Carilion IRB Relying on an External IRB Using an Established Master Agreement

Advarra IRB Studies:

To submit a new Advarra IRB submission in PRISM, please choose the "Request to Rely" Application. Please upload the following documents into PRISM for Carilion IRB approval to Rely on Advarra, which is required prior to submission to Advarra:

- Current Protocol
- Consent with local contact information inserted; HIPAA Authorization language must include all requirements or the Carilion template should be used (bullets and signature boxes tailored to the site/study). Carilion templates can be found at https://www.carilionclinic.org/irb/forms#consent-templates.
- If Legally Authorized Representatives (LARs) are needed to provide consent, as described in the Protocol and Application, please ensure that appropriate signature boxes are included in the Consent and the signature lines are added in the QA/QI IRB Survey addendum. If LARs are not allowed according to the Protocol, please remove references to LARs in the consent signature boxes and remove the QA/QI addendum signature lines.
- Carilion QA/QI addendum (Carilion IRB Survey) tailored for specific study
- Completed Advarra IRB application (Do not request a HIPAA waiver unless not using a consent document)
- Recruitment Materials
- Any other study-specific supplemental documents
- R & D approval letter
- Please check with Organization Integrity & Compliance regarding COI disclosures.
- All research team members will need to complete CITI training (Biomedical Researcher Course. They will also need the Good Clinical Practice Course if the study is FDA regulated or NIH funded).
- Please email the PI's CV to HRPO staff member (if not a current one on file within 2 years). Please do not upload it in Submission Components in PRISM.

*The Carilion IRB approval letter must be submitted to Advarra IRB with the other research documents that were submitted to Carilion IRB.

When Advarra is the IRB of record, Carilion IRB still has local oversight responsibility for studies and requires the following to be reported to Carilion IRB after initial approval in PRISM:

- Local site personnel changes. New research personnel also need to be cleared by the Compliance Department for financial disclosures. Associated documents that

will be revised due to the personnel changes do not need to be submitted to Carilion IRB. If the PI is changed, please upload an acknowledgement document (letter or email) from the PI indicating that he/she accepts the responsibilities as PI, as well as Dept Chair approval. (Please use Change/Update Form)

- Local site reportable events which can include local protocol deviations, local serious adverse events, local serious or continuing non-compliance (Please use Promptly Reportable Information Form)
- Local site audit reports and monitoring reports (Please use Promptly Reportable Information Form)
- Please consult with staff member if a partial HIPAA waiver for a recruitment activity at the local site has not been granted (see Carilion approval letter for HIPAA waiver reference). Please consult with a staff member if a recruitment method is changing significantly from what was originally indicated. (e.g., external patients approached, etc) Further guidance will be provided.
- Please conclude the study in PRISM and notify Advarra.
- **Advarra directly notifies Carilion IRB of all approvals (Initial, Continuing Review (CR), Protocol & Consent Amendments, Promptly Reportable Information forms (PRIs) – so documents do not need to be uploaded into PRISM).**

Advarra IRB has reporting requirements for protocol deviations, serious adverse events, serious or continuing non-compliance, and other items. Please refer to Advarra IRB reporting requirements for any questions about local reportable events in addition to Carilion IRB requirements.

Western-Copernicus Group (WCG) IRB Studies:

To submit a new WCG IRB (formerly known as WIRB) submission in PRISM, please choose the "Request to Rely" Application for Carilion IRB approval to Rely on WCG IRB. Please upload the following documents into PRISM:

- Current Protocol
- Consent with local contact information inserted; HIPAA Authorization language must include all requirements or the Carilion template should be used (bullets and signature boxes tailored to the site/study).
- If Legally Authorized Representatives (LARs) are needed to provide consent, as described in the Protocol and in the Applications, please ensure that appropriate signature boxes are included. If LARs are not allowed according to the protocol, please remove references to LARs in the consent signature boxes and the QA/QI addendum signature lines.
- Carilion QA/QI addendum (Carilion IRB Survey) tailored for specific study

- Completed WCG IRB application (Indicate not transferring to another IRB/Master Services Agreement with Carilion Institution# 57633/ Do not request a HIPAA waiver unless not using a consent document)
- Recruitment Materials
- Any other study-specific supplemental documents
- R & D approval letter
- Please check with Organization Integrity & Compliance regarding COI disclosures.
- All research team members will need to complete CITI training (Biomedical Researcher Course. They will also need the Good Clinical Practice Course if the study is FDA regulated or NIH funded).
- Please email the PI's CV to HRPO staff member (if not a current one on file within 2 years) at irb@carilionclinic.org. Please do not upload it in Submission Components in PRISM.

*The Carilion IRB approval letter must be submitted to WCG IRB with the other research documents that were submitted to Carilion IRB.

When WCG IRB is the IRB of record, Carilion IRB still has local oversight responsibility for studies and requires the following to be reported to Carilion IRB after initial approval in PRISM:

- Local site personnel changes. New research personnel also need to be cleared by the Compliance Department for financial disclosures. Associated documents that will be revised due to the personnel changes do not need to be submitted to Carilion IRB. If the PI is changed, please upload an acknowledgement document (letter or email) from the PI indicating that he/she accepts the responsibilities as PI, as well as Dept Chair approval. (Please use Change/Update Form)
- Local site reportable events which can include local protocol deviations, local serious adverse events, local serious or continuing non-compliance (Please use Promptly Reportable Information Form)
- Local site audit reports and monitoring reports (Please use Promptly Reportable Information Form)
- Please consult with staff member if a partial HIPAA waiver for a recruitment activity at the local site has not been granted (see Carilion approval letter for HIPAA waiver reference). Please consult with a staff member if a recruitment method is changing significantly from what was originally indicated. (e.g., external patients approached, etc) Further guidance will be provided.
- If the study was entered into PRISM, please conclude the study in PRISM in order to update the system. If not in PRISM as it is an older study prior to PRISM, the Carilion IRB does not need to be informed of Conclusions. Please inform WCG and they will notify Carilion IRB directly.

- **WCG IRB directly notifies Carilion IRB of all approvals (Initial, CR, Protocol & Consent Amendments, PRIs – so documents do not need to be uploaded into PRISM).**

WCG IRB has reporting requirements for protocol deviations, serious adverse events, serious or continuing non-compliance, and other items. Please refer to WCG IRB reporting requirements for any questions about local reportable events in addition to Carilion IRB requirements.

National Cancer Institute Central IRB (NCI CIRB) Studies:

To submit a new NCI CIRB submission in PRISM, please choose the "Request to Rely" Application for Carilion IRB approval to Rely on NCI CIRB (must meet specific NCI criteria). Please upload the following documents into PRISM:

- Carilion Application- completed with notation about use of a separate HIPAA Authorization and a request for a partial HIPAA waiver for screening purposes (unless something is specific to the study that is different than usual practice).
- Current Protocol
- Consent with local contact information inserted
- If Legally Authorized Representatives (LARs) are needed to provide consent, as described in the Protocol and in the Application, please ensure that appropriate signature boxes are included in the Consent and HIPAA Authorization. If LARs are not allowed according to the protocol, please remove references to LARs in the Consent/HIPAA Auth signature boxes.
- HIPAA Authorization- Carilion template should be used (bullets and signature boxes tailored to the site/study).
- Adult Gynecological (GYN) Oncology will also submit a separate HIPAA Authorization from Virginia Commonwealth University (VCU) and a Local Contact Sheet (please clearly label documents in the title).
- Recruitment Materials
- Any other study-specific supplemental documents
- R & D approval letter
- Please check with Organization Integrity & Compliance regarding COI disclosures.
- All research team members will need to complete CITI training (Biomedical Researcher Course. They will also need the Good Clinical Practice Course if the study is FDA regulated or NIH funded).
- Please email the PI's CV to a HRPO staff member (if not a current one on file within 2 years) at irb@carilionclinic.org. Please do not upload it in Submission Components in PRISM.

When NCI CIRB is the IRB of record, Carilion IRB still has local oversight responsibility for studies and requires the following to be reported to Carilion IRB after initial approval in PRISM:

- Initial approval by IRB of record for local site- this can be submitted by email (to HRPO staff members) or Change Update Form.
- Local site personnel changes. New research personnel also need to be cleared by the Compliance Department for financial disclosures. Associated documents that will be revised due to the personnel changes do not need to be submitted to Carilion IRB. If the PI is changed, please upload an acknowledgement document (letter or email) from the PI indicating that he/she accepts the responsibilities as PI, as well as Dept Chair approval. (Please use Change/Update Form)
- Local site reportable events which can include local protocol deviations, local serious adverse events, local serious or continuing non-compliance (Please use Promptly Reportable Information Form)
- Local site audit reports and monitoring reports (Please use Promptly Reportable Information Form)
- Please consult with staff member if a partial HIPAA waiver for a recruitment activity at the local site has not been granted (see Carilion approval letter for HIPAA waiver reference). Please consult with a staff member if a recruitment method is changing significantly from what was originally indicated. (e.g., external patients approached, etc) Further guidance will be provided.
- If the study was entered into PRISM, please conclude the study in PRISM. If not because it is an older study prior to PRISM, please use the "paper" Conclusion Form (used prior to PRISM) and attach the NCI conclusion approval.
- **NCI CIRB will NOT communicate directly with Carilion IRB regarding any approval actions**.
- All NCI CIRB approvals going forward (CRs, Protocol & Consent Amendments, Closure to Accrual, PRIs for all sites, etc) **must be emailed to Carilion IRB** (HRPO staff members at irb@carilionclinic.org).

NCI CIRB has reporting requirements for protocol deviations, serious adverse events, serious or continuing non-compliance, and other items. Please refer to NCI CIRB reporting requirements for any questions about local reportable events in addition to Carilion IRB requirements.

VT IRB, VCOM IRB, Radford University IRB:

To submit a new submission in PRISM, please choose the "Request to Rely" Application for Carilion IRB approval to Rely on one of the IRBs noted above. Please upload the following documents into PRISM:

- Carilion Application- completed with notation about use of a separate HIPAA Authorization and a request for a partial HIPAA waiver for screening purposes (unless something is specific to the study that is different than usual practice).
- Current Protocol
- Consent with local contact information inserted
- If Legally Authorized Representatives (LARs) are needed to provide consent, as described in the Protocol and in the Application, please ensure that appropriate signature boxes are included in the Consent and HIPAA Authorization. If LARs are not allowed according to the protocol, please remove references to LARs in the Consent/HIPAA Auth signature boxes.
- HIPAA Authorization- Carilion template should be used (bullets and signature boxes tailored to the site/study).
- Recruitment Materials
- Any other study-specific supplemental documents
- R & D approval letter
- Please check with Organization Integrity & Compliance regarding COI disclosures.
- All research team members will need to complete CITI training (Biomedical Researcher Course. They will also need the Good Clinical Practice Course if the study is FDA regulated or NIH funded).
- Please email the PI's CV to a HRPO staff member (if not a current one on file within 2 years) at irb@carilionclinic.org. Please do not upload it in Submission Components in PRISM.

When VT IRB, VCOM IRB, or Radford University IRB is the IRB of record, Carilion IRB still has local oversight responsibility for studies and requires the following to be reported to Carilion IRB in PRISM after initial approval:

- Initial approval by IRB of record for local site- this can be submitted by email (to HRPO staff members) or Change Update Form.
- Local site personnel changes. New research personnel also need to be cleared by the Compliance Department for financial disclosures. Associated documents that will be revised due to the personnel changes do not need to be submitted to Carilion IRB. If the PI is changed, please upload an acknowledgement document (letter or email) from the PI indicating that he/she accepts the responsibilities as PI, as well as Dept Chair approval. (Please use Change/Update Form)
- Local site reportable events which can include local protocol deviations, local serious adverse events, local serious or continuing non-compliance (Please use Promptly Reportable Information Form)
- Local site audit reports and monitoring reports (Please use Promptly Reportable Information Form)
- Please consult with staff member if a partial HIPAA waiver for a recruitment activity at the local site has not been granted (see Carilion approval letter for HIPAA waiver reference). Please consult with a staff member if a recruitment

method is changing significantly from what was originally indicated. (e.g., external patients approached, etc) Further guidance will be provided.

- If the study was entered into PRISM, please conclude the study in PRISM. If not because it is an older study prior to PRISM, please use the "paper" Conclusion Form (used prior to PRISM) and attach the reviewing site's conclusion approval.
- All reviewing IRB approvals going forward (CRs, Protocol & Consent Amendments, Closure to Accrual, PRIs for all sites, etc) **must be emailed to Carilion IRB** (HRPO staff members at irb@carilionclinic.org).

Reviewing IRBs have reporting requirements for protocol deviations, serious adverse events, serious or continuing non-compliance, and other items. Please refer to the reviewing IRB's reporting requirements for any questions about local reportable events in addition to Carilion IRB requirements.