Working with WIRB
Agenda

- Overview of WCG and WIRB

- WIRB Submission Process
  - Preparing Initial Review Submission
  - Changes in Research
  - Continuing Review
  - My Connexus

- Planned Protocol Deviations and Promptly Reportable Information (PRI)

- Q & A Session
WIRB – Copernicus Group

- Clinical Services Organization
- IRBS:
  - WIRB
  - Copernicus
  - Aspire
  - New England
  - Midlands
  - Hummingbird
Ethics and Compliance History and Experience

Unmatched in the Industry

- 49 Years of Regulatory Experience – First Commercial IRB 1968
- Senior Advisors to: FDA, OHRP, AAHRPP
- Longest AAHRPP Accreditation History – First IRB Accredited
- 40 Certified IRB (CIPs) Professionals on Staff (WIRB and CG)
- WIRB: 5 US Panels (10 meetings per week)
- WIRB/Copernicus Shared Panel 18
Our Quality and Compliance Team
Supported by Nationally Recognized Experts

Our Team’s Backgrounds

- Founder of AAHRPP, former AAHRPP staff
- Chairs of two SACHRP subcommittees
- PRIM&R award recipients
- First called to rescue and transform other IRBs
Institutions – Part of WIRB’s DNA

- 1996 – University of Rochester
- >175 Academic Medical Centers
- 2,200 hospital facilities under contract
- Dedicated Account Manager
- WIRB learns how you operate
- WIRB flexes to your institutional requirements
WIRB Submission Process
Preparing Your Initial Review Submission

- Contact WIRB Client Services (or Account Manager) to ask whether WIRB has reviewed your protocol (provide # or title)
  - If yes –
    - Request a **Connexus Invitation** to the study workspace. WIRB will invite you (you receive a confirmation e-mail)
    - Request WIRB-approved ICF Templates for the study
    - Ask whether the study falls under the Single Review Solution (SRS); protocol number in Connexus is slightly different
  - If no –
    - Compile all protocol/site documents and submit in Connexus as a new study.
Preparing Your **Initial Review Submission**

- 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
Preparing Your **Initial Review Submission**

- Complete Initial Review Submission Form

- Select Submission Type (2 Common Options):
  
  **Initial Review Submission Form**
  
  **HRP-212**
  
  Use Adobe version 11 or later (Reader or Acrobat). Asterisked (*) fields are required.

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

  **Submission Type**

  *Indicate the type of submission and additional form elements will appear

  - 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)
  - Physician submitting for approval of the clinical use of a Humanitarian Use Device (HUD)
  - Physician submitting for approval of a Single Patient Expanded Access
Preparing Your Initial Review Submission

- Complete Initial Review Submission Form
- Select IRB and Indicate Institution Name/Number

**Destination Institutional Review Board (IRB)**

*To whom is this application being submitted?*
- Aspire IRB (Aspire)
- Copernicus Group IRB (CGIRB)
- Midlands IRB (MLIRB)
- New England IRB (NEIRB)
- Western IRB (WIRB)

**Western IRB (WIRB) Institutional Services**

*Will this research be conducted through an organization that has a contract or Master Services Agreement (MSA) to use Western IRB (WIRB) for IRB services?*
- Yes
- No

Provide the following information, if known:

Name of the organization

WIRB Institution #
Preparing Your Initial Review Submission

- Complete Initial Review Submission Form

- Human Subjects Protection Training Requirement

<table>
<thead>
<tr>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>*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.</td>
</tr>
</tbody>
</table>

- ☑️ ACRP Certified Clinical Investigator Training
- ☑️ Collaborative IRB Training Initiative (CITI)
- ☐ DIA Certified Investigator (CCI)
- ☐ SOCRA Clinical Research Professional (CRP)
- ☐ WCG Academy
- ☑️ 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.
Preparing Your Initial Review Submission

- Complete Initial Review Submission Form
- Reference the end of the form for a list of required submission documents

**Required Attachments**

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
- Final protocol (or most recent version with any applicable amendments)
- Supporting documents
- All information intended to be seen or heard by subjects, including:
  - Consent documents (in Microsoft Word compatible format)
  - Information sheets (in Microsoft Word compatible format)
  - Advertisements and recruitment scripts (Advertisements and recruitment materials and changes to advertisements and recruitment materials must be IRB approved before their use)
- Curriculum vitae for the Principal Investigator, if a current one is not already on file with the IRB
- Medical license(s) for the Principal Investigator showing the expiration date, if a current one is not already on file with the IRB
Preparing Your **Initial Review Submission**

- Complete Initial Review Submission Form
- Check Your Work and Finish!

Check submission for completeness

![Warning Window]

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>
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*Email

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<tr>
<th>*Phone</th>
<th>Degrees</th>
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</table>
Preparing Your Initial Review Submission

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 Request Support 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.

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**

- **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**

- Complete Wizard, Upload Documents, and Submit!

![Submission Form](image-url)
Preparing Your Initial Review Submission

- Submit **New Protocol** (if PI-Initiated or new to WIRB)
  - Click “Make Submission” tab

**Make a Submission to the IRB**

Is your submission:

- Initial Review Submission

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
- You receive an e-mail with a link to all WIRB outcome documents
  - If the research is approved, you receive your approval documents
  - If the decision is to Defer or Disapprove, the link contains a regulatory letter with rationale for the decision
- Outcome documents are posted to Connexus for reference
After You Submit…

- 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.
# Contact Information Update Form

**FORM: Contact Information Update**

<table>
<thead>
<tr>
<th>Document No.:</th>
<th>Edition No.:</th>
<th>Effective Date:</th>
<th>Page:</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-202</td>
<td>002</td>
<td>05 Jan 2017</td>
<td>Page 1 of 2</td>
</tr>
</tbody>
</table>

Please complete this form if:
1. You are a new contact replacing a current contact,
2. You would like to be added as an additional contact
3. You are a current contact and any of the information below has changed.

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>Sponsor Name:</th>
<th>Sponsor Protocol #:</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Investigator Name(s):</th>
<th>Study Number:</th>
</tr>
</thead>
<tbody>
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</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.*

<table>
<thead>
<tr>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Company:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>Phone:</td>
</tr>
<tr>
<td>Email:</td>
</tr>
</tbody>
</table>

*Study documents will be sent via e-mail to the address provided*

Are you replacing a current contact?  
- [ ] Yes  
- [ ] No
Change in Research Submissions

- Protocol Changes (Revised Protocol, Amendments, etc.)
- Change in Research Location
- Modified or Additional Recruitment Materials
- New or Changed Subject Materials
- New Consent Forms
- Consent Form Modifications
Change in Research Submission Form

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

Submission Source

*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: Protocol level amendment and/or modification
- Study Site/SMO
- Investigator-initiated study: Amendment and/or modification

To obtain help information for any item, hold your mouse over the item and help information, if any, will appear. This is a smart form. Some form elements will appear or disappear depending on answers to previous questions.

Sponsor Name

*Sponsor Protocol Number

IRB Protocol or Tracking Number

*This change in research is submitted for:
- Review on behalf of one or more principal investigators
- Pre-review (The IRB can assist sponsors and CROs during the planning stages of a change in research for a multi-center study by pre-reviewing the changes. Once the change has been reviewed, the IRB will send a notification to you of the Board’s review. We will not commence applying the change to the investigators in the protocol until we receive written notice from you that the change is acceptable. However, please note that the IRB may determine that the change involves updated risk information that necessitates immediate rollout to investigators, in which case we will initiate changes without awaiting written notice from you.)
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

- Even if you have not started enrolling subjects, you must complete the report and return it to WIRB before the due date printed on it to inform the Board of the study’s status at the site.

- 10 and 20 days after the due date, WIRB staff prepare a “past due” notification.

- 37 days after the due date of the Site Progress Report form, the delinquency is reported to the Board.

- Board may conduct the study renewal review up to 30 days prior to the expiration date listed on the Certificate of Approval.
**Site Continuing Review Report**

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

### Submission Source

*To whom are you submitting this application?*

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

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

<table>
<thead>
<tr>
<th>Sponsor Name</th>
<th>*Sponsor Protocol Number</th>
<th>IRB Protocol or Tracking Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stemnion, Inc.</td>
<td>ST266-PERIO-201</td>
<td>20160529</td>
</tr>
</tbody>
</table>

*Indicate the name of the Principal Investigator for whom you are submitting this form*

Ricardo Teles DDS, DMSc

<table>
<thead>
<tr>
<th>Due Date</th>
<th>Sequence</th>
<th>IRB Report ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/13/2017</td>
<td>1</td>
<td>1539044</td>
</tr>
</tbody>
</table>

### Research Status (Site)

*Indicate the status of the research study:*

- [ ] Active, NO subjects have been accrued
- [ ] Active, subjects have been accrued
- [ ] Enrollment is closed and site is still open
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, 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 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

2.2. Information not listed above does not require prompt reporting to Aspire IRB, CGIRB, MLIRB, NEIRB, or WIRB.
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 8.1 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
- MSKCC Example

*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 493, 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
Questions?

• **Contact Jacob Johnson (Account Manager):**
  
  Office:  (360) 570-1310  
  Email:  jhjohnson@wirb.com  

• **Contact WIRB Client Services:**
  
  Office:  (360) 252-2500  
  (800) 562-4789  
  Fax:  (360) 252-2498  
  Email:  clientservices@wirb.com
Thank You!