



Commercial IRB Submission Cover Page

All submissions to be reviewed by a Commercial IRB must be accompanied by this UNC-Chapel Hill signed cover page in order to be processed. UNC-Chapel Hill OHRE Staff will complete the UNC-Chapel Hill specific forms, sign this institution cover page, and return a copy to the submitting party via IRBIS

Upon receiving this signed cover page from the UNC-Chapel Hill OHRE, submit the signed Cover Page and all required submission documents to the external IRB selected below.

Designated Commercial IRB:

Institution Information

University of North Carolina at Chapel Hill
Contact E-mail: IRBrelance@unc.edu
Phone: 919-966-3113

Study & Contact Information

Principal Investigator: _____ Sponsor: _____
Protocol #: _____ UNC IRB #: _____
Protocol Title: _____

Study Site Main Point of Contact

Name: _____

E-mail: _____

HIPAA

All consent forms should have the following language inserted: **"You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records."** As UNC requires a separate standalone HIPAA authorization form, HIPAA language must be removed from the ICF to be used at UNC.

- a. Has a partial waiver been granted by UNC?
- b. Has a full waiver been granted by UNC?

Site Specific Consent Form:

Conflict Management Plan:

- a. All COI's have been completed, are there any conflict management plans?
- b. Insert CMP language, if applicable:

Subject Injury Language

N/A Minimal Risk Study

Standard Subject Injury Language

Alternate Language Below as Approved by OCT

Language:

Example Template Only - Do not fill

Ancillary Reviews:

Radiation Safety:

Language, if applicable:

IBC Review:

Date approved, if applicable:

Additional Considerations (Required Language Checked):

NC Mandatory Disease Reporting:

NC Mandatory Abuse/Neglect:

University of Chapel Hill Institutional Sign-Off

This is to confirm that UNC hereby authorizes Reviewing IRB selected above to be the reviewing IRB on the above listed protocol. This institution should be copied on correspondence between the designated Commercial IRB and UNC employees as well as granted access to approval documents.

OHRE Signatory:

Date:

Notes from OHRE Office: