Study Master File Checklist

This template guide can be used to implement the CCP in Africa. It should be accessible to study staff so that they can refer to it when implementing the study.

Guidance is provided in *blue text* and should not be copied to your File (paper/electronic).

	Sections	*Guidance*
1	PROTOCOL	
a	Protocol	*This section should contain the current version of the protocol.* *Sub-sections can be created in this folder for drafts and previous versions, which have now been superseded.* *Creating a Version History Log is a useful way of keeping track of each updated protocol and its amendments and could also be saved in this section.*
b	Study Standard Operating Procedures (SOPs)	*Develop standard operational procedures (SOPs) to be used by study staff for a quick reference guide during study implementation.* *This should include all aspects of the study (e.g. clinical, sampling processes, laboratory etc.) – copies can be stored here.*
2	PATIENT INFORMATION & CONSENT	
a	Patient information sheet (PIS) & Informed Consent Forms (ICF)	*Templates are available and can be adapted to your local setting; You may wish to develop simple study flow charts that can be stuck on walls in consulting room, doctors/nurses room, staff tea room etc.* *This section should contain the current versions of these documents.* *If any updates are made, the old versions should be clearly marked as superseded.*
3	CASE REPORT FORMS	
a	Case Report Form (CRF)	*A modified CRF have been created for ALERRT and are available in electronic format.* *The current CRF should be saved in this section with any superseded versions marked accordingly.*
b	CRF guidance	*[IF USING THE ISARIC DATA PLATFORM] Data entry guides for the CORE and RAPID Case Report Forms have already been created and would be included here.*

4	ETHICS	
a	Initial application and approval	*This section should contain at least the following items:* • *Ethics application form* • *All supporting documents submitted to the ethics committee (e.g. Patient Information Sheets & Informed Consent Forms etc.)* • *Cover letter (where required)* • *Approval letter(s)* • *Any queries returned by ethics prior to approval and the study team's response*
b	Amendments	*A sub-section should be created in this folder for each submitted amendment.* *Each sub-folder should contain at the least the following items:* • *Amendment notification* • *All supporting documents associated with the amendment (e.g. revised Patient Information Sheets & Informed Consent Forms etc.)* • *Cover letter (where required)* • *Approval letter(s)*
c	Annual Progress Reports *[if required]*	*Some committees require an annual progress report: Use this section to store each report submitted to the ethics committee, with any queries from the committee.*
5	SPONSOR	
a	Agreement with Sponsor	*The final signed agreement should be saved here with any amendments and the correspondence relating to the agreement.*
b	Sponsorship confirmation	*Any documentation relating to registration for sponsorship and confirmation documents should be filed in this section*
c	Chief Investigator (CI)	*A CI will be responsible for all aspects of the study at theirs and other sites (if this is being conducted in many facilities).* *File a copy of the CI's CV and GCP certificate.*
6	INSURANCE	
a	Insurance policy documents	*This section should contain copies of the relevant insurance documentation provided by the sponsor as well as any other additional insurance that is required for the study.*
7	FUNDING AND FINANCE	
a	Study budget *[if required]*	*A copy of the study budget should be saved here with any related correspondence.*
b	Grant application *[if required]*	*The study's funding applications should be saved here with submission acknowledgements and any queries relating to the application.*
c	Grant award letter	
d	Reports/ updates to funding bodies *[if required]*	*This section should contain copies of each report or informal update sent to funding bodies relating to the study.*

8	COMMITTEES *[add other committees as required]*	
a	Study Management Group	*This section should contain documents related to study management e.g. signed charters, meeting agendas and meeting minutes.*
9	SITES *[if required]*	
a	List of sites/ investigators	*If you are running this study across many facilities/sites, this section should contain an up-to-date list of all sites participating in the study, including the name and contact details of the Principal Investigator (PI) and site status (i.e. open, in set-up, closed)*
b	Site agreements	*Signed agreements and amendments between the sponsor and each site should be saved in this section*
10	CENTRAL LABORATORIES	
a	List of central laboratories	*It is useful to keep an up-to-date list of all central laboratories participating in the study and their contact details.* *If more than one laboratory is involved, detail the role/ responsibility of each laboratory.*
b	Lab accreditation documents	*Accreditation documents for all laboratories participating in the study should be saved here.*
c	Laboratory contracts	*This should contain all signed laboratory contracts.*
d	Laboratory manual	*All applicable manuals relating to sample management at site and at the central laboratory level should be saved here.*
e	Sample documentation	*Templates for sites to log samples taken and shipped are useful tools to create to record sample activity.*
f	Sample tracker	*A sponsor sample tracker is also useful to track sample shipments, their receipt at the lab, their analysis and when results are returned to sites (where applicable) or entered on the data capture system.*
11	QUALITY CONTROL	
a	Protocol deviation reports	*A template protocol deviation report should be created and sent to sites to ensure that deviations are reported to the sponsor in a consistent manner. All final versions of the protocol deviation reports associated with the study should be saved here, with ongoing reports that were incomplete at the time of submission and related correspondence. All incidents should be closed before archiving. A protocol deviation report log is also useful to track the status of deviations and monitor trends in incidents.*
b	Internal audit reports	*This section should contain a log of all internal audits that have taken place on the study, in addition to audit reports and correspondence.*

12	STUDY STAFF	
a	Delegation log *[if required]*	*This is a log of all sponsor/ coordinating centre staff who are working on the study, including their roles, start date, end date and delegated tasks. This log should be updated each time a new member of staff joins or leaves the study, or when their delegated tasks change.*
b	Training log *[if required]*	*A training log should be kept and updated throughout the study to document the training undertaken by all study staff.*
13	RISK ASSESSMENTS AND MONITORING	
a	Risk assessment	*This section should contain the final version of the study risk assessment (preferably signed by the CI).*
b	Monitoring plan	*The final monitoring plan should be filed with updated versions, drafts, superseded documents and any related correspondence.*
c	Monitoring templates and tracking log	*Templates for documenting monitoring activities should be created for the study team to use each time an activity is undertaken.* *The templates included in this section will be guided by the requirements of the monitoring plan.* *A tracking log is a useful way of keeping track of the status of all past and future monitoring activities and should be an accurate and up-to-date record of the activities undertaken throughout the study.*
14	DATA MANAGEMENT ANALYSIS AND OUTPUT	
a	Data protection	*File all relevant documentation relating to your institutional data protection requirements.* *If your study has sites in Europe also file a copy of the GDPR and transparency statement here*
b	Analysis and output	*This section should contain the contact details and CV of anyone analysing the study data. Contracts between the any collaborating organisations should also be held here.* *The final analysis plan should also be saved with any previous versions marked as superseded.*
16	PUBLICATIONS	
a	Final study report	*The final published study report should be saved here. A sub-folder should be created containing drafts and author correspondence.*
b	Other publications	*Copies of any other published work generated by the study team should be held here.*
17	ARCHIVING *[if required]*	
a	Box lists	
b	Archiving forms	
18	GENERAL CORRESPONDENCE	

Study Master File Example Template, Version 1, 4th May 2020 [Based on the WHO/ISARIC Clinical Characterisation Protocol (CCP), Version 3.1/3.2; Citation: Dunning, J. W., et al. (2014). "Open source clinical science for emerging infections." Lancet Infect Dis 14(1): 8-9].