1/E2: Research subject/representative information leaflet including the consent form(s)

E3: Any advertising texts or other recruitment material

E4: Other information material

E5: News letters or letters with study results (*after* approval of the research)

F. Questionnaires, patient diaries, patient cards, etc. (if applicable)

F1: Questionnaires

F2: Patient diary

F3: Patient card

F4: Other

G. Insurance information

G1: Insurance certificate for WMO research with human subject insurance or written request for exemption from insurance obligation

G1. Declaration human subjects insurance

G2: Proof of coverage of investigator or sponsor, for example liability insurance

H. CVs

H1: CV independent expert (doctor or other independent expert(s))

H2: CV coordinating investigator for multicentre research (if applicable)

I. Information per participating centre in the Netherlands

I1: List of participating centres and principal investigators

I2: Research declaration from the head of department/healthcare group manager (or equivalent) per centre (for external review/multicentre research) (in force until 1-7-2015).

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I3: CV of the principal investigator per centre

I4: Other information per participating centre

J. Additional information regarding financial compensation (if not mentioned on the ABR form)

J1: For research subjects

J2: For investigators and centres

K. Other relevant documents:

K1: Copy of reviews by other institutions, e.g. grant giving body or scientific committees or recommendations by regulatory authorities)

K2: Overview foreign competent authorities to where the protocol was submitted, together with copy of reviews by foreign MRECs/ECs or authorised authorities, e.g. VHP 

K3: Signed clinical trial agreement from sponsor or funder and the investigator and/or institution

K4: Scientific publications (regarding previous/comparable research provided by the submitting party)

K5: DSMB: Data Safety Monitoring Board (composition, charter)

K6: Other documents (e.g. letters for general practitioners/treatment consultants, recommendation of the radiation committee)

L. Safety information (after approval of the study)

L1: SUSARs 

L2: Periodic line listings SUSARs 

L3: Development Safety Update Reports 

L4: SAEs

L5: Advice DSMB (Data Safety Monitoring Board)

L6: Other relevant safety information

M. Progress reports and research results

M1: Progress reports

M2: Summary of research results/scientific publications

M3: Clinical trial reports