



JOINT CLINICAL TRIALS OFFICE (JCTO)

Completing CSEC Submission Part A

CSEC Submission Part A is the first step in submitting a study for CSEC review. Upon submission of CSEC Submission Part A, the appropriate CSEC will contact the user specified in the form with a link to CSEC Submission Part B and the IRB Protocol Number.

1. Access CSEC Submission Part A in REDCap.

CSEC Submission Part A is the initial step taken when submitting a study for CSEC review. CSEC Submission Part A is available at <http://jcto.weill.cornell.edu/csecform>. This form is accessible in several other locations:

A. CSEC Website accessible from the IRB Homepage

B. eIRB Front Page:

The link to the CSEC Form A is available when a user logs into eIRB.

The screenshot shows the eIRB website interface. At the top, there is a red header with the Weill Cornell Medical College logo and the text "Weill Cornell Medical College" on the left, and "User: Brown, Scott" on the right. Below the header is a navigation bar with tabs for "Home", "My IRB Protocols", "Protocol Search", and "Logout".

On the left side, there are sections for "Contact the IRB" (646-962-8200, IRB@med.cornell.edu) and "Contact the CSEC" (GeneralCSEC@med.cornell.edu, CancerCSEC@med.cornell.edu). Below these are "Helpful Links" including "Immediate reporting policy", "IRB Policies and Procedures", "Policy on consenting non-English speaking subjects", "Human subjects training", "State of Compliances", "Information about WCMC IRBs", "IRB Roster release", "New IRB Forms", and "IRB FAQs".

In the center, there is a notice: "Effective August 15, 2013, the IRB process for initial submissions has changed. The Clinical Study Evaluation Committee (CSEC) now handles eIRBs 'Create New Protocol' functionality. To initiate a new IRB application, please visit <http://jcto.weill.cornell.edu/csecform>. For more information, visit http://weill.cornell.edu/research/research_integrity/institutional_review_board/csec.html." The URL <http://jcto.weill.cornell.edu/csecform> is highlighted with a red box.

Below the notice is a table titled "WCMC IRB Meeting Schedule":

WCMC IRB Meeting Schedule			
IRB G1 - Mondays	IRB G2 - Tuesdays	IRB CA1 - Mondays	IRB CA2 - Wednesdays
July 15	July 23	July 22	July 17
August 5, 19	August 13, 27	August 12, 26	August 7, 21
September 3, 16	September 10, 24	September 9, 23	September 4, 18
October 7, 21	October 15, 29	October 14, 28	October 2, 16

Below the table, it states: "Agendas close 1 week prior to the meeting date." and "G1 and G2 refer to the General IRBs; CA1 and CA2 refer to the Cancer IRBs".

On the right side, there is an "UPDATES" section. The first update states: "The IRB Office strongly recommends that only Mozilla Firefox be used to access eIRB." Below this is a note: "NOTE: Only the PI can submit submissions (new protocols, amendments, renewals, etc.) using eIRB. To submit, they must be given editing rights under 'Access Permissions' for the specific submission." A second note states: "NOTE: There is 4000 character limit for each question. If you exceed this you will get an error and the response won't be saved. Attach the most recently approved IRB protocol application and reference the corresponding question in your response." At the bottom of the updates, it says: "To learn more about how to use eIRB and view the FAQs, please visit: http://weill.cornell.edu/research/research_integrity/institutional_review_board/eirb.html".



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C. eIRB “Create New Protocol” Link:

The link to the CSEC Form A is available when a user clicks on the “Create New Protocol” link in eIRB. The following pop-up window appears:

The Clinical Study Evaluation Committee (CSEC) now handles the
Create New Protocol functionality.

Please visit <http://jcto.weill.cornell.edu/csecform/> to start this process.

CLOSE



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2. Complete CSEC Submission Part A.

Resize font:

Weill Cornell Medical College NewYork-Presbyterian

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Clinical Study Evaluation Committee (CSEC) Submission - Part A

Welcome to Part A of the CSEC submission process. As noted in the form below, CSEC will use some of the information you provide to create a protocol in eIRB. Currently you cannot save changes to Part A and return later to continue the submission process. However, there is no time limit for completing Part A. Please click the 'Submit' button at the bottom of this page only once. After completing Part A, you will receive an email with instructions for completing Part B and the IRB protocol number for this submission.

For a list of frequently asked questions about the CSEC submission process, please [click here](#). If you have additional questions, please contact GeneralCSEC@med.cornell.edu or CancerCSEC@med.cornell.edu.

Principal Investigator

CSEC will use this information to specify a Principal Investigator for this protocol in eIRB.

First name <small>* must provide value</small>	<input style="width: 90%;" type="text"/>
Last name <small>* must provide value</small>	<input style="width: 90%;" type="text"/>
CWID <small>* must provide value</small>	<input style="width: 90%;" type="text"/> <small>Please provide only a CWID (e.g. abc123 NOT abc123@med.cornell.edu).</small>
CWID (for verification) <small>* must provide value</small>	<input style="width: 90%;" type="text"/> <small>Please provide only a CWID (e.g. abc123 NOT abc123@med.cornell.edu).</small>
Department/Division <small>* must provide value</small>	<input style="width: 90%;" type="text"/>

Administrative Contact

CSEC will use this information to specify an Administrative Contact for this protocol in eIRB.

First name <small>* must provide value</small>	<input style="width: 90%;" type="text"/>
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A. The Principal Investigator and Administrative Contacts

The personnel specified in CSEC Submission Part A will also be assigned those roles in eIRB when the protocol record is created by CSEC.

B. Will the Administrative Contact also be responsible for completing Part B of the CSEC submission process?

Will the Administrative Contact also be responsible for completing Part B of the CSEC submission process? <small>* must provide value</small>		<input type="radio"/> Yes <input checked="" type="radio"/> No	reset
Only the CSEC Contact specified in the following four fields will receive email instructions and system access to complete Part B of this CSEC application.			
First name <small>* must provide value</small>	<input type="text"/>		
Last name <small>* must provide value</small>	<input type="text"/>		
CWID <small>* must provide value</small>	<input type="text"/>	CSEC will email instructions for completing Part B only to this CWID. Please provide only a CWID (e.g. abc123 NOT abc123@med.cornell.edu).	
CWID (for verification) <small>* must provide value</small>	<input type="text"/>	CSEC will email instructions for completing Part B only to this CWID. Please provide only a CWID (e.g. abc123 NOT abc123@med.cornell.edu).	

The IRB Administrative Contact has the option of being designated to complete CSEC Submission Part B by the clicking “Yes” radial button. If a different individual should be designated to complete CSEC Submission Part B, click “No” and enter that individual’s name and CWID in the provided fields.



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3. Upon completion of CSEC Submission Part A, click .

The CSEC will receive an automated email informing of the completion of CSEC Submission Part A. The CSEC will process Part A and send an email to the specified designee provided. This email will include the newly created IRB Protocol Number for study and a link to access CSEC Submission Part B.

Study Information

CSEC will use this information to specify the Title and IRB Review Type for this protocol in eIRB. Additionally, CSEC will complete the Required Summary for this protocol in eIRB.

Title
* must provide value

Expand

IRB Review Type
* must provide value

Initial Protocol (Full Board, Expedited, Exempt)
 Emergency Use
 Central IRB
 Cooperative

reset

What is the risk level of the proposed research study?
* must provide value

Greater than Minimal Risk
 Minimal Risk (Expedited)
 Minimal Risk (Exempt)

reset

Should this study be reviewed by the General or Cancer CSEC?
* must provide value

General
 Cancer

reset

Almost There

By clicking the Submit button below, you acknowledge that the information provided above is accurate. Only the Administrative Contact or CSEC Contact specified above will receive an email with instructions for completing Part B and the IRB protocol number for this submission. Both the Administrative Contact and Principal Investigator specified above will have access to the protocol in eIRB.

Please contact GeneralCSEC@med.cornell.edu or CancerCSEC@med.cornell.edu if you have any questions.

Submit

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