

HowTo: Submit your clinical safety application?

KB0011993 - https://wcmcpd.service-now.com/kb_view.do?sysparm_article=KB0011993

Introduction

This article explains how to submit the clinical safety application and is intended for Research Coordinators and Principal Investigators. Depending how you answer questions on the Intake form, SASP will indicate that you may require either Institutional Biosafety Committee and Radiation Safety Committee. These fields will be marked red – Not Started, which means you must complete them.

Procedure

Submit the Institutional Biosafety Committee (IBC) Application

1. Click the **Research Safety** module from the left navigation menu of WRG.
2. Click the **Create New Protocol** button.
3. Select the **Clinical Safety Application for IBC/RSC – Initial** radio button and click Continue.
4. Ensure **Copy from an existing protocol** is No and click Continue.
5. Enter the **Title** and click Continue.
 - a. The title should be the same name as the Human Subjects application.
6. Enter the name of the **PI** and click **Continue**. A new window will appear.
 - a. Note that your name will appear by default. If you are entering this on behalf of a PI, please update their name here.
7. Click the orange **Clinical Safety Application for IBC/RSC** link.
8. Click the **dropdown menu** and make the appropriate selection. The relevant questions for your selection will appear below.
9. Answer all the questions on the form.
10. Click the **Save** button, followed by the **Completed** checkbox.
 - a. On the main page, ensure the Status column reads as Complete.
11. Click the **Linkages** button in the top navigation.
 - a. In the **dropdown menu** select **Human Protocol** and then click the orange **Add** button.

- b. A new window will pop-up. In the **Select by Number** textbox, enter the Human Subjects record number. Then click **Go**.
 - c. Once the page finishes loading, scroll to the bottom of the page and select the checkbox next to the Human Subjects record you want to link. Then click **Select**.
- 12. Click the **Submissions** button in the top navigation.
- 13. Click the **Clinical Safety Application for IBC/RSC – Initial** link.
- 14. Click the orange **Submit** button.

Submit the Radiation Safety Dosimetry Request

1. Click the **Research Safety** module from the left navigation menu of WRG.
2. Click the **Radiation Safety Dosimetry Request** button. A form will pop up.
3. Answer all questions on this form.
4. After submission, this form will be routed to the appropriate groups who will communicate back with you the dosimetry values which are needed to complete your Radiation Safety Committee (RSC) application.

Submit the Radiation Safety Committee (RSC) Application

1. Click the **Research Safety** module from the left navigation menu of WRG.
2. Click the **Create New Protocol** button.
3. Select the **Clinical Safety Application for IBC/RSC – Initial** radio button and click Continue.
4. Ensure **Copy from an existing protocol** is No and click Continue.
5. Enter the **Title** and click Continue.
 - a. The title should be the same name as the Human Subjects application.
6. Enter the name of the **PI** and click Continue. A new window will appear.
 - a. Note that your name will appear by default. If you're entering this on behalf of a PI, please update their name here.
7. Click the orange **Clinical Safety Application for IBC/RSC** link.
8. Click the **dropdown menu** and make the appropriate RSC selection. The relevant questions and upload sections for your selection will appear below.
9. Answer all the questions on the form.
10. Click the **Save** button, followed by the **Completed** checkbox.
 - a. On the main page, ensure the Status column reads as Complete.

11. Click the **Linkages** button in the top navigation.
 - a. In the **dropdown menu** select **Human Protocol** and then click the orange **Add** button.
 - b. A new window will pop-up. In the **Select by Number** textbox, enter the Human Subjects record number. Then click **Go**.
 - c. Once the page finishes loading, scroll to the bottom of the page and select the checkbox next to the Human Subjects record you want to link. Then click **Select**.
12. Click the **Submissions** button in the top navigation.
13. Click the **Clinical Safety Application for IBC/RSC – Initial** link.
14. Click the orange **Submit** button.

Next Steps

After submission, your application will enter a review and approval route. If you're entering on behalf of the PI it will go to them for review and approval, followed by back office approval before moving forward to committee review.

Additional Resources

- [HowTo: Submit an Intake Form \(Study Activation\)](#)
- [Overview: The Study Activation Status Page \(SASP\)](#)
- [HowTo: Submit Protocol to the PRMC in ePRMS](#)
- [HowTo: Submit your Initial IRB Application](#)
- [HowTo: Approve + Certify on an IRB Application](#)
- [HowTo: Complete Items on your Task Lists in WRG](#)