Working with WCG-WIRB – Yeshiva University

Agenda

- **Overview of WCG and WIRB**
- **Submission Process**
- **Submission Form Assistance**
  - Initial Review
  - Change in Research (Modifications)
  - Promptly Reportable Information (PRI)
  - Continuing Review Report Form (CRRF)
- **MyConnexus Submission Overview**
- **Note on the New Common Rule**

Overview of WCG-WIRB

WIRB-Copernicus Group Overview

Several Companies, One United Mission:

Provide the people who perform clinical trials with the highest quality of services to accelerate the scientific advancement of human health, while ensuring that the risks of progress never outweigh the value of human life.

wcg WIRB

Institutions – Part of WCG-WIRB's DNA

- >200 Academic Medical Centers
- 2,800 hospital facilities under contract
- Dedicated Account Manager
- WCG-WIRB learns how you operate
- WCG-WIRB flexes to your requirements

Ethics and Compliance History and Experience
Unmatched in the Industry

- 50+ Years of Regulatory Experience – First Commercial IRB 1968
- Senior Advisors to: FDA, OHRP, AAHRPP
- Longest AAHRPP Accreditation History – First IRB Accredited
- Re-Accredited with No Findings
- 20 Successful FDA Audits - Dating Back to 1983
- Over 500 Successful Sponsor/CRO Audits
- 40+ Certified IRB (CIPs) Professionals on Staff
- WCG-WIRB: 5 US Panels (10 meetings per week)

Submission Assistance and MyConnexus Submission Overview

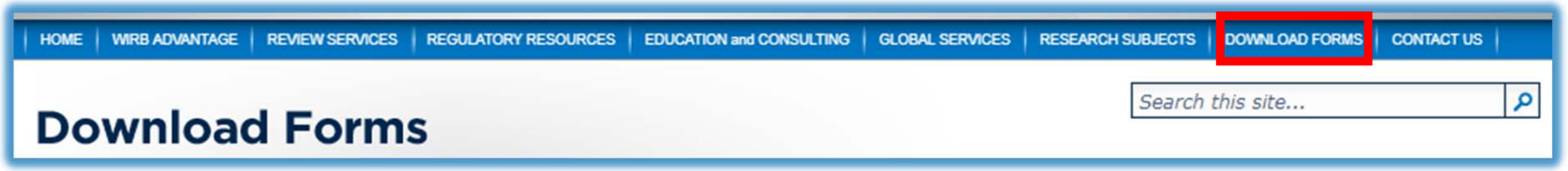
Preparing Your Initial Review Submission: Additional PI Site

- Contact WCG-WIRB Client Services (or Account Manager) to ask whether WCG-WIRB has reviewed your protocol (provide # or title)
- If yes –
  - Request WCG-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 and submit in Connexus as a new study.

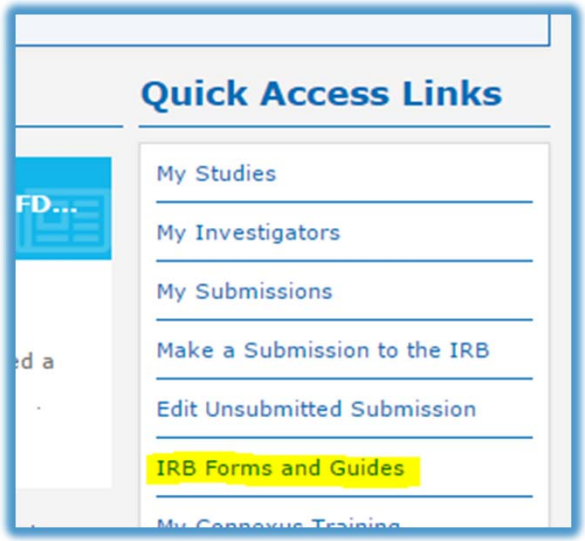
Preparing Your Initial Review Submission

Smart PDF forms are available in two locations:

- **WIRB.com** > Download Forms

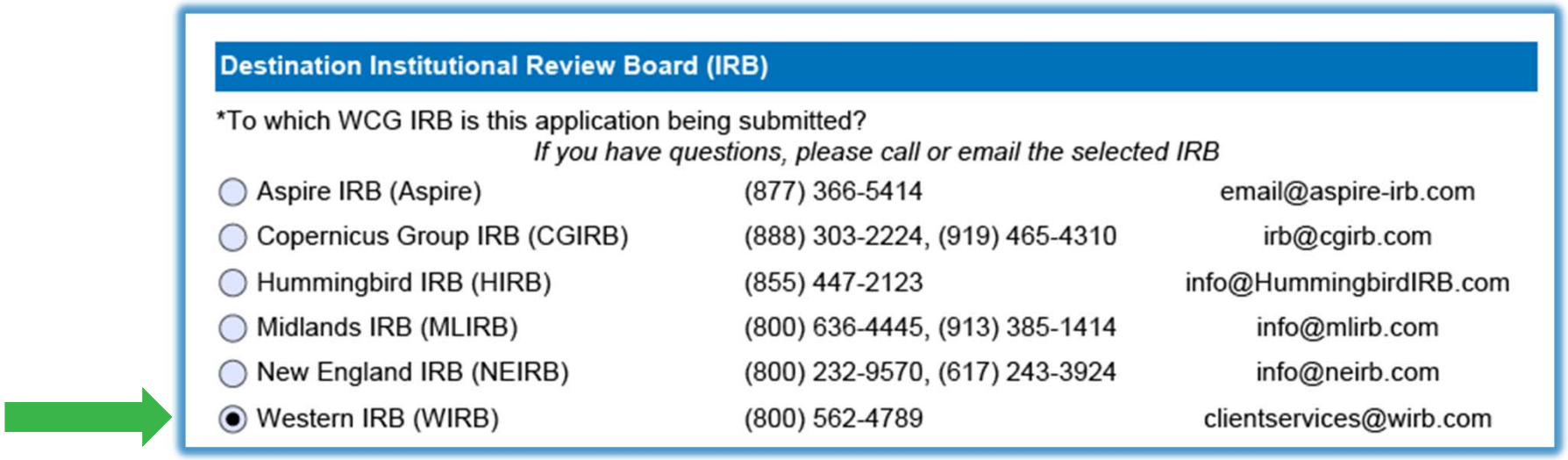


- **MyConnexus** > Quick Access Links > IRB Forms and Guides



Preparing Your Initial Review Submission

- Complete Initial Review Submission Form
  - Select WIRB as Destination IRB



Destination Institutional Review Board (IRB)

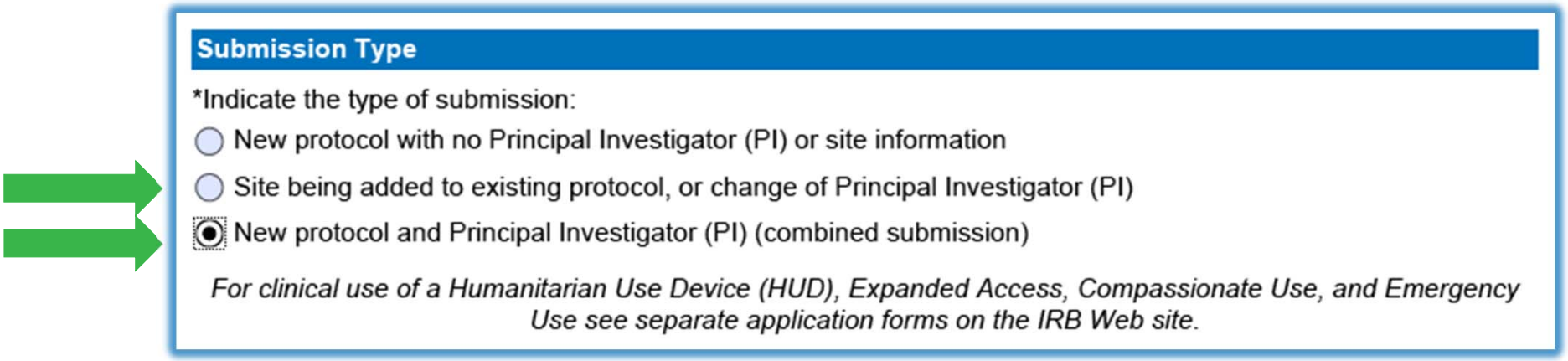
*To which WCG IRB is this application being submitted?

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

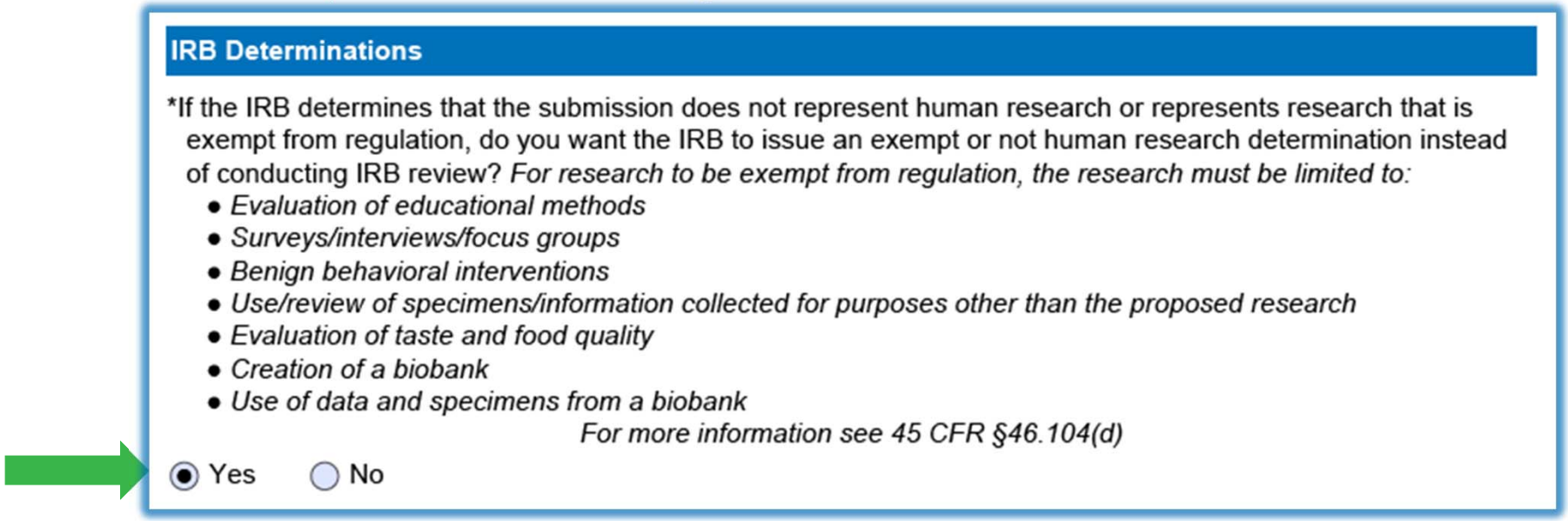
Preparing Your Initial Review Submission

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



Preparing Your Initial Review Submission

- Complete Initial Review Submission Form
  - Exempt from IRB oversight:



IRB Determinations

*If the IRB determines that the submission does not represent human research or represents research that is exempt from regulation, do you want the IRB to issue an exempt or not human research determination instead of conducting IRB review? *For research to be exempt from regulation, the research must be limited to:*

- *Evaluation of educational methods*
- *Surveys/interviews/focus groups*
- *Benign behavioral interventions*
- *Use/review of specimens/information collected for purposes other than the proposed research*
- *Evaluation of taste and food quality*
- *Creation of a biobank*
- *Use of data and specimens from a biobank*

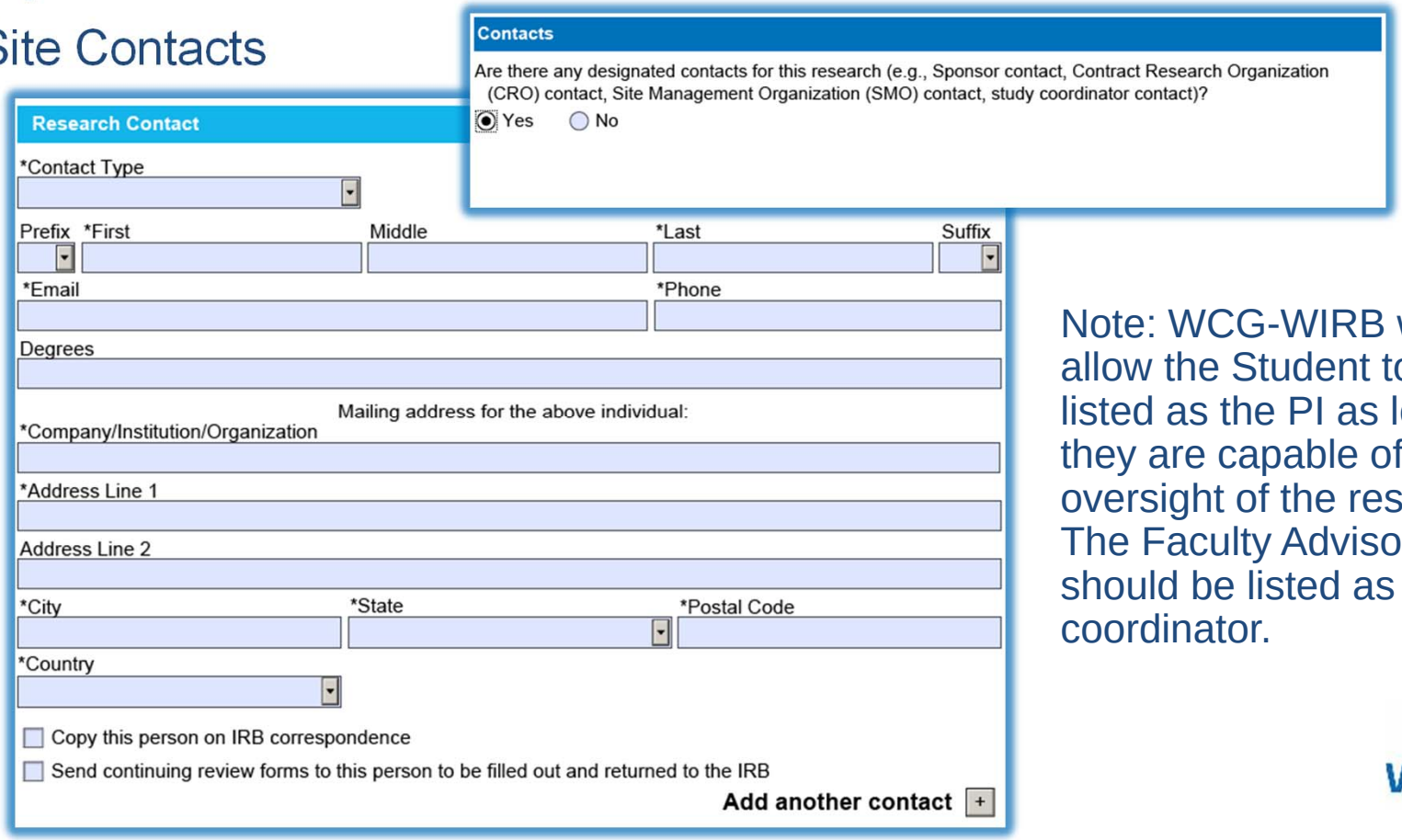
For more information see 45 CFR §46.104(d)

(●) Yes ( ) No

Note: WCG-WIRB does not require status updates if the research is found exempt from IRB oversight. However, you must provide substantive changes in you research for re-evaluation.

Preparing Your Initial Review Submission

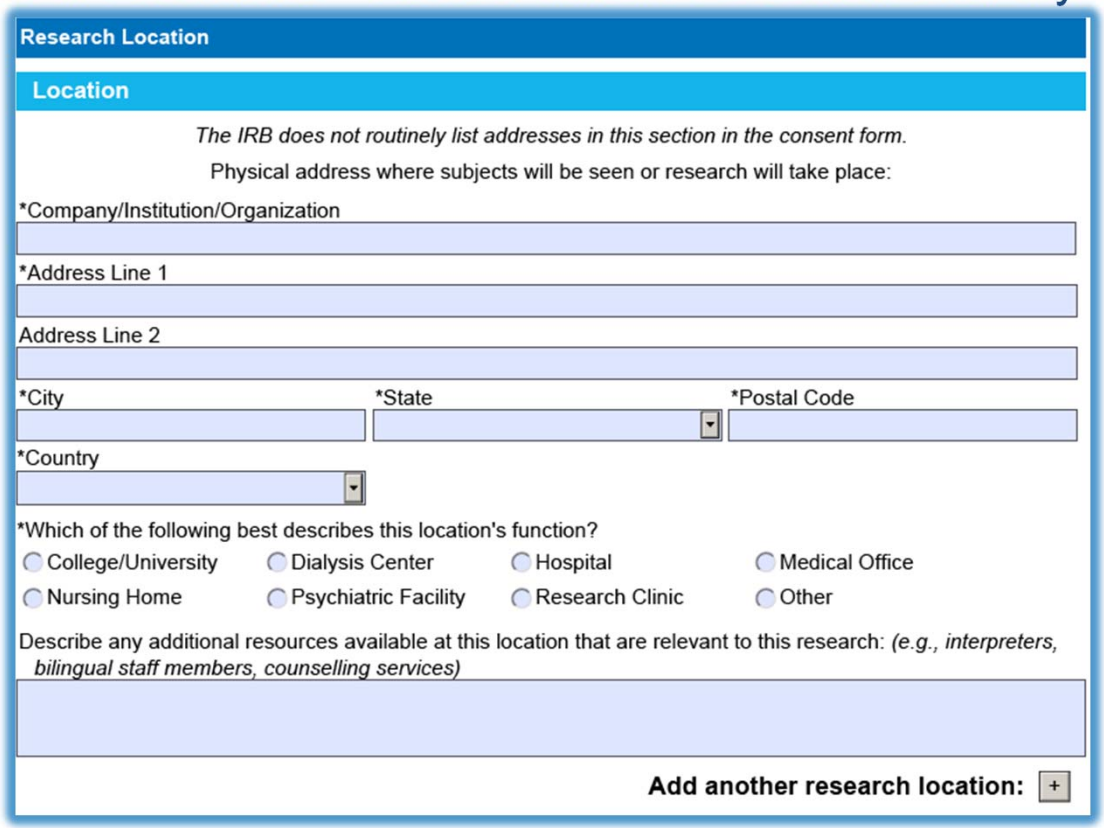
- Complete Initial Review Submission Form
  - Site Contacts



Note: WCG-WIRB will allow the Student to be listed as the PI as long as they are capable of the oversight of the research. The Faculty Advisor should be listed as a coordinator.

Preparing Your Initial Review Submission

- 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

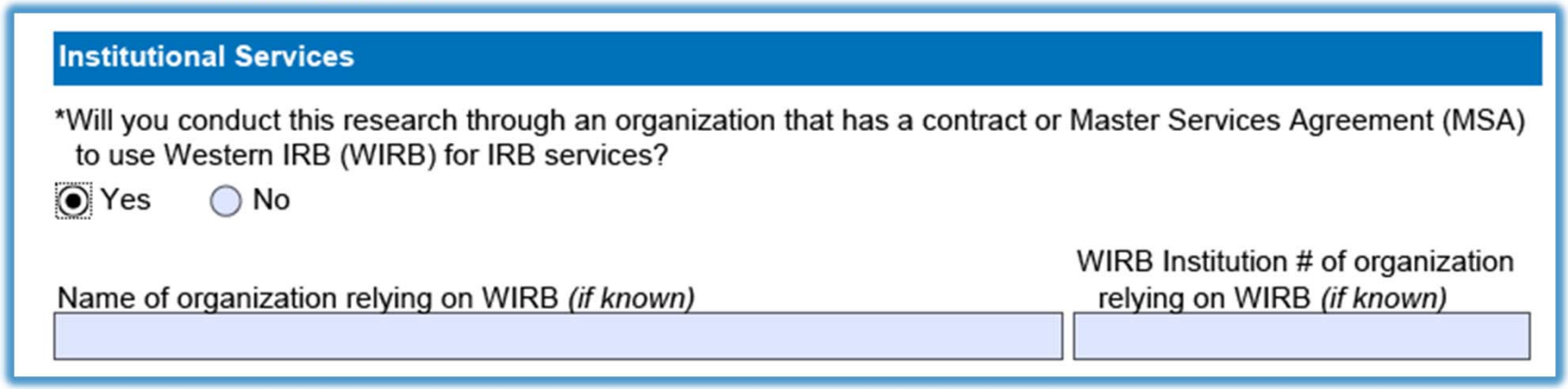
Nursing Home | Psychiatric Facility | Research Clinic | Other

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

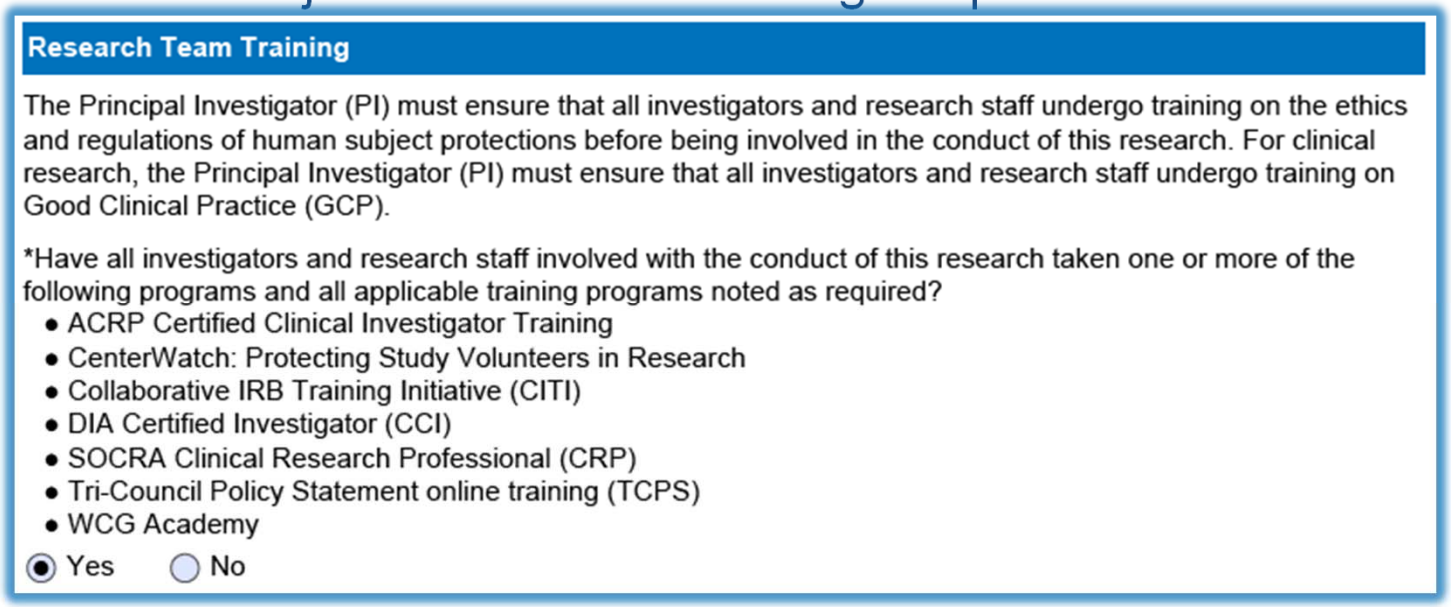
- Complete Initial Review Submission Form
  - Select YES to Institutional Services and Indicate Institution Name/Number:



Yeshiva University Institution ID: **127265**

Preparing Your Initial Review Submission

- Complete Initial Review Submission Form
  - Human Subjects Protection Training Requirement



Research Team Training

The Principal Investigator (PI) must ensure that all investigators and research staff undergo training on the ethics and regulations of human subject protections before being involved in the conduct of this research. For clinical research, the Principal Investigator (PI) must ensure that all investigators and research staff undergo training on Good Clinical Practice (GCP).

*Have all investigators and research staff involved with the conduct of this research taken one or more of the following programs and all applicable training programs noted as required?

- ACRP Certified Clinical Investigator Training
- CenterWatch: Protecting Study Volunteers in Research
- Collaborative IRB Training Initiative (CITI)
- DIA Certified Investigator (CCI)
- SOCRA Clinical Research Professional (CRP)
- Tri-Council Policy Statement online training (TCPS)
- WCG Academy

◉ Yes ○ No

Note: WCG-WIRB does not require Certificates of Training.

Preparing Your Initial Review Submission

- Complete Initial Review Submission Form
  - Conflict of Interest / Financial Interest Disclosure

Financial Interest Disclosure

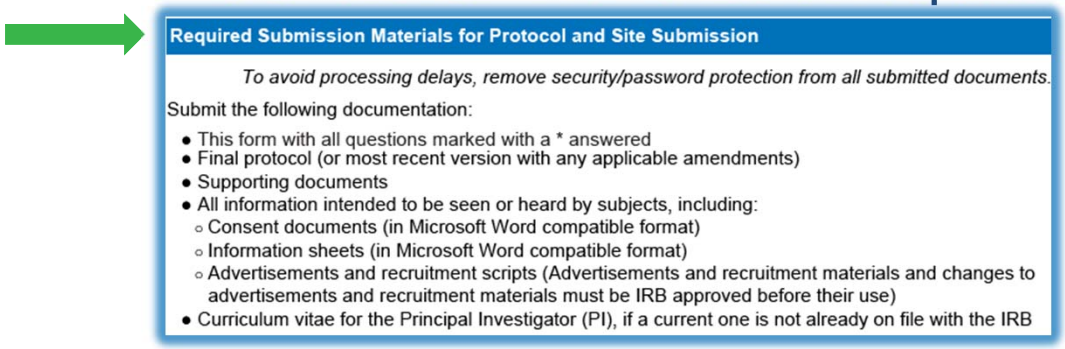
*Does the Principal Investigator (PI), the PI's immediate family, or any other research personnel or their immediate families, have any of the following financial interests in an entity that is sponsoring the research, or an entity that is manufacturing the product or service being tested?

- Any remuneration from the entity in the previous twelve months that exceeds $5,000, when aggregated for the individual and their immediate family. *(Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, or paid authorship)*
- Any equity interest in the entity. *(Equity interest includes any stock, stock option, or other ownership interest)*
- Any intellectual property rights and interests *(e.g., patents, copyrights)*
- Any governance or executive relationship with the entity *(e.g., board of director, CEO)*

○ Yes ◉ No

Submission Documents

- The form will guide you as to what documents are required for submission
  - There will be ⚠ signs in the form if supplemental forms are required
- Reference the end of the form for a list of required documents



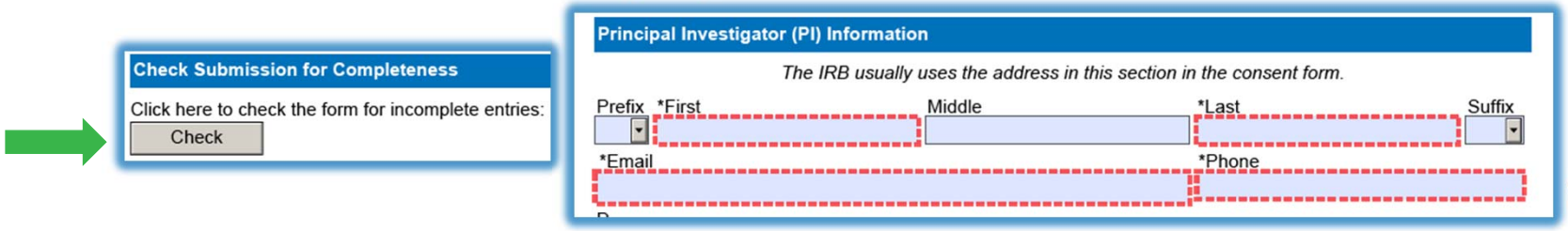
Required Submission Materials for Protocol and Site Submission

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
- 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 (PI), if a current one is not already on file with the IRB

- The form includes a tool to check for missing entries
  - Missing entries will be highlighted



Check Submission for Completeness

Click here to check the form for incomplete entries:

Check

Principal Investigator (PI) Information

The IRB usually uses the address in this section in the consent form.

Prefix *First Middle *Last Suffix

*Email *Phone

Preparing Your Initial Review Submission

- Ensure that you have complied with your local Yeshiva University processes

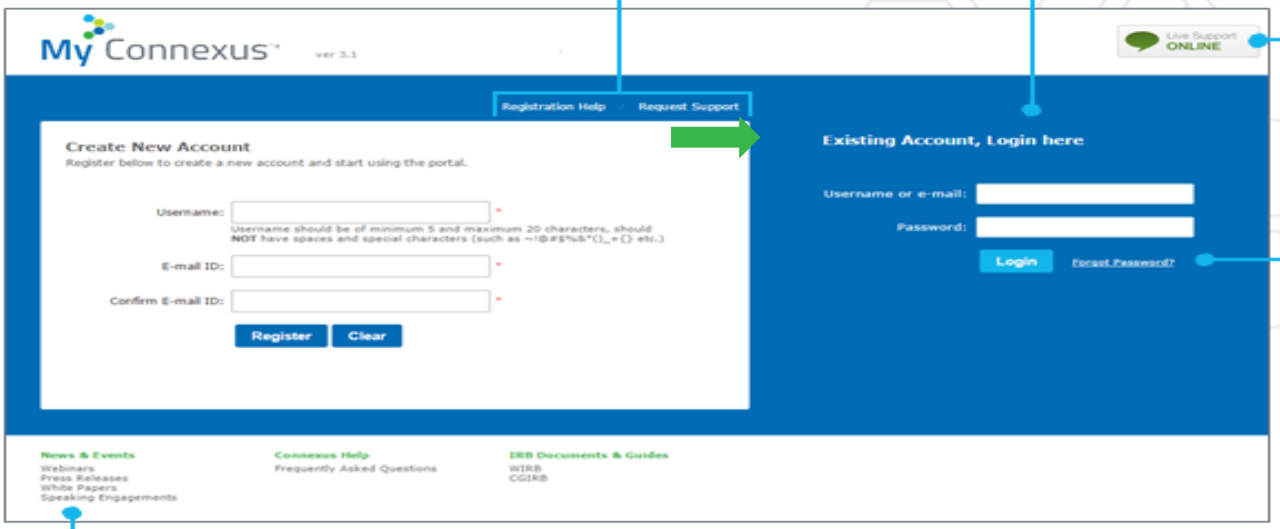
Yeshiva University

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 **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.



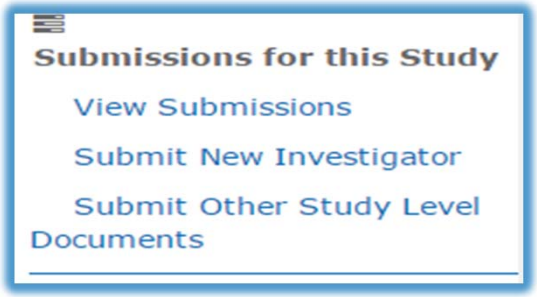
Live Support
Click the **Live Support ONLINE** button to chat with a representative. If there are no representatives available, you can leave a message.

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

Quick links
Access helpful links without having to login.

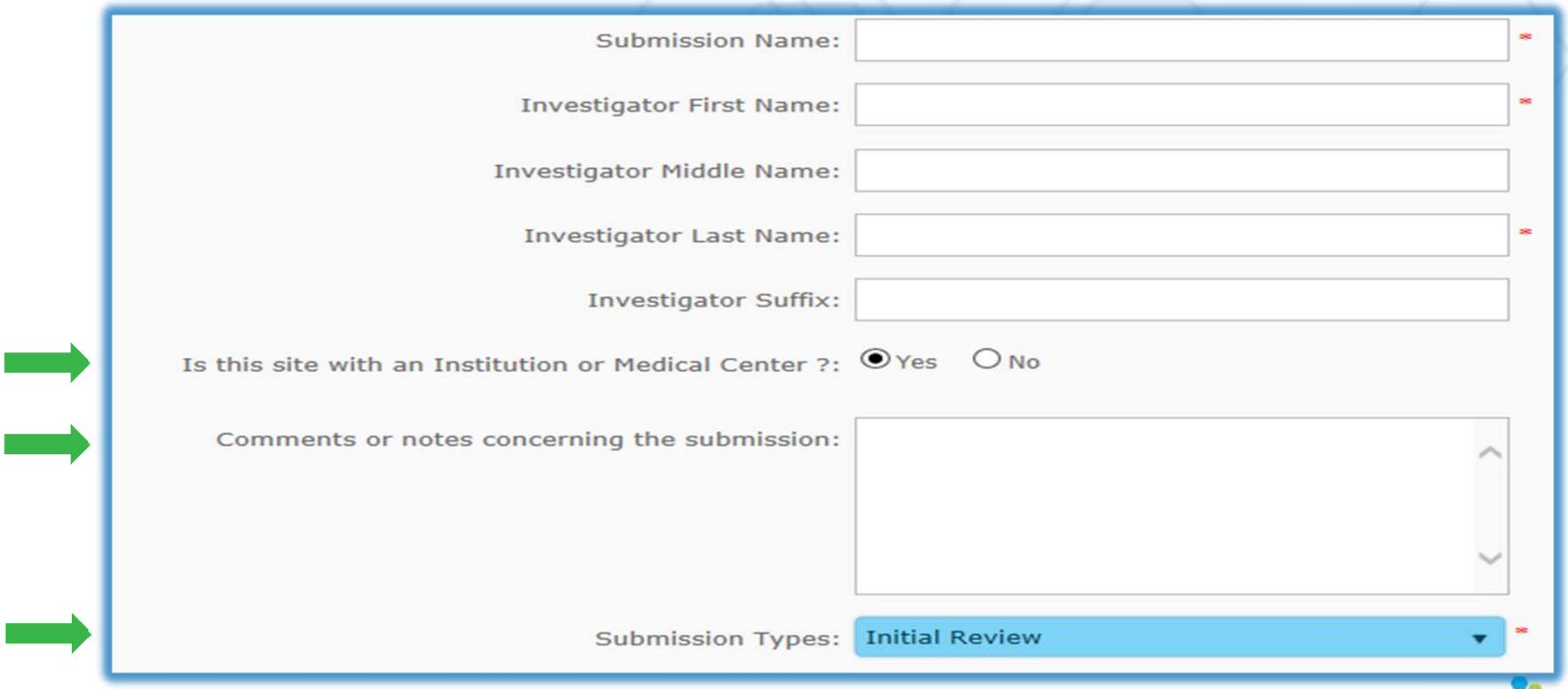
Preparing Your Initial Review Submission: Additional PI Site

- 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

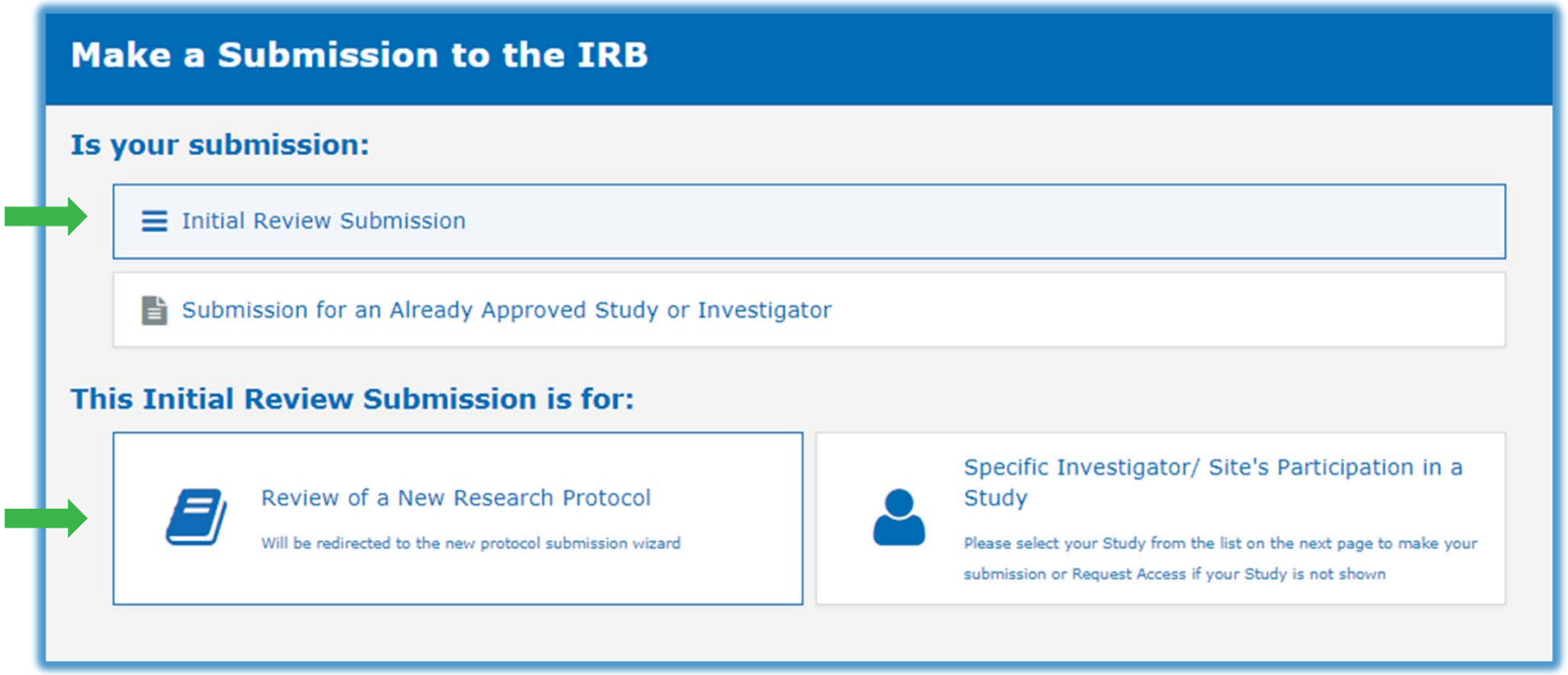


Preparing Your Initial Review Submission: Additional PI Site

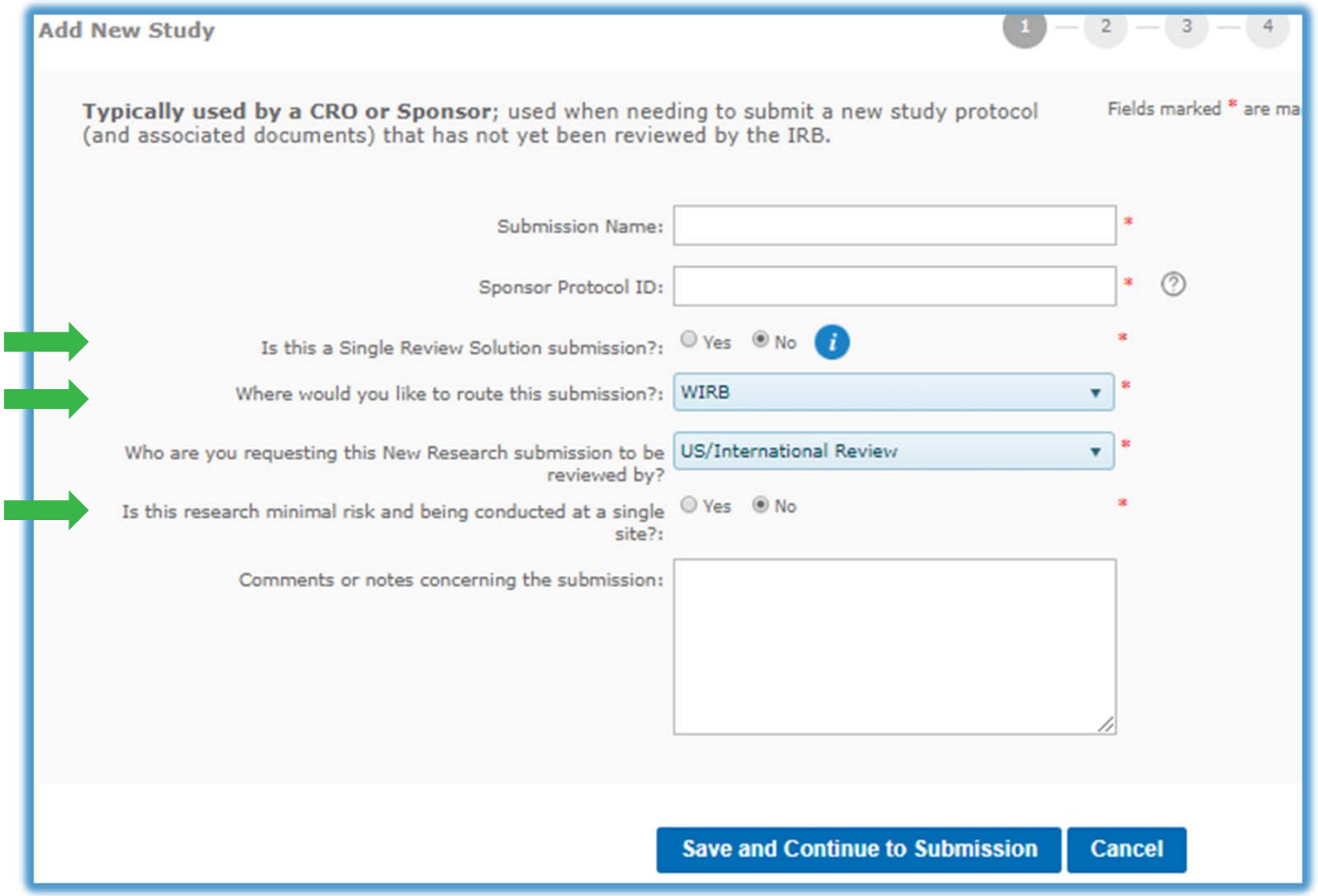
- Complete Wizard, Upload Documents, and Submit!



Preparing Your Initial Review Submission: New Study



Preparing Your Initial Review Submission: New Study



After You Submit...

- You receive a **Submission Tracking Number**
- WCG-WIRB staff prepares the submission
- A WCG-WIRB panel or expedited reviewer reviews the research for your site
- WCG-WIRB staff assembles and finalizes documents
- You receive an e-mail with a link to all WCG-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 MyConnexus for reference

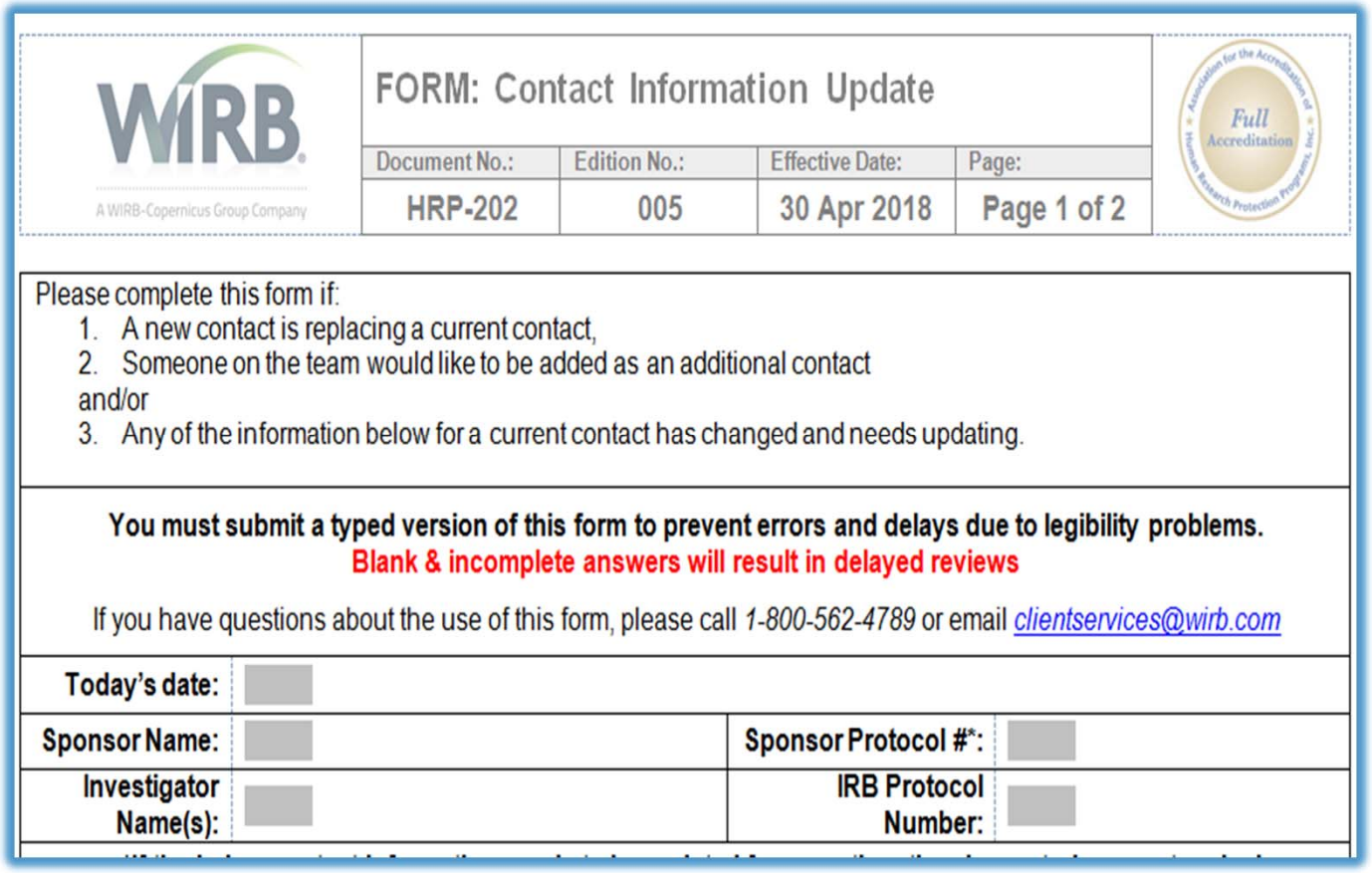
After You Submit…

- You will receive a Certificate of Action “COA” with your Outcome Documents. It will list the following:
  - WCG-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 MyConnexus workspace for your PI.
- Use the Contact Information Update Form for changes to study contacts or continuing review contacts.

Contact Information Update Form

- Necessary to update the contacts who receive CRRFs



WIRB
A WIRB-Copernicus Group Company

FORM: Contact Information Update

Document No.:	Edition No.:	Effective Date:	Page:
HRP-202	005	30 Apr 2018	Page 1 of 2

Full Accreditation

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.

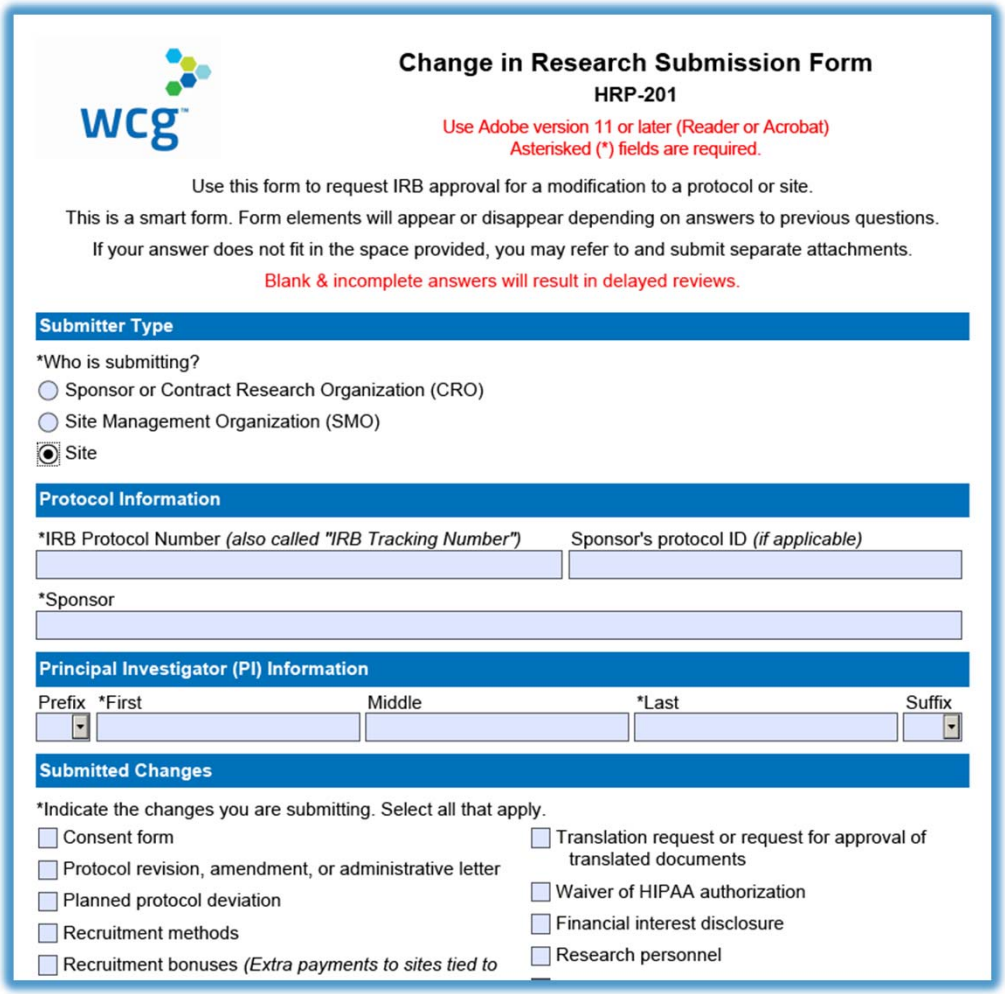
You must submit a typed version of this form to prevent errors and delays due to legibility problems.
Blank & incomplete answers will result in delayed reviews

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:**	

wcg WIRB

Modifications and Amendments



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

Principal Investigator (PI) Information

Prefix | *First | Middle | *Last | Suffix

Submitted Changes

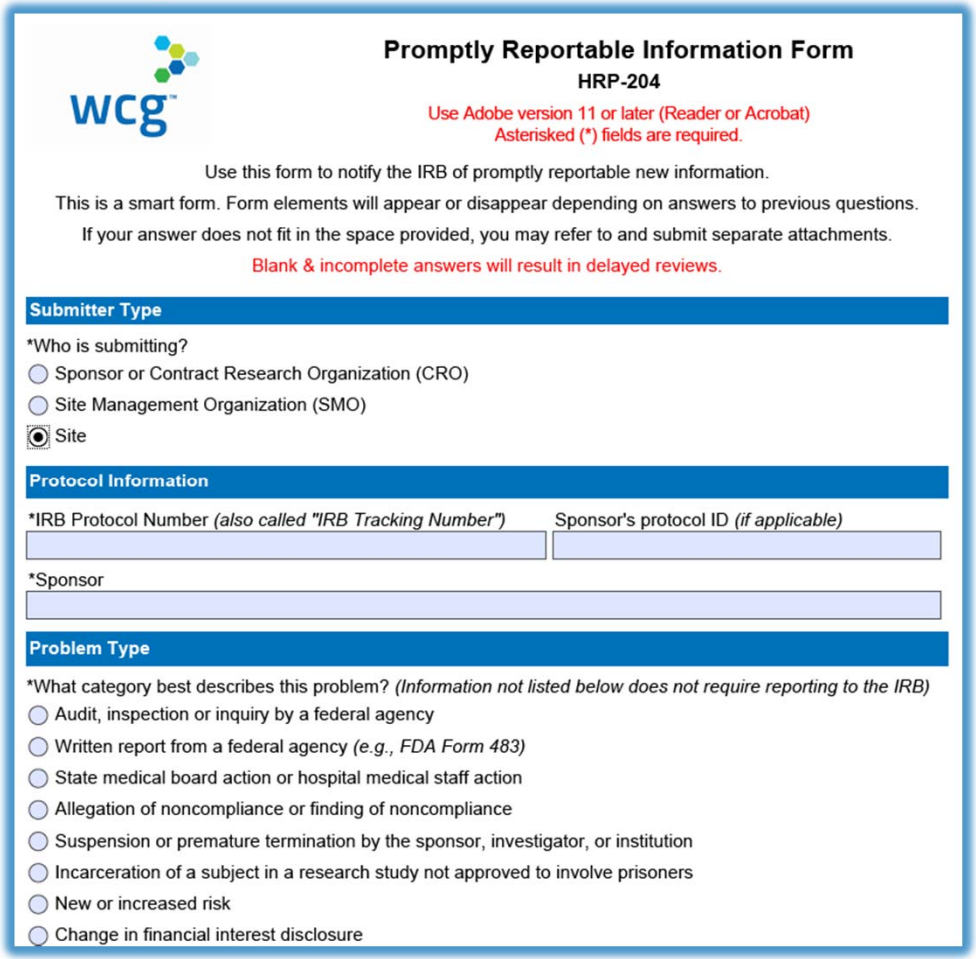
*Indicate the changes you are submitting. Select all that apply.

- ☐ Consent form
- ☐ Protocol revision, amendment, or administrative letter
- ☐ Planned protocol deviation
- ☐ Recruitment methods
- ☐ Recruitment bonuses *(Extra payments to sites tied to*
- ☐ Translation request or request for approval of translated documents
- ☐ Waiver of HIPAA authorization
- ☐ Financial interest disclosure
- ☐ Research personnel

Amendments and modifications can be submitted using our "**Change in Research**" form

- ❑ Add additional research locations
- ❑ Indicate if there is a change in financial disclosure
- ❑ Sponsors can submit changes on your behalf

Reportable Information (AEs, UPs, etc.)



Promptly Reportable Information Form
HRP-204

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

Use this form to notify the IRB of promptly reportable new information.
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

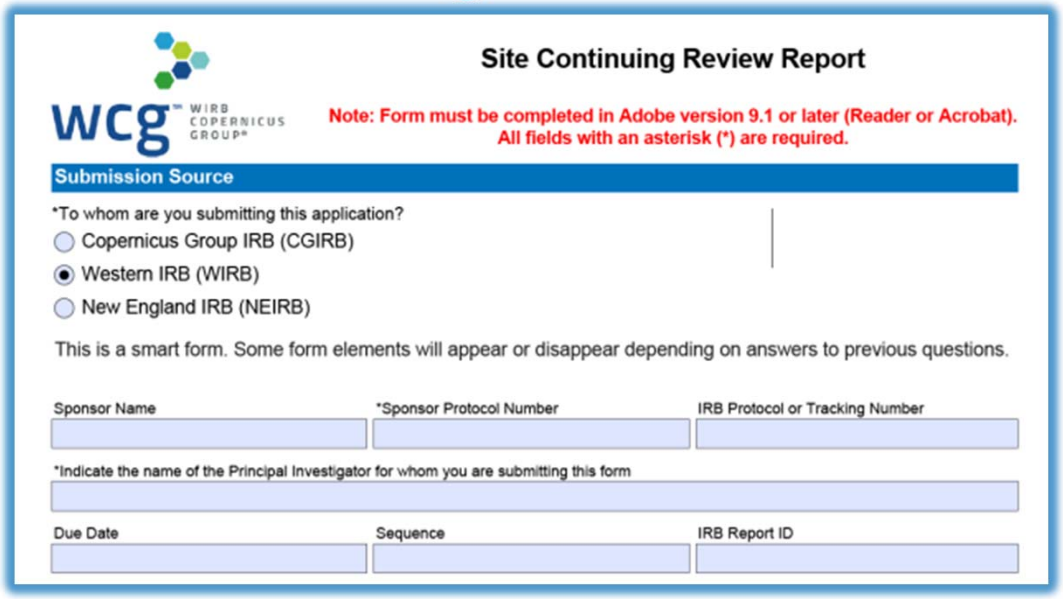
Problem Type

*What category best describes this problem? *(Information not listed below does not require reporting to the IRB)*
- ○ Audit, inspection or inquiry by a federal agency
- ○ Written report from a federal agency *(e.g., FDA Form 483)*
- ○ State medical board action or hospital medical staff action
- ○ Allegation of noncompliance or finding of noncompliance
- ○ Suspension or premature termination by the sponsor, investigator, or institution
- ○ Incarceration of a subject in a research study not approved to involve prisoners
- ○ New or increased risk
- ○ Change in financial interest disclosure

The "**Promptly Reportable Information**" form is used to report any adverse events or unanticipated problems

- ❑ The form will guide you as to what problems to report
- ❑ WCG-WIRB will review the report and if significant, communicate with appropriate parties
- ❑ If we find that the event does not constitute an increased risk to subjects, we will file it without action.
- ❑ If you need an email stating the event was filed, contact your Account Manager.

Continuing Review



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)
- ◉ 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.

Sponsor Name | *Sponsor Protocol Number | IRB Protocol or Tracking Number

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

Due Date | Sequence | IRB Report ID

NOTE: The above fields will be filled in for you. This form is emailed to the appropriate person(s) on file based on the Initial Review Submission form.

The "**Continuing Review Report Form**" will be sent automatically to the individual(s) listed on the Initial Review form

- ❑Forms are sent out approximately 86 days before the study expiration date, and are due approximately 56 days before the study expiration date
- ❑All sites are brought on to a single protocol-level expiration date
- ❑If you receive initial approval within 90 days of the protocol-level expiration date, you will automatically be brought on to the next continuing review period
- ❑Work order is reviewed 10-14 days before expiration date

Note on the New Common Rule

- WCG-WIRB will only review federally-funded studies under the new Common Rule unless requested otherwise
- Consent Form Template with a summary is available on our Download Forms page

We Are Here to Partner With You – Contact Us!

General Questions

WCG-WIRB Client Services

+1 360.252-2500 | **clientservices@wirb.com**

Escalated/Urgent Questions

Jon Gellert

+1 360.570.1309 | **jgellert@wirb.com**

Presentation by

Christopher Gennai, CIP

+1 360.252.2460 | **cgennai@wirb.com**


wcg
Thank You