**Carilion Clinic Institutional Review Board**

**Research Documents Organization Checklist**

In order to comply with Good Clinical Practice recommendations and to maintain appropriate study documentation, investigators or coordinators must create and maintain the following documents for all studies, **regardless of level of IRB review or funding source**:

1. **Regulatory Binder that includes the following:**

⁪ IRB Application

Maintain hard copies of the current version as well as all previously **IRB-approved** versions. You do not need to keep draft versions. If possible, also note the file name and location of the electronic version of the most recently approved application.

⁪ Protocol

 If there is protocol (for many studies, the IRB application will serve as the protocol), maintain hard copies of the current version as well as all previous versions.

⁪ Informed Consent Forms

All IRB-approved versions, including the current IRB-approved informed consent. *(File all signed and dated informed consent documents in the research subject files. See below.)* This section should also include IRB-approved assent forms, LAR forms, and/or consent to continue participation in a study (to be signed by minors who come of age during the study). When signed consent has been waived and an information sheet is mandated, all IRB-approved versions of the information sheet should be included in this section.

⁪ Other IRB Approved Materials

All approved versions of recruitment materials such as scripts, flyers, brochures; Case Report Forms (CRFs); Data Collection Forms (if applicable.) Maintain originals of all IRB approved versions. *(Maintain completed and signed copies of CRFs or completed data collection forms for each study subject in separate subject study file/binder. See below.)*

⁪ Curriculum Vitae (CV)

File a current copy of the CV of each IRB approved research team member and other study personnel.

⁪ Professional license

File a copy of the current license for each licensed professional involved in the

conduct of the study. Keep all versions on file.

⁪ Financial Disclosures

File a copy of the signed financial disclosures for all research team members

involved in the conduct of the study.

⁪ Miscellaneous

Keep all audit reports, monitoring reports, grant applications, contractual agreements,

Certificates of Confidentiality, CITI Training Certificates, Data Safety Monitoring Plans, Package Inserts, Investigator Brochures (drug study), and FDA Form 1572, if applicable. If your study involves an external laboratory, keep a copy of the lab certificate (CLIA), reference lab values, and CV of the lab supervisor. If your study involves distribution of a study drug, keep a drug accountability log for tracking purposes.

1. **Correspondence Binder that includes the following:**

⁪ All pertinent and key communication and correspondence with investigators,

 research team members, Research and Development, and funding

 agencies/foundations.

⁪ Correspondence with sponsor/monitors including but not limited to information

 such as formal letters, pertinent email messages, study updates, progress reports,

 safety updates/reports, amendments to protocol, reports of adverse events and

 protocol deviations, requests for protocol exceptions, if applicable.

⁪ Correspondence with data safety monitoring boards/committees including but not

 limited to regularly scheduled reports and interim findings, if applicable.

1. **IRB Documentation:**

⁪ Initial submission packet

IRB application, including supporting documents such as grant applications,

recruitment materials, informed consent document, any surveys or questionnaires, etc.

⁪ IRB correspondence

All IRB correspondence received from and submitted to IRB including formal

letters such as approval letters and pertinent e-mail messages.

⁪ Change/Update Forms

All modifications/clarifications submitted for IRB approval

⁪ Evidence of student training about how to obtain informed consent if students are assigned and approved to do so and the Principal Investigator has affirmed on the IRB Application that such training has taken place.

⁪ Continuing Review Forms

All continuing review applications and supporting materials submitted to the IRB.

⁪ Promptly Reportable Information forms

All promptly reportable events, corrective action plan, and any follow-up documentation and/or communication

⁪ Conclusion

Conclusion report after completion of study

1. **Research Subject Files:**

⁪ Case Report Forms or Data Collection Forms

Maintain completed and signed copies of forms for each study subject in a subject specific study file or binder.

⁪ Informed Consent Forms

File all signed and dated informed consent documents in the subject study file or binder.

⁪ Checklist for documenting Informed Consent process

 An example can be found at https://www.carilionclinic.org/irb/forms

⁪ Completed and signed Inclusion/Exclusion Checklist, with notations of the location of the source documentation for the criteria or Screening Forms (if applicable)

⁪ Notes to File

Maintain notes to file for each subject in the subject study file or binder as needed.

⁪ Research subject specific correspondence, including emails or telephone logs

1. **Other Logs/Tracking Records:**

⁪ Enrollment Log. The enrollment log should give an overview of all subjects

enrolled if this is appropriate to your study. List all enrolled subjects and/or study ID numbers, including dates of enrollment and any important information such as randomization group, as appropriate. Some studies also may need a screening log to track screening or screen fails prior to enrollment.

⁪ Delegation of Duties Log and Study Staff Signature Log for the research

 team. The Delegation of Duties Log should describe the role of each team member and

 particularly which members may consent subjects. Make sure this log does not

 contradict your protocol or IRB Application. The Study Staff Signature Log should show

 the signatures of all study team members. These logs may be kept in the regulatory

 binder.

For specific questions regarding your study, please contact the IRB at 981-8015 or 853-0728.