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](http://www.wirb.com) in the “Download Forms” section
    - Connexus - Quick Access Links – IRB Forms and Guides
Preparation 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

  - Aspire IRB (Aspire)  (877) 366-5414  email@aspire-irb.com
  - Copernicus Group IRB (CGIRB) (888) 303-2224, (919) 465-4310  irb@cgirb.com
  - Hummingbird IRB (HIRB)  (855) 447-2123  info@HummingbirdIRB.com
  - Midlands IRB (MLIRB)  (800) 636-4445, (913) 385-1414  info@mlirb.com
  - New England IRB (NEIRB)  (800) 232-9570, (617) 243-3924  info@neirb.com
  - 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

- Aspire IRB (Aspire) (877) 366-5414 email@aspire-irb.com
- Copernicus Group IRB (CGIRB) (888) 303-2224, (919) 465-4310 irb@cgirb.com
- Hummingbird IRB (HIRB) (855) 447-2123 info@HummingbirdIRB.com
- Midlands IRB (MLIRB) (800) 636-4445, (913) 385-1414 info@mlirb.com
- New England IRB (NEIRB) (800) 232-9570, (617) 243-3924 info@neirb.com
- 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

<table>
<thead>
<tr>
<th>Research Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Contact Type</td>
</tr>
<tr>
<td>Prefix</td>
</tr>
<tr>
<td>*Email</td>
</tr>
<tr>
<td>Degrees</td>
</tr>
</tbody>
</table>

- **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

**Contacts**

- **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**
Prepping Your Initial Review Submission

**STEP 3:** Complete Initial Review Submission Form

- **Research Locations – List all where research activity conducted**

<table>
<thead>
<tr>
<th>Research Location</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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:</td>
</tr>
<tr>
<td>*Company/Institution/Organization</td>
<td></td>
</tr>
<tr>
<td>*Address Line 1</td>
<td></td>
</tr>
<tr>
<td>Address Line 2</td>
<td></td>
</tr>
<tr>
<td>*City</td>
<td>*State</td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
<tr>
<td>*Which of the following best describes this location’s function?</td>
<td></td>
</tr>
<tr>
<td>College/University</td>
<td>Dialysis Center</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>Psychiatric Facility</td>
</tr>
</tbody>
</table>

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

- [ ] ACRP Certified Clinical Investigator Training
- [x] Collaborative IRB Training Initiative (CITI)
- [ ] DIA Certified Investigator (CCI)
- [ ] SOCRA Clinical Research Professional (CRP)
- [ ] WCG Academy
- [x] CenterWatch: Protecting Study Volunteers in Research
- [ ] Tri-Council Policy Statement online training (TCPS) *(Required for research in Canada)*
- [ ] Local institution's training or other training
- [ ] None

- **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

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**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

Use Adobe version 11 or later.

Asterisked (*) fields are required.

**Principal Investigator (PI) Information**

Tell us how to contact the Principal Investigator (PI)

<table>
<thead>
<tr>
<th>Prefix</th>
<th>*First</th>
<th>Middle</th>
<th>*Last</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Email

*Phone

Degrees
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, log in to the right.

MyConnexus

Quick links
Access helpful links without having to login.

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.
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!
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

  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 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

Recent WCG Announcements

No announcements to show...
# 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](#)

<table>
<thead>
<tr>
<th>PI NAME</th>
<th>COUNTRY</th>
<th>IRB</th>
<th>SPONSOR</th>
<th>IRB TRACKING</th>
<th>INSTITUTION TRACKING</th>
<th>STATUS</th>
<th>STATUS DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thompson, Carmen</td>
<td>N/A</td>
<td>WIRB</td>
<td>N/A</td>
<td>WCG9-15-465 DavidMt_Test</td>
<td>N/A</td>
<td>Pending</td>
<td>November 17, 2017</td>
</tr>
<tr>
<td>thompson, carmen</td>
<td>N/A</td>
<td>WIRB</td>
<td>N/A</td>
<td>WCG9-15-462 DO NOT PROCESS OR REVIEW</td>
<td>N/A</td>
<td>Pending</td>
<td>October 20, 2017</td>
</tr>
</tbody>
</table>

### Reports
- Site Expiration
- Studies By Site
- Outcome Document By Site
- Site Status
- Continuing Review Status

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[Logo: WCG WIRB COPERNICUS GROUP®]
Managing Your Site in Connexus

- Locate in Connexus under My Investigators

**Thompson, Carmen**

- **STATUS: PENDING**
- **Details**
  - IRB Tracking Number: WCG0-15-455
  - Institutional Tracking Number: N/A
  - 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

- Approval documents displayed here
  - Click to view or make submissions
  - Click to manage access to this site workspace only
Contact Information Update Form

- Necessary to update the contact who receives IRB correspondence

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<table>
<thead>
<tr>
<th>Form: Contact Information Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document No.: HRP-202</td>
</tr>
<tr>
<td>Edition No.: 005</td>
</tr>
<tr>
<td>Effective Date: 30 Apr 2018</td>
</tr>
<tr>
<td>Page: 1 of 2</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Today's date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor Name:</td>
</tr>
<tr>
<td>Sponsor Protocol #:</td>
</tr>
<tr>
<td>Investigator Name(s):</td>
</tr>
<tr>
<td>IRB Protocol Number:</td>
</tr>
</tbody>
</table>

*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

Use this form to request IRB approval for a modification to a protocol or site. Asterisked (*) fields are required.

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
- Translation request or request for approval of translated documents
- Protocol revision, amendment, or administrative letter
- Waiver of HIPAA authorization
- Planned protocol deviation
- Recruitment methods
- Other change

- 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.)
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.
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

<table>
<thead>
<tr>
<th>IRB</th>
<th>Due Date</th>
<th>IRB Tracking Number</th>
<th>Seq #</th>
<th>IRB Report ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
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, CGIIRB, MLIRB, NEIRB, or WIRB.

1.2. For research overseen by an IRB other than Aspire IRB, CGIIRB, 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 risk
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 effect
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

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

**IRB Protocol or Tracking Number**

**Date of this report**

**Date of occurrence (if known)**

**Subject ID (if applicable)**

**Is the subject still enrolled in the study?**

**Submitting body:**

**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 disciplinary action or diversion action).
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!