wcg SRS™

WIRB-COPERNICUS GROUP

Single Review Solution Welcome Kit

Welcome to SRS

Hello!

The WIRB-Copernicus Group (WCG) is pleased to have been selected as the IRB of record for this clinical trial. WCG is proud to count among its clients the world's largest and most well-recognized sponsors and CROs, as well as the nation's foremost research institutions and community-based (central) sites.

This clinical trial has been submitted for review using WCG's proprietary Single Review Solution™, or SRS, as we like to call it. Utilizing the SRS review process will allow for a more efficient, more comprehensive review solution that encompasses both institutional and central sites. The protocol, informed consent, and other study related documents will receive review by one of our SRS Review Boards. Each site, whether institutional or central, will be reviewed through the expedited review process. Additionally, institutional sites will be reviewed by Western Institutional Review Board (WIRB), while central sites will be reviewed by Copernicus Group Independent Review Board (Copernicus IRB). Through the use of our online portal, Connexus, users of SRS at the sponsor and CRO level will have access to all study and site information and outcome documents, while individual sites will only have access to their site-specific workspace. In brief, SRS provides sponsors and CROs with a more streamlined review process, while not disrupting the way in which institutional and central sites are used to working with WCG.

Enclosed in this packet, you will find more detail about the Single Review Solution, including frequently asked questions, information about the onboarding process, any relevant forms related to SRS, as well as pertinent contact information, should you ever have any questions along the way.

We are delighted to provide this enhanced review service to you, and look forward to working with you during the course of this trial.

Frequently Asked Questions

I. Single Review Solution - A Brief Description

As you may know, WIRB and Copernicus IRB are members of the WIRB-Copernicus Group, the world's largest provider of regulatory and ethical review services for human research. Through the transformational SRS process, WCG provides a streamlined, comprehensive, ethical review solution that supports the speed and efficiency that sponsors and CROs desire, while meeting the unique needs of institutions.

With the SRS process in place, you will have the opportunity to participate in trials developed to combine the powerful IRB review capabilities of Copernicus IRB, with the expansive list of experienced, efficient institutions for which WIRB serves as an IRB of Record. WIRB's experience as a trusted parter to institutions, coupled with the industry-leading services of Copernicus IRB, assures an efficient and thorough IRB review process through SRS.

II. Frequently Asked Questions - Central Sites

1. What is SRS?

The Single Review Solution was developed by the WIRB-Copernicus Group to bring added value to WIRB and Copernicus IRB clients. The goal of SRS is to generate efficiency for all stakeholders. To achieve this goal, the WIRB-Copernicus Group has harmonized the best practices of WIRB and Copernicus IRB to deliver a more efficient, more comprehensive, and higher quality review service, while respecting the unique needs of institutions and preferences of sponsors.

2. How does SRS work?

When a sponsor elects to partner with the WIRB-Copernicus Group, they are looking for a comprehensive solution. SRS marries the industry-leading services of Copernicus IRB with the trusted institutional expertise of WIRB. Under the SRS process, the sponsor and/or CRO will submit the protocol, informed consent, and other study-level documents for review to Copernicus IRB. The SRS Board will review the protocol, informed consent, and study-related documents, and once approval is granted, outcome documents will be available to you through our online portal, Connexus. Central sites will be submitted for expedited review to Copernicus IRB, while institutional sites will submit for review at WIRB. The site's approval documentation will be available on Connexus at a global level for the Sponsor and CRO, while sites will only be able to see their specific information.

3. As a central site, what are the benefits of utilizing SRS?

When your site is selected for participation in a trial, we guarantee that the review is conducted as efficiently as possible, and with the highest quality outcome, helping you to demonstrate speed and efficiency through the study start-up phase. We deliver even greater value to you with SRS; by leveraging our relationship with Copernicus IRB, we make your site more attractive to industry sponsors.

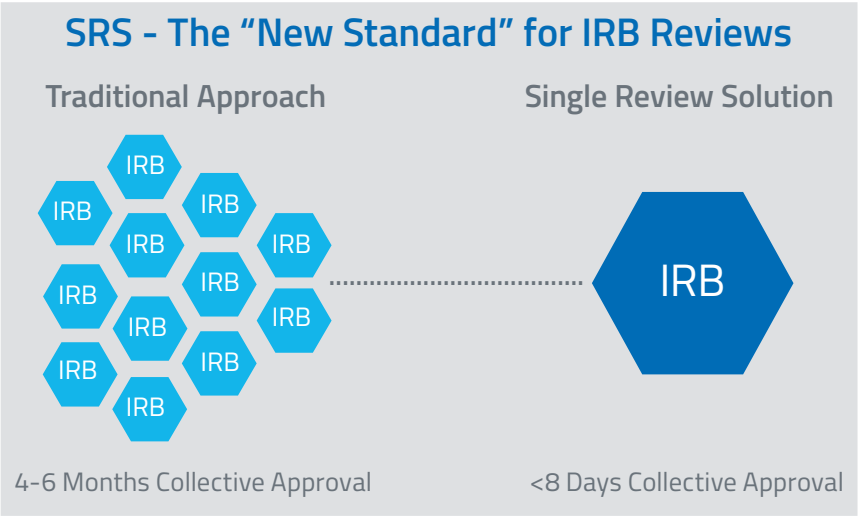
4. When submitting a new central site for approval, which IRB address do I list on the 1572?

When submitting a new central site for approval, you will list the Copernicus Group Indepdent Review Board address on the 1572:

Copernicus Group Independent Review Board
1 Triangle Drive, Suite 100
Durham, NC 27713

5. How do I register for Connexus?

To register for Connexus as a central site, please click here, or visit: connexus.cgirb.com



Frequently Asked Questions *Continued...*

III. Frequently Asked Questions - Institutional Sites

1. What is SRS?

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2. How does SRS work?

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3. As an institutional site, what are the benefits of utilizing SRS?

Because you are our valued client, we work hard to make sure that your site is at the top of every sponsor's site selection list. When your site is selected for participation in a trial, we guarantee that the review is conducted as efficiently as possible, and with the highest quality outcome, helping you to demonstrate speed and efficiency through the study start-up phase. We deliver even greater value to you with SRS; by leveraging our relationship with WIRB, we make your site more attractive to industry sponsors. In doing so, we bring more research funding to your door, at no additional cost or effort to you.

4. When submitting an institutional site for approval, which IRB address do I list on the 1572?

When submitting an institutional site for approval, you will list the Western Institutional Review Board address on the 1572:

Western Institutional Review Board
1019 39th Avenue SE, Suite 120
Puyallup, WA 98374

5. How do I register for Connexus?

To register for Connexus as an institutional site, please click here, or visit: connexus.wirb.com

6. Will there be changes to my relationship with WIRB?

Your agreement is with WIRB; you are a WIRB client. WIRB will remain responsible to you for all matters relating to the review of each SRS site. We are simply leveraging Copernicus IRB's strong relationship with sponsors to better serve you. Rest assured that your information will be received by a WIRB employee, and the review of your sites will be conducted by WIRB. While WIRB will rely on the protocol review of Copernicus IRB, we will continue to use the forms, documentation, processes and methods of communication to which you are accustomed to for non-SRS trials.

7. Does SRS affect my billing?

Participating in a trial undergoing SRS will not affect your billing process; you will continue to be billed in the manner to which you are accustomed. If we invoice you directly, or invoice the sponsor on your behalf, we will continue to do so in accordance with your preference.

Frequently Asked Questions *Continued...*

IV. Frequently Asked Questions - Sponsors and CROs

1. What is SRS?

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2. How does SRS work?

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3. As a sponsor and/or a CRO, what are the benefits of utilizing SRS?

SRS connects WCG's industry clients with over 1,000 academic medical centers, universities and hospitals for which WIRB is an IRB of record. Using Copernicus IRB's central site review processes, WCG provides a single, seamless review of the protocol and its associated sites. The most highly sought-after review solution in the industry, SRS saves time and money by dramatically decreasing the unnecessary administrative burdens of the study start-up process. But, among its many advantages, SRS allows our clients to work with a single IRB, and to manage the IRB review process and its related documentation in one place.

4. When utilizing a trial undergoing SRS, who do I work with? Do I have a single point of contact?

When utilizing the SRS process, you will have a single point of contact (POC). At the beginning of the study, your Client Relations Manager will introduce you to your POC who will be with you throughout the lifetime of the study, providing you with stability and efficient management of your clinical trial.

Onboarding Checklist

I. Submissions to Copernicus IRB Through the SRS Process

Submitting a new protocol or a new central site to Copernicus IRB utilizing the SRS process? Not sure what to include in your submission? Don't worry! Below is an inclusive list of the items needed to make a complete submission to Copernicus IRB.

Study Level Submission Requirements:

Required Documentation to Complete an SRS Submission

1. New Study Application Form
2. Protocol (Final)
3. Informed Consent(s) (Word Version)
4. SRS Agreement/Indemnification Form

Other Documents Often Submitted

1. Investigator's Brochure
2. Supplemental Materials (Recruitment Materials, Diaries, etc.)

Central Site Submission Requirements:

*Required Documentation to Complete an SRS Central Submission (*May be completed by Site, Sponsor, or CRO)*

1. Investigator Site Questionnaire: Completed for the primary research site that is listed in section three of the 1572.
2. Investigator Site Questionnaire for Additional Sites: Completed for any secondary sites listed in section three of the 1572.
3. Current Curriculum Vitae (CV) of PI: CVs must verify affiliation to at least one study site and must be current within two years.
4. Current Professional License of PI: If PI is licensed in Massachusetts, a copy of the research license must also be included in the submission (Controlled Substance License).

II. Submissions to WIRB Through the SRS Process

Submitting an institutional site to WIRB utilizing the SRS process? Not sure what to include in your submission? Don't worry! Below is an inclusive list of the items needed to make a complete submission to WIRB.

New Principal Investigator (PI) Submission Requirements:

1. Investigator Submission Form for Multi-Center Protocols
2. Current Curriculum Vitae (CV) of PI and Each Sub-Investigator
3. Current Professional License of PI: If PI is licensed in Massachusetts, a copy of the research license must also be included in the submission (Controlled Substance License).
4. Informed Consent(s) (Word Version)
5. Institutional Sign-Off (If required by the institution)

Contact Information

Have questions? Need answers? We're here to help! Please feel free to contact us via email, telephone, or mailing address if you need anything at all.

Copernicus Group Independent Review Board (Copernicus IRB)

ADDRESS:
1 Triangle Drive
Suite 100
Durham, NC 27713

PHONE NUMBERS:
Office: 919.465.4310
Toll Free: 888.303.2224
Fax: 919.465.4311

EMAIL ADDRESS:
Email: irb@cgirb.com

WEBSITE:
Website: www.cgirb.com

Western Institutional Review Board (WIRB)

ADDRESS:
1019 39th Avenue SE
Suite 120
Puyallup, WA 98374

PHONE NUMBERS:
Office: 360.252.2500
Toll Free: 800.562.4789
Fax: 360.252.2498

EMAIL ADDRESS:
Email: clientservices@wirb.com

WEBSITE:
Website: www.wirb.com

www.wcgclinical.com