Overview of 7T Trial Master File (TMF) content

Documents for 01: Grant application

- Grant application (if no grant application, still write this on the first tab but leave empty)

Documents for 02: Approvals

1. Monitors besøgslog
2. GCP-enhedens godkendelse til forsøgsstart (will be provided by the GCP unit)
3. Rapport for initiering hos forsøgsansvarlig (will be provided by the GCP unit)
4. Samarbejdsaftale (will be provided by the GCP unit)
5. Monitoreringsplan (will be provided by the GCP unit)
6. Risikovurdering (will be provided by the GCP unit)
7. Approval from Lægemiddelstyrelsen
8. Approval from VEK + approval for addendums
9. Latest approved version of the protocol sent to VEK (must be signed and dated by the Forsøgsansvarlige)
10. Latest approved version of the protocol sent to Sundhedsstyrelsen (must be signed and dated by the Forsøgsansvarlige and the investigator)

Documents for 03: Ethical Protocol

These are all VEK approved documents

1. All older versions of the protocol
2. Anmeldelsesskema
3. Protokol resumé
4. Deltagerinformation
5. Samtykkeerklæring
6. Fuldmagtserklæring
7. Annonceopslag
8. Ulempegodtgørelse

…. Etc. basically all the documents you have gotten approved by VEK in both current and previous versions

Documents for 04: Study Initiation forms

1. Approved and signed study initiation form (approved by the Forretningsudvalg)
2. Approved and signed study initiation form from your research institution (if applicable)

Documents for 05: Data Protection

1. Approval from the Data Protection Agency
2. Anmeldelsesskema approved by the Data Protection Agency
3. Sikkerhedsskema approved by the Data Protection Agency

Documents for 06: Access and documentation

1. Filled out and signed "Opgavefordelings- og signaturliste"
2. Delegation list (if you have delegated the power to give the oral information to someone who is not responsible for the project - in most of our projects Hartwig is responsible but delegates the power to give the oral information)
3. For all relevant people you must have
    a. Signed and dated CV's
    b. " 7 Tesla MR Scanner Operator Certification form" for everyone who will be using the 7 T scanner
    c. GCP Course Certificate

Documents for 07: Adverse events/reactions

1. "Adverse events and reactions statement"
2. "Indberetning af hændelser"
3. "Rapportering af alvorlige hændelser"
4. "Eksempel på indberetningsskema"
5. "Eksempel på årlig rapport"
6. DRCMR documents relating to incidental findings
7. Skema til hændelser – medicinsk udstyr
8. "Indberetningsskema til lægemiddelstyrelsen"

Documents for 08: Participants' documentation

1. Kildedataliste (signed and dated)
2. Oral information procedure (if you have patients instead of healthy subjects)

Documents for 10: Project Termination

In additional folder (not in the TMF)

ALL information which can be used to identify healthy subjects/patients

1. Key to translate X number to person (identification log)
2. Screening liste
3. Subject ID
4. All signed informed consent forms
5. All Signed MR control forms
6. All signed TMS control forms
7. All signed Fuldmagtserklæringer (GCP og Lægemiddelstyrelsens ret til adgang)
8. All signed inclusion- and exclusion sheets (see example in folder)