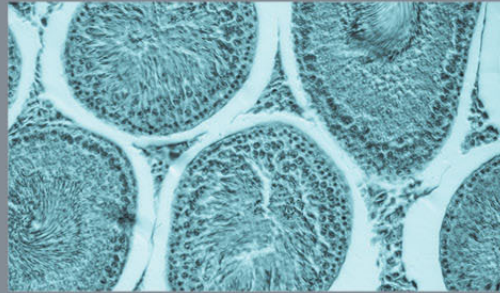


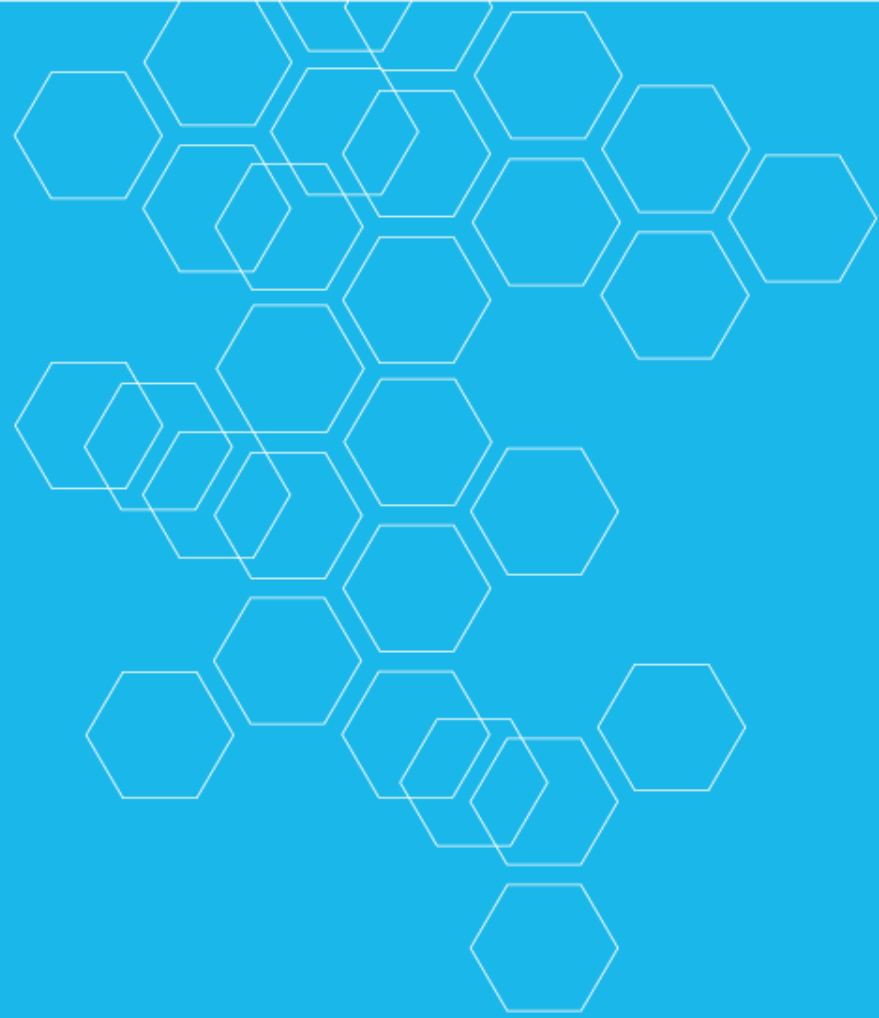
Working with WIRB



November 14th, 2019

Agenda

- ◆ Overview of WCG & WIRB
- ◆ Stony Brook - WIRB Submission Process
 - Preparing Initial Review Submission
 - Managing Site in MyConnexus
 - Continuing Review
 - Change in Research
 - Promptly Reportable Information
- ◆ Connexus Demonstration
- ◆ Q & A



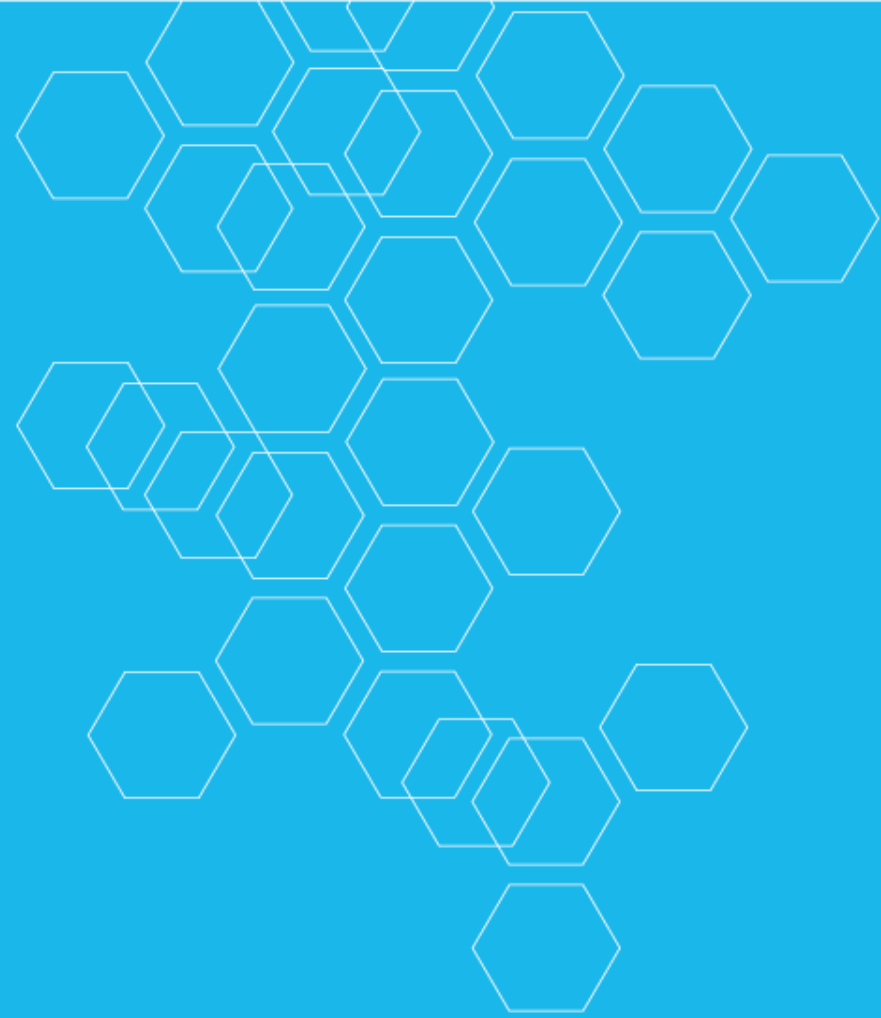
Overview of WCG and WIRB

WIRB – Copernicus Group

- Clinical Services Organization
- 6 IRBs:
 - WIRB
 - Copernicus Group “CGIRB”
 - Aspire
 - New England
 - Midlands
 - Hummingbird

Single Review Solution aka “SRS” Studies

- ◆ Dual Review Studies between WIRB and one of our sister IRB’s.
 - Typically Copernicus Group “CGIRB”
- ◆ We both are the “central” IRB
- ◆ Institutional sites like Stony Brook will go to WIRB for review and central sites go to our sister IRB.
- ◆ The Sponsor will submit updates on your behalf after initial review
 - Revised Protocols, Amendments, New Ads, etc.



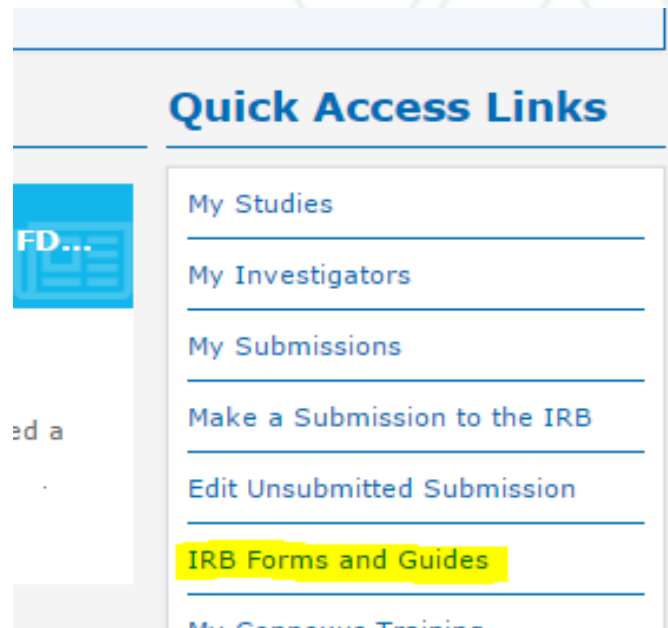
Stony Brook – WIRB Submission Process

Preparing Your Initial Review Submission

- ◆ **STEP 1:** Contact WIRB Client Services to ask whether WIRB has reviewed your protocol (provide # or title)
 - ◆ If yes –
 - ◆ Request WIRB-approved ICF Templates for the study
 - ◆ Ask whether the study falls under the Single Review Solution (SRS)
 - ◆ If no –
 - ◆ Compile all protocol/site documents for submission

Preparing Your Initial Review Submission

- ◆ STEP 2: Download Initial Review Submission Form
 - ◆ SMART Form PDFs are available in two places:
 - ◆ www.wirb.com in the “Download Forms” section
 - ◆ Connexus - Quick Access Links – IRB Forms and Guides



Preparing Your Initial Review Submission

- ◆ STEP 3: Complete Initial Review Submission Form
 - ◆ Select Submission Type (2 Common Options):

Destination Institutional Review Board (IRB)

*To which WCG IRB is this application being submitted?

If you have questions, please call or email the selected IRB

- | | | |
|--|--------------------------------|-------------------------|
| <input type="radio"/> Aspire IRB (Aspire) | (877) 366-5414 | email@aspire-irb.com |
| <input type="radio"/> Copernicus Group IRB (CGIRB) | (888) 303-2224, (919) 465-4310 | irb@cgirb.com |
| <input type="radio"/> Hummingbird IRB (HIRB) | (855) 447-2123 | info@HummingbirdIRB.com |
| <input type="radio"/> Midlands IRB (MLIRB) | (800) 636-4445, (913) 385-1414 | info@mlirb.com |
| <input type="radio"/> New England IRB (NEIRB) | (800) 232-9570, (617) 243-3924 | info@neirb.com |
| <input type="radio"/> Western IRB (WIRB) | (800) 562-4789 | clientservices@wirb.com |

Submission Type

*Indicate the type of submission:

- New protocol with no Principal Investigator (PI) or site information
- Site being added to existing protocol, or change of Principal Investigator (PI)
- New protocol and Principal Investigator (PI) (combined submission)

For clinical use of a Humanitarian Use Device (HUD), Expanded Access, Compassionate Use, and Emergency Use see separate application forms on the IRB Web site.

Preparing Your Initial Review Submission

- ◆ STEP 3: Complete Initial Review Submission Form
 - ◆ Select WIRB as IRB and Indicate Institution Name/Number

Destination Institutional Review Board (IRB)

*To which WCG IRB is this application being submitted?

If you have questions, please call or email the selected IRB

- | | | |
|---|--------------------------------|-------------------------|
| <input type="radio"/> Aspire IRB (Aspire) | (877) 366-5414 | email@aspire-irb.com |
| <input type="radio"/> Copernicus Group IRB (CGIRB) | (888) 303-2224, (919) 465-4310 | irb@cgirb.com |
| <input type="radio"/> Hummingbird IRB (HIRB) | (855) 447-2123 | info@HummingbirdIRB.com |
| <input type="radio"/> Midlands IRB (MLIRB) | (800) 636-4445, (913) 385-1414 | info@mlirb.com |
| <input type="radio"/> New England IRB (NEIRB) | (800) 232-9570, (617) 243-3924 | info@neirb.com |
| <input checked="" type="radio"/> Western IRB (WIRB) | (800) 562-4789 | clientservices@wirb.com |

Institutional Services

*Will you conduct this research through an organization that has a contract or Master Services Agreement (MSA) to use Western IRB (WIRB) for IRB services?

- Yes No

Name of organization relying on WIRB (if known)

WIRB Institution # of organization
relying on WIRB (if known)

→ **Stony Brook University**

133384

Preparing Your Initial Review Submission

◆ STEP 3: Complete Initial Review Submission Form

◆ Site contacts

Contacts

Are there any designated contacts for this research (e.g., Sponsor contact, Contract Research Organization (CRO) contact, Site Management Organization (SMO) contact, study coordinator contact)?

Yes No

Research Contact

*Contact Type

Prefix *First

Middle

Last

Suffix

*Email

*Phone

Degrees

Mailing address for the above individual:

*Company/Institution/Organization

*Address Line 1

Address Line 2

*City

*State

*Postal Code

*Country

Copy this person on IRB correspondence

Send continuing review forms to this person to be filled out and returned to the IRB

Add another contact

Preparing Your Initial Review Submission

- ◆ STEP 3: Complete Initial Review Submission Form
 - ◆ Research Locations – List all where research activity conducted

Research Location

Location

The IRB does not routinely list addresses in this section in the consent form.
Physical address where subjects will be seen or research will take place:

*Company/Institution/Organization

*Address Line 1

Address Line 2

*City *State *Postal Code

*Country

*Which of the following best describes this location's function?
 College/University Dialysis Center Hospital Medical Office
 Nursing Home Psychiatric Facility Research Clinic Other

Describe any additional resources available at this location that are relevant to this research: (e.g., interpreters, bilingual staff members, counselling services)

Add another research location:

Preparing Your Initial Review Submission

- ◆ STEP 3: Complete Initial Review Submission Form
 - ◆ Human Subjects Protection Training Requirement

Training

*Indicate the types of human research subjects protection training that the Principal Investigator (PI) and the PI's research staff have had on the protection of human research subjects and that new research staff will have. Select all that apply.

- | | |
|--|--|
| <input type="checkbox"/> ACRP Certified Clinical Investigator Training | <input checked="" type="checkbox"/> CenterWatch: Protecting Study Volunteers in Research |
| <input checked="" type="checkbox"/> Collaborative IRB Training Initiative (CITI) | <input type="checkbox"/> Tri-Council Policy Statement online training (TCPS)
<i>(Required for research in Canada)</i> |
| <input type="checkbox"/> DIA Certified Investigator (CCI) | <input type="checkbox"/> Local institution's training or other training |
| <input type="checkbox"/> SOCRA Clinical Research Professional (CRP) | <input type="checkbox"/> None |
| <input type="checkbox"/> WCG Academy | |

- ◆ **Note:** WIRB does not require source documentation of Certificates of Training. These should be housed appropriately in your regulatory binder and provided to the reliance administrator as required.

Preparing Your Initial Review Submission

- ◆ STEP 3: Complete Initial Review Submission Form
 - ◆ Reference the **end** of the form for a list of required submission documents

Required Submission Materials for Site Only Submission

To avoid processing delays, remove security/password protection from all submitted documents.

Submit the following documentation:

- This form with all questions marked with a * answered
- Advertisements and recruitment scripts specific to your site (Advertisements and recruitment materials and changes to advertisements and recruitment materials must be IRB approved before their use)
- Curriculum vitae for the Principal Investigator (PI), if a current one is not already on file with the IRB

Preparing Your Initial Review Submission

- ◆ STEP 3: Complete Initial Review Submission Form
 - ◆ Check Your Work and Finish!

Check submission for completeness

Check

Warning: JavaScript Window -



There are 95 incomplete entries that have been highlighted in red.

OK



Use Adobe version 11 or later
Asterisk (*) fields are required

Principal Investigator (PI) Information

Tell us how to contact the Principal Investigator (PI)

Prefix	*First	Middle	*Last
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
*Email			
<input type="text"/>			
*Phone	Degrees		
<input type="text"/>	<input type="text"/>		

Preparing Your Initial Review Submission

◆ STEP 4: Log into Connexus



Create a New Account

If you are a new user, you must create a new account to access the system. Fill in the form with the required information and click the **Register** button to continue. If you need help, click the **Registration Help** link. You can also **Request Support** via the provided link.

Existing User Login

If you already have an existing account, login to the right.

Registration Help Request Support

Live Support ONLINE

Create New Account
Register below to create a new account and start using the portal.

Username:
Username should be of minimum 5 and maximum 20 characters, should NOT have spaces and special characters (such as ~!@#%&'()*+,-./:; etc.)

E-mail ID:

Confirm E-mail ID:

Register Clear

Existing Account, Login here

e-mail:

Password:

Login Forgot Password?

News & Events
Webinars
Press Releases
White Papers
Speaking Engagements

Connexus Help
Frequently Asked Questions

IRB Documents & Guides
WIRB
CGIRB

Live Support

Click the **Live Support ONLINE** button to chat with a representative. If there are no representatives available, you can leave a message.

Forgot Password

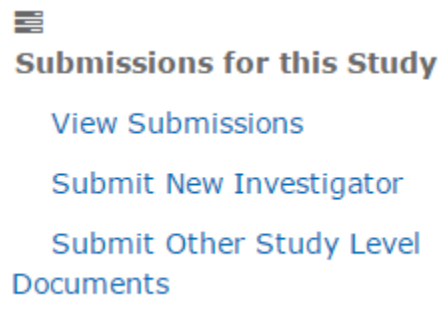
Click the **Forgot Password?** link to reset your password.

Quick links

Access helpful links without having to login.

Preparing Your Initial Review Submission

- ◆ STEP 5: Find Study (if additional site to existing study)
 - ◆ Click the “My Studies” tab
 - ◆ Find the study to be submitted and click on the blue “IRB Tracking” number to select
 - ◆ Under “Submissions for this Study” select “Submit New Investigator” at the top right of your screen



Preparing Your Initial Review Submission

◆ STEP 6: Complete Wizard, Upload Documents, and Submit!

Submit New Investigator Site

1 — 2 — 3 — 4

Used when making a new investigator site submission. If your study does not appear in the drop down menu, please contact your Study Contact or the IRB to grant you access.

Fields marked * are mandatory

Study: 996633 (Pending) *

Submission Name: *

Investigator First Name: *

Investigator Middle Name:

Investigator Last Name: *

Investigator Suffix:

Is this site with an Institution or Medical Center?: Yes No

Where would you like to route this submission?: *

Comments or notes concerning the submission:

Submission Types: *

Save and Continue to Submission

Cancel

Preparing Your Initial Review Submission

- ◆ To Submit New Protocol (new to WIRB)
 - ◆ Click “Make Submission” tab

Make a Submission to the IRB

Is your submission:

- ☰ Initial Review Submission
- 📄 Submission for an Already Approved Study o

This Initial Review Submission is for:

- 📖 Review of a New Research Protocol
Will be redirected to the new protocol submission wizard

- ◆ Complete Wizard, Upload Documents, and **Submit!**

After You Submit...

- ◆ You receive a **Submission Tracking Number**
- ◆ WIRB staff prepares the submission
- ◆ A WIRB panel or expedited reviewer reviews the research for your site
- ◆ WIRB staff assembles and finalizes documents
- ◆ Outcome documents are sent to email list and posted to Connexus under the PI Workspace

- You will receive a Certificate of Action “COA” with your Outcome Documents. It will list the following:
 - WIRB Board Action Date “Approval Date”
 - Expiration Date
 - Approved Research Location(s) and PI
 - The documents that were reviewed
 - List of study personnel on the email distribution list.
- You can add others to the Connexus workspace for your PI.
- Use the Contact Information Update Form for changes to study contacts or continuing review contacts.

Managing Your Site in Connexus

- ◆ Locate in Connexus under My Investigators

My Connexus™ Dashboard My Submissions Make Submission My Studies My Investigators Submission Status Tracker Connexus User

My Dashboard

Welcome to My Connexus!

Through this personalized system, you will be able to revel in up-to-date information on what matters most in your world.

Enjoy best in class updates on clinical research news, recent WCG announcements, current study opportunities, and everything you need to submit, review, and retrieve submission documents from the IRB- all accessible right at your fingertips.

Recent Clinical Research News

A Reckless and Needless Use ...

A researcher in China claims to have edited the germline of twin girls born recently using the CRISPR gene editing technology. Scientists and eth...

Atlantic Monthly

Created on December 3, 2018

Gottlieb pushes for funding to...

FDA Chief, Scott Gottlieb, spoke recently of the need for more funding to enlarge its investment in reviewing gene therapy products, citing a hun...

STAT News

Created on December 3, 2018

FDA plans overhaul of decade...

FDA announced plans designed to ensure that new medical devices reflect up-to-date safety and effectiveness features. The current system generall...

STAT News

Created on December 3, 2018

Show more

Recent WCG Announcements

to announcements to show...

Quick Access Links

[My Studies](#)

[My Investigators](#)

[My Submissions](#)

[Make a Submission to the IRB](#)

[Edit Unsubmitted Submission](#)

[IRB Forms and Guides](#)

[My Connexus Training](#)

[Recent Clinical Research News](#)

[Recent WCG Announcements](#)

Managing Your Site in Connexus

- ◆ Locate in Connexus under My Investigators

My Investigators

Please see below a list of Investigators you currently have access to. Select an Investigator link below to view Site level documents and make Site level submissions.

Don't see your Investigator below? [Click Here](#)

Reports

- [Site Expiration](#)
- [Studies By Site](#)
- [Outcome Document By Site](#)
- [Site Status](#)
- [Continuing Review Status](#)

Q Thompson

Status Date Since Anytime

PI NAME	COUNTRY	IRB	SPONSOR	IRB TRACKING	INSTITUTION TRACKING	STATUS	STATUS DATE
Thompson, Carmen	N/A	WIRB	N/A	WCG9-15-465 DavidMit_Test	N/A	Pending	November 17, 2017
thompson, carmen	N/A	WIRB	N/A	WCG9-15-462 DO NOT PROCESS OR REVIEW	N/A	Pending	October 20, 2017

Managing Your Site in Connexus

◆ Locate in Connexus under My Investigators

My Investigators > Investigator Details

Thompson, Carmen

STATUS: PENDING

Click to view or make submissions

Click to manage access to this site workspace only

Approval documents displayed here

Submissions for this Investigator

- View Submissions for this Investigator
- Make a Submission for this Investigator

Manage Access for this Investigator

- Contacts for this Investigator
- IRB Forms and Guides

Details

IRB Tracking Number WCG9-15-465	Sponsor N/A
Institutional Tracking Number N/A	IRB WIRB
Country N/A	
Expiration Date N/A	

Pending on November

Documents

Enter a Key Word to filter from the entire Grid Below (i.e. Title, IRB)

Document Type: All

Date Transmitted Since: Anytime


0 document(s) selected. Create .zip file for download

<input type="checkbox"/>	DOCUMENT TYPE	DOCUMENT TITLE	IRB	DATE REVIEWED	DATE TRANSMITTED	DOWNLOAD
No documents to show...						

Need Help

Contact Information Update Form

- ◆ Necessary to update the contact who receives IRB correspondence

 <small>A WIRB-Copernicus Group Company</small>	FORM: Contact Information Update				
	Document No.:	Edition No.:	Effective Date:	Page:	
	HRP-202	005	30 Apr 2018	Page 1 of 2	

Please complete this form if:

1. A new contact is replacing a current contact,
2. Someone on the team would like to be added as an additional contact and/or
3. Any of the information below for a current contact has changed and needs updating.

You must submit a typed version of this form to prevent errors and delays due to legibility problems.
Blank & incomplete answers will result in delayed reviews

If you have questions about the use of this form, please call 1-800-562-4789 or email clientservices@wirb.com

Today's date:

Sponsor Name:

Sponsor Protocol #*:

Investigator Name(s):

IRB Protocol Number:

***If the below contact information needs to be updated for more than the above study or protocol, please include a list of the additional studies or protocols needing the changes:**

New/Updated Contact Information

Change in Research Submission Form



Change in Research Submission Form

HRP-201

Use Adobe version 11 or later (Reader or Acrobat)
Asterisked (*) fields are required.

Use this form to request IRB approval for a modification to a protocol or site.

This is a smart form. Form elements will appear or disappear depending on answers to previous questions.

If your answer does not fit in the space provided, you may refer to and submit separate attachments.

Blank & incomplete answers will result in delayed reviews.

Submitter Type

*Who is submitting?

- Sponsor or Contract Research Organization (CRO)
- Site Management Organization (SMO)
- Site

Protocol Information

*IRB Protocol Number (also called "IRB Tracking Number")

Sponsor's protocol ID (if applicable)

*Sponsor

Submitted Changes

*Indicate the changes you are submitting. Select all that apply.

- Consent form
- Protocol revision, amendment, or administrative letter
- Planned protocol deviation
- Recruitment methods
- Recruitment bonuses (Extra payments to sites tied to the rate or timing of recruitment or enrollment)
- Subject materials (Advertisements, scripts, recruitment materials, retention materials, diaries, ID cards, etc.)
- Translation request or request for approval of translated documents
- Waiver of HIPAA authorization
- Other change



Continuing Review

- ◆ Submit a “Site Progress Report” aka Continuing Review Report Form.
- ◆ WIRB sends sites a Site Progress Report three weeks prior to the due date listed on the form, which is about 77 days prior to the expiration date of the study.
- ◆ The form will be emailed to the individual listed on the initial review submission form.

Continuing Review Report Form



Site Continuing Review Report HRP-251

Use Adobe version 11 or later (Reader or Acrobat)
Asterisked (*) fields are required.

Use this form to submit continuing review information for a site.

This is a smart form. Form elements will appear or disappear depending on answers to previous questions.

Blank & incomplete answers will result in delayed reviews.

Continuing Review Information

IRB	Due Date	IRB Tracking Number	Seq #	IRB Report ID
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

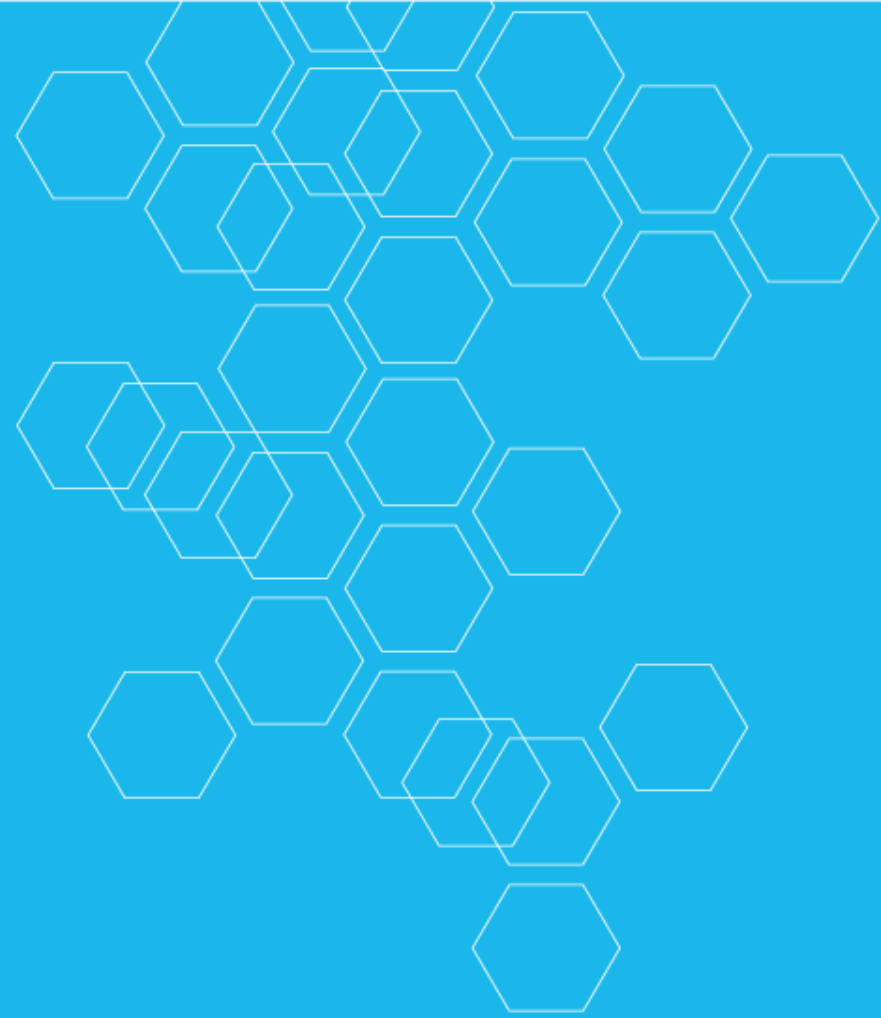
Protocol title

Sponsor Protocol ID

Sponsor Name

Principal Investigator (PI)





Planned Protocol Deviations & Promptly Reportable Information

Planned Protocol Deviations

Requesting changes before they take place

- ◆ Submit a Change in Research Submission Form.
- ◆ Anything that needs board approval before the event takes place.
 - Examples: Inclusion / Exclusion criteria, out of window visit.
- ◆ It usually takes about 3-4 business days for approval of the deviation.
- ◆ Send urgent requests to the Account Manager via email.

Promptly Reportable Information



POLICY: Prompt Reporting Requirements

Document No.:	Edition No.:	Effective Date:	Page:
HRP-071	001.3	09 Aug 2016	Page 1 of 1

1. PURPOSE

- 1.1. This guidance describes the information that investigators must promptly report to the IRB when the research is subject to oversight by Aspire IRB, CGIRB, MLIRB, NEIRB, or WIRB.
- 1.2. For research overseen by an IRB other than Aspire IRB, CGIRB, MLIRB, NEIRB, or WIRB, investigators should follow the requirements of that IRB.

2. POLICY

- 2.1. Investigators are to report the following information items to the IRB within 5 days:
 - 2.1.1. New or increased risk¹
 - 2.1.2. Protocol deviation that harmed a subject or placed subject at risk of harm
 - 2.1.3. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
 - 2.1.4. Audit, inspection, or inquiry by a federal agency
 - 2.1.5. Written reports of federal agencies (e.g., FDA Form 483)
 - 2.1.6. <Allegation of Noncompliance> or <Finding of Noncompliance>
 - 2.1.7. Unauthorized disclosure of confidential information
 - 2.1.8. Unresolved subject complaint
 - 2.1.9. Suspension or premature termination by the sponsor, investigator, or institution
 - 2.1.10. Incarceration of a subject in a research study not approved to involve prisoners
 - 2.1.11. Adverse events or IND safety reports that require a change to the protocol or consent
 - 2.1.12. State medical board actions
 - 2.1.13. Unanticipated adverse device effect²
 - 2.1.14. Information where the sponsor requires prompt reporting to the IRB

Promptly Reportable Information

Reporting events that have already taken place

- ◆ Use the Promptly Reportable Information Submission Form.
- ◆ Select the appropriate option from the form, and include the following information:
 - Date of occurrence and discovery
 - Brief description or outline of the topic/process/problem being documented
 - Cause of issue or actions taken leading to issue
 - Actions needed to correct issue
 - Changes proposed to prevent recurrence
 - Method of implementation

Promptly Reportable Information

Reporting events that have already taken place

- ◆ After you submit, you will only hear back from us if the event leads to a Board review.
- ◆ We will contact you within 30 business days. Otherwise, no news is good news.
- ◆ If the Medical Reviewer determines that the event meets the criteria of serious non-compliance, continuing non-compliance, etc., then we will inform the study contacts of the upcoming Board Meeting.

Promptly Reportable Information Submission Form



Promptly Reportable Information Submission Form Use to submit promptly reportable new information

**Note: Form must be completed in Adobe version 9.1 or later (Reader or Acrobat).
All fields with an asterisk (*) are required.**

*To whom are you submitting this application?

- Copernicus Group IRB (CGIRB)
 Western IRB (WIRB)
 New England IRB (NEIRB)

*Indicate the source/type of submission:

- Sponsor or CRO
 Study Site / SMO

This is a smart form. Some form elements will appear or disappear depending on answers to previous questions.

Identifying Information

Principal Investigator's Name:

Prefix	*First	Middle	*Last	Suffix
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

*IRB Protocol or Tracking Number	*Date of this report	Date of occurrence (if known)
<input type="text"/>	<input type="text"/>	<input type="text"/>

Subject ID (if applicable)	*Is the subject still enrolled in the study?	*Submitting body:
<input type="text"/>	<input type="text"/>	<input type="text"/>

Type of Problem (Information not listed below does not require prompt reporting to us)

*Select all that apply: Audit, inspection or inquiry by a federal agency

Provide the date of the inspection including the beginning and end dates.

Clarify if a study approved by this IRB was audited and identify the study.

For Health Canada inspections, please provide the rating received.

Written report from a federal agency (e.g., FDA Form 483)

Submit a complete copy of all reports and correspondence related to the inspection (e.g. FDA Form 482 and 483, site's response to the 483, FDA letter responding to the site, EIR Summary, FDA WARNING Letter, Health Canada Inspection Notice, Health Canada Exit Notice).

State medical board action

Submit a copy of state medical board licensing documentation [e.g. a physician's (suspended) license, a physician profile, or a physician licensing profile indicating a



Questions?

- Contact WIRB-Copernicus Group Client Services:

Office: (360) 252-2500

(800) 562-4789

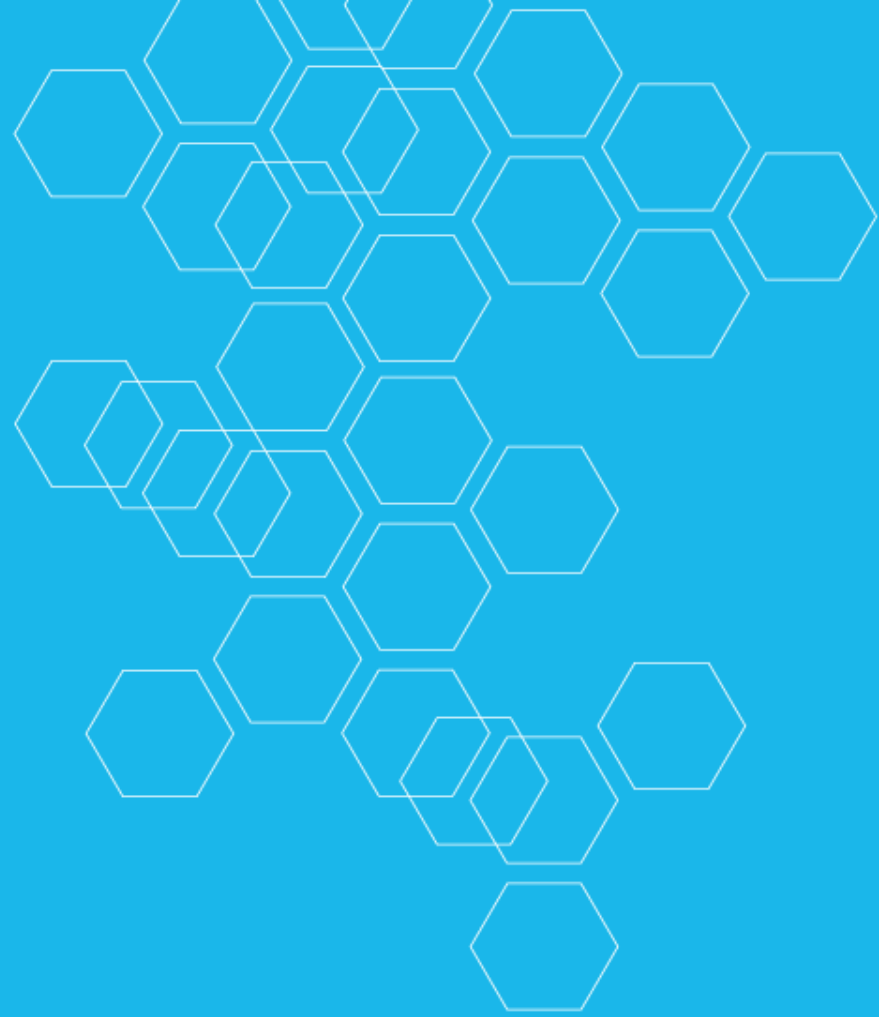
Fax: (360) 252-2498

Email: clientservices@wirb.com

- Contact Jon Gellert (Account Manager):

Office: (360) 570-1309

Email: jgellert@wirb.com



Thank You!