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 accessible versions (secure electronic or hard copies) 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), provide secure electronic or 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.

2) 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.

3) 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

4) 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 or provide access to electronic records.
- ☐ Checklist for documenting Informed Consent process
  Guidance can be found at Consent Guidance on IRB website

□ 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

5) 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.