|  |
| --- |
| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on Essential Documents. Update it as necessary for your specific study.** * This templated tool provides a way to track the location of various Essential Documents for easy review by monitors or auditors as well as to assist in staff onboarding and maintenance. This can be used as a memo within a Regulatory Binder. Study staff can also provide more specific memos within a regulatory or participant binder section to indicate a location external to that specific binder.
* This tool can also be used to identify the location of records that may be best stored as study-agnostic documents in a Central File-type system. For example, staff qualifications such as CVs/resumes, licenses, and Human Subjects Protection training may be best stored separately from any study-specific binder. This allows for more efficient review and maintenance when a research team has more than one study. Any study-specific training should still be stored in study-specific binders.
* Essential Documents are those documents that both individually and together allow for a complete evaluation of the conduct of a research study and the quality of the data produced. See [ICH Good Clinical Practice Section 8](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf) guidelines for a full definition.
* Essential Documents fall into one of two categories: participant and regulatory. Participant-related forms are for a specific individual while regulatory documents are those that are either blank, approved versions of things or pertain to the study or participant pool as a whole.
	+ Participant: can include but not limited to signed consent forms, completed questionnaires and case report forms, completed adverse event forms, visit records or progress notes
	+ Regulatory: can include but not limited to blank versions of consents, questionnaires, case report forms, other-IRB approved items, regulatory submission memos, overall tracking for safety events or biospecimen shipping, and staff qualifications
* The manner in which Essential Documents are kept can be paper, electronic, or a mix depending on the specific document. The word “binder” is often used as a catch-all term but can mean an actual three-ring binder or even an electronic filing system. Generally speaking, individually-identifiable records, ID-coded study data, and regulatory documents are kept separate. The IRB submission should detail how these various records are kept and maintained and that process should be followed as approved.
* Additional resources for Essential Documents are available within the [Standard Operating Procedure guidance document](https://www.bumc.bu.edu/ohra/required-training/institutional-standard-operating-procedures-sops/).
* Delete the CRRO template version date and add in the study-specific version date of this document.
 |

| **Document** | **Location** |
| --- | --- |
| [Both the [Standard Operation Procedure](https://www.bumc.bu.edu/ohra/required-training/institutional-standard-operating-procedures-sops/) and [ICH GCP Section 8](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf) provide a more extensive list of examples.] | [Location could be as specific as a Tab within a Regulatory Binder or just the Regulatory Binder. Or it could include a reference to a specific room number where participant binders are stored or a shared drive pathway to electronic files.] |
| Protocol, Current, IRB-Approved | Regulatory Binder |
| Protocol, Archived and Outdated | Archived Documents Regulatory Binder |
| Consent – Blank, Current IRB-Approved | Regulatory Binder |
| Consent – Blank, Archived and Outdated | Archived Documents Regulatory Binder |
| Consent – Signed by Participant/Researcher | Individual Participant Binder |
| Completed Electronic-Only Case Report Forms | REDCap |
| Completed Paper Case Report Forms | Individual Participant Binder |
| Blank Case Report Forms (all) | Regulatory Binder |
| Biospecimen Shipping Log | Regulatory Binder |
| Shipping Company Tracking Receipt | Regulatory Binder |
| Staff Licensure | Central Files – Staff Information |
| Staff Study-Specific Training Logs | Regulatory Binder |