



PHCIRB SUBMISSION REQUIREMENTS

Forms Guidance

- It is imperative that you read and adhere to the instructions in the submission forms. Many of the submission forms will direct you to ALSO submit a succinct proposal along with the submission form. Example:

Proposal Details

Along with this cover sheet you must provide a succinct proposal incorporating details for each section title listed below. Do not delete sections that do not apply – simply enter 'N/A' in that section.

- The submission forms are NOT revision friendly. Please gather all required information prior to populating the form and follow the instructions at the end of the form:

NOTE: IMPORTANT FINAL STEPS (in order)

1) Select the print option, save the form, as a PDF, then include the form with the materials for submission to ORS@piedmont.org or to be uploaded into IRBNet.

2) Click the 'Submit' button.

Failure to follow the above steps will result in an unreadable form AND the need to complete the form again.

CHART REVIEW

- Training
 - CITI Group 2
 - Basic Chart Review
 - Just Ask Webinar
- Submission Forms
 - Protocol on Chart Review Template
(<https://app.smartsheet.com/b/form/31a39b552cf140878de5780e7c762e44>)
 - New Protocol Application
(<https://app.smartsheet.com/b/form/b0934efc2e534a2fb2b1713a1309820c>)
 - Alterations or waiver of informed consent Form
(<https://app.smartsheet.com/b/form/73999bcc409548efa5f2c58b941eda56>)
 - Alterations or Waiver of HIPAA Form
(<https://app.smartsheet.com/b/form/8da23b9655264d788af673d204409d44>)
- Other
 - Signed/dated CV

CLINICAL / MEDICAL RESEARCH INVOLVING DRUGS AND/OR DEVICES

- Training
 - CITI Group 1
 - Human Subjects Research (HSR)
 - Good Clinical Practice (GCP)
 - Just Ask Webinar
- Submission Forms
 - Research Protocol Template and Cover Sheet
(<https://app.smartsheet.com/b/form/d348f26e47244084b37961abc1862ab2>)
 - New Protocol Application
(<https://app.smartsheet.com/b/form/b0934efc2e534a2fb2b1713a1309820c>)
 - Link to consent templates (chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/file:///H:/2025-02-PHC-Assent-Consent-Links.pdf)
 - HIPAA Authorization Form
(<https://app.smartsheet.com/b/form/d8a4b60d20eb4f0a902af094c8747a9e>)
 - Revocation Letter Form
(<https://app.smartsheet.com/b/form/456b5c80715842fb97192c4ac6007a97>)
- Other
 - Signed/dated CV

EXEMPT RESEARCH (includes educational tests, surveys, interviews, etc...)

- Training
 - CITI Group 2
 - Basic Chart Review/Minimal Risk
 - Just Ask Webinar
- Submission Forms
 - Request for Verification of Exempt Status
(<https://app.smartsheet.com/b/form/7aa8a35617cb483aaa8c142f06644e72>)
- Other
 - Signed/dated CV

QUALITY IMPROVEMENT PROPOSAL

- Training
 - Not applicable for non-research categorizations
- Submission Forms
 - Quality Improvement Proposal Cover Sheet
(<https://app.smartsheet.com/b/form/b134f81dc5c44ab4bf4b8526f1e158ea>)
- Other
 - Signed/dated CV

SPECIMEN PROTOCOL PROPOSAL

- Training
 - CITI Group 2
 - Basic Chart Review/Minimal Risk
 - Just Ask Webinar
- Submission Forms
 - Specimen Protocol Template and Cover Sheet
(<https://app.smartsheet.com/b/form/a779c5b793db4dfda5a373c78042688a>)
 - New Protocol Application
(<https://app.smartsheet.com/b/form/b0934efc2e534a2fb2b1713a1309820c>)
- Other
 - Signed/dated CV

OTHER SUBMISSIONS

AMENDMENT/MODIFICATION REQUEST

- Request for Modification form
(<https://app.smartsheet.com/b/form/98eb053ffbb94346b19f6a55cfcbe38>)

REPORT OF AN INTERNAL DEATH

- Internal Death Report
(<https://app.smartsheet.com/b/form/663243ae243a41c29e8c8491889ae5b8>)

REPORT OF PROTOCOL DEVIATION OR VIOLATION

- Protocol Deviation/Violation Report form
(<https://app.smartsheet.com/b/form/7efdd64ddb8c4081b8cd4c03111d2cd0>)

RENEWAL REQUEST

- Continuing Renewal Request form
(<https://app.smartsheet.com/b/form/1b338e5e5a5f41779d9c0cef88c38b63>)

REPORT OF UNANTICIPATED PROBLEMS AND SERIOUS ADVERSE EVENTS

- Report of Unanticipated Problems (UPs) and Serious Adverse Events (SAEs) form
(<https://app.smartsheet.com/b/form/661afe027e91468e9e0e65b88ecf5fc4>)

STUDY CLOSURE

- Study Closure Request form
(<https://app.smartsheet.com/b/form/0a73acbfeb3a4dfe80bb4b34594c97b1>)
- Continued Exemption or Closure of Exempt project
(<https://app.smartsheet.com/b/form/08fc3e2dce2845eeaec6bd861bd015cd>)

EMERGENCY USE REQUEST

- Emergency Use Request form
(<https://app.smartsheet.com/b/form/a5c22918fcf448eeac6e8aae2bddabe3>)