Essential Documents for Research Studies

Research Office, Department of Medicine

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The core of a good trial or research study is the quality of the documentation. Organization and proper filing of essential study documents not only demonstrates compliance with good clinical practice but also ensure successful management of the study by the investigator, the team and if necessary the sponsor or coordinating site. At the initiation of any study a study master file should be created to keep all documentation listed here in one location. Each study should have its own file and this file should be maintained as needed to ensure all required documentation is current and accurate.

Essential documentation required for any study conducted in the Department of Medicine is as follows:

Title of Document	**Purpose of Document**	**Version Controlled**
Research Ethics Board (REB) Approval Certificates and updates	Documentation of approval listing the approved consent forms, questionnaires, and study materials	Yes
Site Approval Forms and Renewals	Documentation of approval from the institution. For Fraser this will be in the form of a LOA, for other sites this may be an email conformation	
Regulatory Authority Approvals *if applicable*	Documentation of all regulatory approval i.e. NOL from Health Canada	
Study Protocol and any Amendments - *signed by all members of the investigative team*	All members of the study team should be aware of the current approved protocol	Yes
Information provided to study participants including consent forms – *all versions and applicable translations*	Documentation of all information which is approved and authorized for use during the study	Yes
Training Log	Documentation of necessary training required i.e. TPCS-2 certificates, protocol training logs etc.	
Participant identification code *if applicable*	Documentation required in the event that participants must be unblinded	
Participant enrolment log	Documentation of chronological enrolment of participants by study number (study number/dates)	
Case Report Form (CFR) *if applicable*	Documentation of approved data collection forms for reference	Yes
Signed agreements between involved parties *if applicable*	Any signed agreements which may be between investigator/site/institution which pertain to the study	
Financial Documentation *if applicable*	Documentation for sub-site agreements or studies involving payment per patient or an agreed upon payment for service.	
Audit certificates *if applicable*	Documentation of any audits of inspections done for the purposes of validation	
Signed informed consent forms	Documentation that informed consent was obtained for all study participants	Yes
Final reports required for REB		

Additional Suggested Documentation for Studies as per GCP Guidelines

Title of Document	Purpose of Document	Notes
Organization Chart/ Delegation of Authority Document	Document who is authorized to work on the study, and the roles of each study team member. Serves as historical record.	May include a signature sheet which provides a record of the signature and initials of all individuals on the study.
CV and Investigator Qualifications of Investigators / Sub-investigators	Provide documentation of qualifications	Each CV should be signed and dated May include copies of certificates for staff
Normal Value(s)/range(s) for medical/ laboratory and test procedures which will be performed as part of the study	Provides a set reference for what is considered to be normal values at the time of the study.	
Relevant Communications (including meeting notes, letters, memos)	Documents discussions or information relevant to study administration, protocol violations, etc.	

Reference:

ICH Guidelines Step 5, Canada
Good Clinical Practice: Consolidated Guidance (ICH-E6)