Completing CSEC Submission Part B

Upon completion of CSEC Submission Part A, the CSEC will create a new protocol in eIRB and assign a user specified in Part A to complete CSEC Submission Part B in REDCap. The questions contained in CSEC Submission Part B examine the scientific merit and feasibility of the proposed study.

1. **Receive the email form CSEC**

CSEC sends an email to the user specified in CSEC Submission Part A.

**A. Link to CSEC Submission Part B**

This link leads to REDCap, the system that contains the CSEC Submission data.

**B. IRB Protocol Number**

The IRB protocol number is the unique identifier for the protocol in eIRB. This information will aid in identifying the protocol when completing the IRB submission process.
2. Log into REDCap

REDCap can be accessed by using a valid Weill Cornell Medical College CWID and password. Click the “Log In” button to enter the system. Access to REDCap will be granted by the CSEC staff based on the information in CSEC Submission Part A.

A. When entering REDCap for the first time, the user will have to register

Log in to REDCap with a WCMC CWID and password and click the “Submit” button.
B. On the REDCap home screen, click the “My Projects” tab

![Image of REDCap home screen]

Welcome to REDCap!

REDCap is a secure, web-based application for building and managing online surveys and databases. Using REDCap’s stream-lined process for rapidly developing projects, you may create and design projects using 1) the online method from your web browser using the Online Designer; and/or 2) the offline method by constructing a ‘data dictionary’ template file in Microsoft Excel, which can be later uploaded into REDCap. Both surveys and databases (or a mixture of the two) can be built using these methods.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a brief summary video (4 min). If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the Training Resources page.

Please note that any publication that results from a project utilizing REDCap should cite grant support ("Research Reported in this publication was supported by the National Center For Advancing Transnational Science of the National Institute of Health Under Award Number UL1TR000457").

NOTICE: If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact REDCap Walk-in Clinic
Time: Every Thursday Morning 11am - noon
Location: ICB conference room, Weill Greenberg Building, 13th Floor (1305 York Ave at 70th)

CSEC Submission Process

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C. On the “My Projects” tab, click the “CSEC Submission Process” link

![Image of My Projects table]

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Records</th>
<th>Fields</th>
<th>Instruments</th>
<th>Type</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSEC Submission Process</td>
<td>815</td>
<td>161</td>
<td>2 forms 1 survey</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>TEST3CSEC Submission ProcessTEST3</em></td>
<td>120</td>
<td>167</td>
<td>2 forms 1 survey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*CSEC Submission Process JCTOsandbox</td>
<td>418</td>
<td>159</td>
<td>2 forms 1 survey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Archive 2015.30.03 v2 - CSEC Submission Process</td>
<td>1,681</td>
<td>172</td>
<td>2 forms 1 survey</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
D. On the “CSEC Submission Process” page, click the “CSEC Submission Process – Part B” link

E. Select the appropriate study based on IRB Protocol Number and Principal Investigator. The first time accessing your forms, you will use the “Incomplete Records” pull-down
3. Complete CSEC Submission Form B

CSEC Submission Process

Actions: Download PDF of instrument(s)  Share instrument

CSEC Submission Process - Part B

Editing existing Participant ID 9 (IRB # 1308014208)  PI: R, Scott Short Title: Test 3/30/15_v3

Participant ID 9

Welcome to Part B of the CSEC submission process. You can save this in-progress submission and return later to edit it by clicking the 'Save Record' button at the bottom of this page.

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.

Enrollment (The CSEC does not consider screen failures enrollments)

Is this study a Multi-Institutional Trial?

- Yes
- No

A. Total number of subjects expected to be enrolled Locally (at WCMC/NYPH)

B. Expected Time to Complete LOCAL Enrollment (Years)

Expected Annual Local Enrollment (A/B):

What is the expected duration of study for individual subjects (the anticipated duration subjects will be on study, including follow-up in days/months)

Expected End Date of the study

Study indication/study population

Non Technical Research Plan

Study Design:

Created: August 5, 2013
Last Edited: April 27, 2015
A. The PI will be required to upload a signed score and signature sheet prior to CSEC submission

The blank score and signature sheet can be accessed at: http://weill.cornell.edu/research/pdf/CSEC_Score_SignatureSheet.pdf. This link is available on the form.

B. The user may create a PDF copy of the CSEC Submission Part B so the Principal Investigator can review the CSEC submission before signing the PI score and signature sheet

Click the “All forms/survey with saved data” option from the PDF pull-down to create a PDF version of all the CSEC Submission Forms (at the top of the screen). This will allow the study PI to view and assess the study data prior to CSEC evaluation.
C. Click the “Upload document” link to attach the signed Principal Investigator score and signature sheet

[Image]

D. Click the “Yes” radio button on the “Are you ready to send this submission to CSEC for review?” question

This is the final step prior to submitting the study for CSEC review. Only click “Yes” when all other questions have been completed.

E. Change Form Status to “Complete” and click the “Save and Continue” button

An automated email will be sent to the CSEC informing them that the study is ready for CSEC Review.

NOTE: This instruction assumes that CSEC Submission Part B will be completed in one session. You can also save your work and return later. Save your work by clicking the “Save and Continue” button (do not set Form Status to “Complete” unless the CSEC Submission Part B is complete). You can return to CSEC Submission Part B at anytime by following Steps 1 and 2 above. You will not have to re-register (step 2A).