

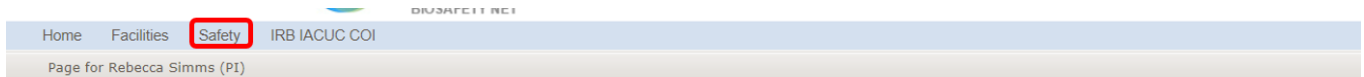
BiosafetyNet Continuing Review (CR)- Submission Instructions for PIs/ Coordinators for Clinical Human Gene Transfer (HGT) studies

You will receive a reminder email from the BiosafetyNet system 90, 60 and 30 days out from your CR expiration date.

NOTE: Only one CR can be open at a time.

Locating your studies in BiosafetyNet:

- 1) When you log into [BiosafetyNet](#) you will be taken to your “Inbox.” If there is anything which requires an action from they will be listed in your “Inbox.”
- 2) To access your approved protocols click on the safety tab at the top of the BiosafetyNet page.



My Current Actions

- Create Safety Submission
- Create Safety Incident
- Help Center
- Submissions

My Inbox

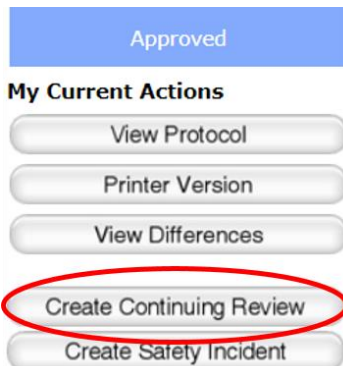
ID	Name	Date Created	Date Modified	State
AMEND2_PROTO2018-024	test	5/8/2018 9:30 AM	5/8/2018 9:30 AM	Pre-Submission
AMEND1_PROTO2018-016	Reportable Event #1	4/24/2018 4:54 PM	4/26/2018 3:14 PM	Pre-Submission
PROTO2017-020	Tony Test 8/18/2017	8/18/2017 10:40 AM	4/12/2018 10:29 AM	Pre-Submission

- 3) Click on the “Active” tab and all of your approved protocols should be listed here:

ID	Name	Date Modified	State	PI	Submission Type	Safety Review Type
PROTO2017-007	Test #2	6/3/2018 9:57 AM	Approved	Simms	Initial Protocol	Biosafety
PROTO2017-006	Application for Rebecca Test Simms	5/23/2018 9:57 AM	Suspended	Simms	Initial Protocol	Biosafety
PROTO2018-016	Issues00001445 - Testina	5/18/2018 9:57 AM	Lapsed	Simms (PI)	Initial Protocol	Biosafety

To create a Continuing Review in BiosafetyNet:

- 4) Open the approved study.
- 5) Use the **Create Continuing Review** activity on the left hand side of the page



- 6) Once the **Create Continuing Review** activity has been selected you will be taken into the Continuing Review page.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Safety Changes Continue >>

Safety Changes

1. Have any changes occurred with any of the following aspects of your protocol since the original submission approval?

- Infectious agents used
- Biosafety level (BSL)
- Risk group (RG)
- Containment equipment
- Personnel
- Procedures

Yes No Clear

2. If yes, please declare such changes by submitting a separate modification. Please note approval must be secured prior to initiation of the changes.

3. Please make sure all Protocol Team Members have current training:

Team Member	Phone	E-Mail	Training Completed
Rebecca Simms (PI)	211-333-3333	demo@webridge.com	2/10/2017 2/14/2016

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Safety Changes Continue >>

- 7) Item 1- Review if you have had any changes to your protocol since the protocol was approved.
Note: No changes can be made to the protocol at the time of continuing review.
- 8) Item 3- Review the current personnel listed on your protocol.
Note when the biosafety office reviews the submitted CR, they will check and update personnel training.
- 9) Click **Continue** to go to **Safety Accidents and Problems** page.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Safety Accidents and Problems

Safety Accidents and Problems

1. Have any accidents occurred that resulted in inoculation, ingestion or inhalation of biohazardous materials, or is there any danger of environmental contamination?

Yes No Clear

2. If yes, provide a complete description and resolution of the events:

3. Have any problems occurred pertaining to safety containment, equipment, or facility failure?

Yes No Clear

4. If yes, provide a complete description and resolution of the problems:

- 10) Item 1- Indicate if any accidents have occurred since approval or last CR. If “Yes,” provide information in item 2.
- 11) Item 3- Indicate if there have been any problems pertaining to safety containment, equipment or facility failure. If “Yes,” provide information in item 4.
- 12) Click **Finish** to complete the CR

13) Use the **Submit** activity to submit the CR.

In the supporting documents, you will need to upload the CR that has been submitted to the IRB. In the Submission pop up box, you will be asked to check that you agree with the “Investigators assurance”

1) Go to the related IRB study’s CR submission into the eIRB ARC system and select the **Printer-Friendly Version** button. Save the CR as a PDF.

In eIRB

In Bulls IRB

- 2) Upload the PDF version of the IRB CR submission to the **Supporting Documents** portion of the Submit pop up box. If there are any other documents that need to be reviewed as part of the CR (deviation log; SAE log) these can also be uploaded here.

Submit

Investigator's Assurance

The Principal Investigator is responsible for the following:

- Providing adequate training and supervision of staff in good laboratory techniques and practices required to ensure safety and for procedures in dealing with accidents.
- Enforcing federal regulations regarding laboratory safety for all persons who work under his/her direction, ensuring appropriate physical containment and for the proper disposal of all hazardous waste such as radioactive material, chemical waste, recombinant or synthetic nucleic acids, bacterial, viruses and other biohazardous agents.
- Reporting adverse events such as a work related injury or spill of hazardous and/or radioactive material, that could result in unexpected exposure of laboratory personnel and /or the public to the relevant institutional oversight committee.
- Ensuring that co-investigators, if any, employ the necessary safeguards to protect laboratory personnel, students and the community from potential hazards posed by the project.
- Complying with shipping requirements for hazardous materials including recombinant or synthetic nucleic acids, bacterial, viruses and other biohazardous agents.

I understand my responsibility with regard to laboratory safety and certify that the protocol, as approved by the relevant institutional oversight committee, will be followed during the period covered by this research project. Any future changes will be submitted for committee review and approval prior to implementation.

I understand the protocol will be reviewed periodically; it is my responsibility to complete and submit the continuing review form used for the periodic oversight committee review in a manner in accordance with deadlines communicated by the relevant committee.

If you have finished filling out your application, click "OK". Afterwards you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

*If you are not ready to submit your application, click **Cancel**.*

*** I agree with the above statement:**

1. Comments:

2. Supporting documents:

Add	
Document Name	Date Modified
Upload Revision IRB study CR PDF.pdf	2/7/2018 1:24 PM

- 3) Click **OK** to submit your CR for review.