



## 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 filling 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](mailto: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/98eb053ffbb94346b19f6a55cfcbef38> )

## 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> )