



Well Cornell Medical College  **NewYork-Presbyterian**

**JOINT CLINICAL TRIALS OFFICE (JCTO)**

# ***Navigating the Clinical Study Evaluation Committee (CSEC)***

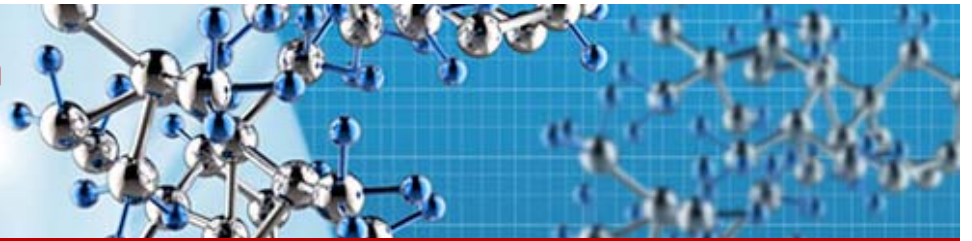
**Scott Tagawa, MD,  
Irene Karpenko, CCRP,  
& Sheetal Ramnath, CCRP**

Presented by the Quality Assurance Unit of the Joint Clinical Trials Office



## Purpose of the CSEC

- To improve the scientific quality of clinical research at NYP/WCMC
- To review a study for *scientific merit* and *feasibility*.
- To provide an environment for input, guidance and mentorship amongst all faculty members who participate in clinical research



## CSEC Meetings Schedule

- **Cancer CSEC A (Chair: Scott T. Tagawa, M.D.)**
  - Meets every 2<sup>nd</sup> and 4<sup>th</sup> Thursday of the month
- **Cancer CSEC B (Chair: Tsiporah B. Shore, M.D.)**
  - Meets every 1<sup>st</sup> and 3<sup>rd</sup> Thursday of the month
- **General CSEC A (Chair: Manish Shah, M.D.)**
  - Meets every 1<sup>st</sup> and 3<sup>rd</sup> Thursday of the month
- **General CSEC B (Chair: Claire Henchcliffe, M.D.)**
  - Meets every 2<sup>nd</sup> and 4<sup>th</sup> Monday of the month
- **General CSEC C (Chair: Timothy Wilkin, M.D.)**
  - Meets every 1<sup>st</sup> and 3<sup>rd</sup> Tuesday of the month



## Cancer and General Committees

- Studies which include a patient population with cancer will be reviewed by the Cancer CSEC (includes retrospective chart reviews or tissue collection studies)
- All other studies are reviewed by General CSEC



## CSEC Agenda

- Agenda for Cancer CSEC meetings is sent on Thursday or Friday the week prior to the meeting.
- Agenda for General CSEC meetings is sent the Mon, Tue, or Thurs the week prior to the meeting.
- The agenda will be forwarded to the PI and administrative contact of the studies being reviewed.



## CSEC Attendance

- While attendance by the PI and/or any member of the study team is not required, it is encouraged.
- The PI and/or any member of their team can participate in the discussion and review process, as well as present any information that may be helpful in the review.



## Studies Requiring CSEC Review

- All human subjects research which will be submitted to the IRB is required to go through CSEC.
- Studies which are classified as “Exempt – Minimal Risk” require a Part A submission. The CSEC administrator will review the Part A submission and create a protocol in eIRB. The CSEC administrator will then inform the PI and administrative contact that the study is exempt from CSEC review.
  - For assistance in determining whether a study would qualify for an Exempt status, please contact the IRB ([irb@med.cornell.edu](mailto:irb@med.cornell.edu))
- For General CSEC studies only: applications which will undergo full board TRAC review do not require CSEC review (part A must still be completed to generate an IRB number and create an IRB application)
- Single Patient/Emergency Use INDs do not require CSEC review, and completion of Part A is not required. PI or study coordinator should send an email to [GeneralCSEC@med.cornell.edu](mailto:GeneralCSEC@med.cornell.edu) or [CancerCSEC@med.cornell.edu](mailto:CancerCSEC@med.cornell.edu), and a CSEC Administrator will create an IRB application and generate IRB #.



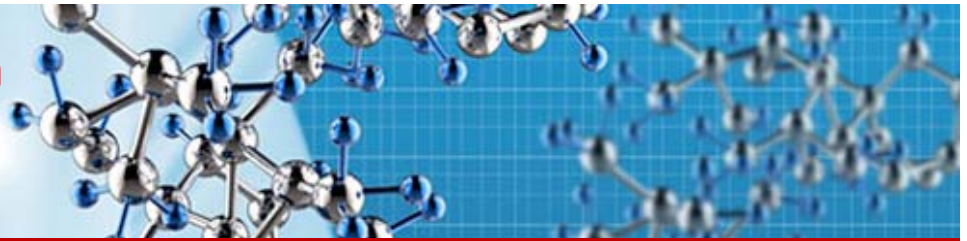
# How to Submit a Study

CSEC submission is a two-part process in REDCap.

## Step 1

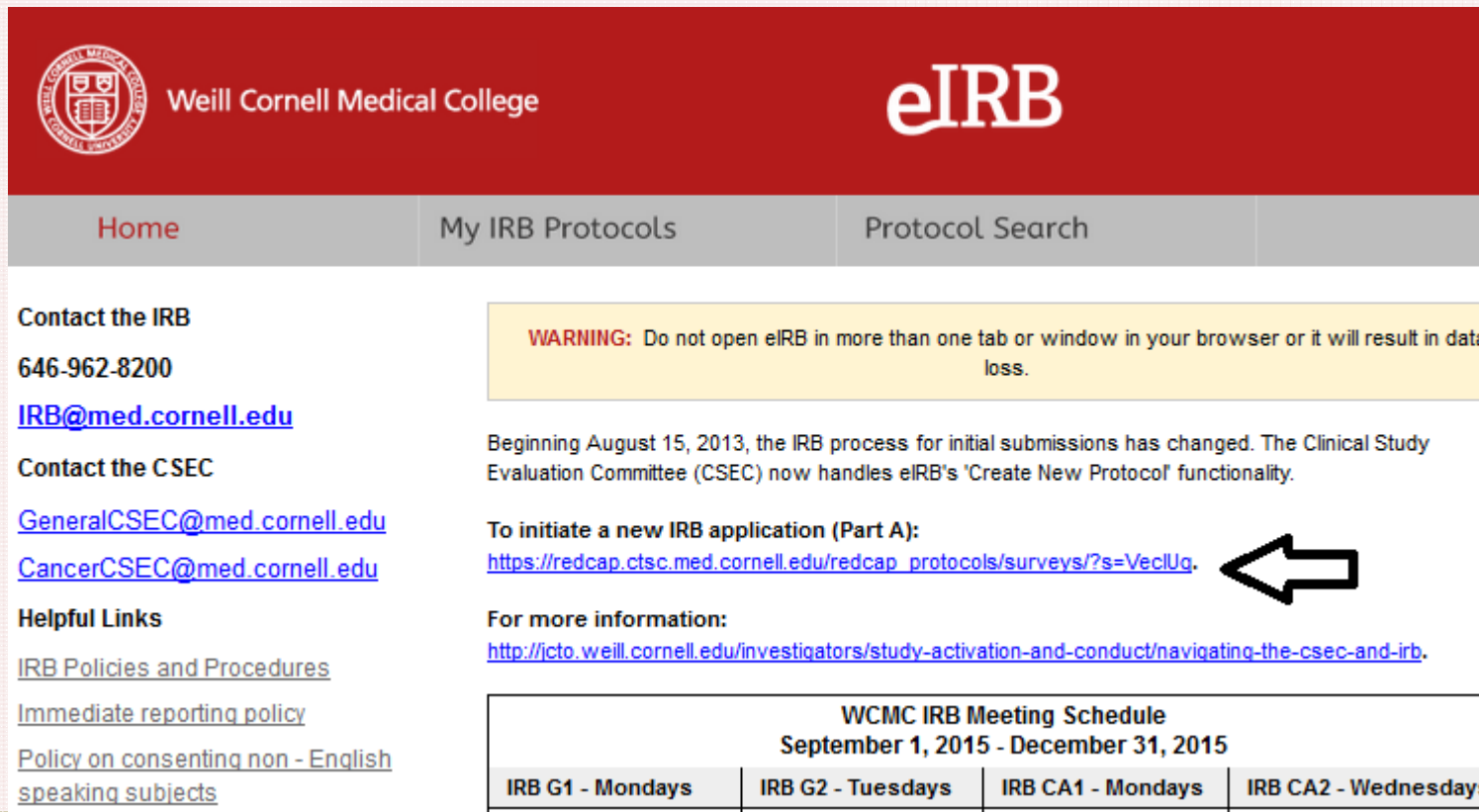
- PI or administrative contact will create a CSEC **Part A** application in REDCap.
  - Clinical Research Categorization (e.g. interventional, observational, etc.), Primary Purpose, Treatment Type, Study/Funding Source, Phase, Risk Level, etc.
- The CSEC administrators are notified that a new Part A has been created.
- The CSEC administrator creates a new application and IRB protocol number for the study in eIRB, and grants the Administrative Contact access to Part B of the CSEC application.





# How to Submit a Study, cont'd

Part A of the CSEC application can be generated through the "Home" page of 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 "eIRB" in large white letters on the right. Below the header is a navigation bar with four tabs: "Home" (highlighted in red), "My IRB Protocols", "Protocol Search", and an empty tab. The main content area is divided into several sections:

- Contact the IRB:** 646-962-8200, [IRB@med.cornell.edu](mailto:IRB@med.cornell.edu)
- Contact the CSEC:** [GeneralCSEC@med.cornell.edu](mailto:GeneralCSEC@med.cornell.edu), [CancerCSEC@med.cornell.edu](mailto:CancerCSEC@med.cornell.edu)
- Helpful Links:** [IRB Policies and Procedures](#), [Immediate reporting policy](#), [Policy on consenting non - English speaking subjects](#)
- WARNING:** Do not open eIRB in more than one tab or window in your browser or it will result in data loss.
- Beginning August 15, 2013, the IRB process for initial submissions has changed. The Clinical Study Evaluation Committee (CSEC) now handles eIRB's 'Create New Protocol' functionality.**
- To initiate a new IRB application (Part A):** [https://redcap.ctsc.med.cornell.edu/redcap\\_protocols/surveys/?s=VeclUg](https://redcap.ctsc.med.cornell.edu/redcap_protocols/surveys/?s=VeclUg). A large black arrow points to this link.
- For more information:** <http://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/navigating-the-csec-and-irb>.
- WCMC IRB Meeting Schedule**  
September 1, 2015 - December 31, 2015

IRB G1 - Mondays	IRB G2 - Tuesdays	IRB CA1 - Mondays	IRB CA2 - Wednesdays
------------------	-------------------	-------------------	----------------------



## How to Submit a Study, cont'd

### Step 2:

- After the CSEC administrator grants the study administrative contact access to **Part B** of the CSEC application, it can begin to be completed
  - Target accrual, Study Design, Statistical Considerations, Study Rationale, Study Objectives, Eligibility Criteria, Budget Details, Pharmacy and Pathology use details, Study Significance, etc
- After the study administrative contact completes and submits the application, the CSEC administrator will be notified and will begin an administrative review.
- Submissions missing required documents will be returned (protocol, informed consent, budget, algorithm, PI score sheet, human tissue form).
- After the administrative review, the submission will be assigned to the agenda for the next CSEC meeting.



## Common Administrative Errors

CSEC submissions are reviewed by CSEC administrators prior to being assigned to a CSEC agenda. The following issues may cause a submission to be returned prior to committee review:

- Questions on the applications are left blank. All questions must be answered, even if the question is not applicable (“Not applicable” must be entered into the field)
- Required documents are not attached
- The application is not internally consistent (e.g. application states that the study is externally funded, but the reimbursement is indicated as “\$0”)
- Missing documentation of collaboration agreement if indicated that other departments, institutions, etc will be collaborating
- Responses exceed the 4000 character limit



## Supporting Documents

All attachments in REDCap must be in PDF format

- Algorithm: when there are competing studies, an algorithm is required to explain the prioritization of studies
- Documentation of Collaboration: required when it is indicated that other department/external investigator or institution will be involved in the study (email correspondence is sufficient).
- Human Tissue Form: required when it is indicated that the research study will be utilizing tissue – does not need to be approved
- Use of Drugs Form: required when it is indicated that the research study will be using pharmacy (does not



## Supporting Documents, cont'd

- Clinical Trials Summary Template: required when it is indicated that the study will recruit subjects prospectively
- Budget: required for all studies with an external funding source.
- Protocol: required for all interventional/therapeutic studies. If the study is investigator-initiated (IIT), a protocol template is available and can be found here:  
<http://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/researchers-toolbox>



# Common Reasons Studies are not Approved at Meetings

- The research plan lacks a statistical plan (e.g. no justification for sample size or sample size not clearly stated, not clearly stated whether the study is descriptive or comparative, etc.)
- The study design is not adequately described.
- The study is not properly designed to assess the stated primary objective
- The importance of the study to the PI is not clearly explained.



# CSEC Review Categories

CSEC review is focused in the following areas:

- **Scientific merit**
  - There is a clearly stated purpose, adequate background information is provided and supports the study plan
- **Feasibility**
  - Comprehensive, realist, and cost-effective budget is outlined, there is a realistic timeframe for completion
- **Study Significance**
  - Importance of the study to the PI, participation in the project is expected to improve the PI's standing in the research community.
- **Informed Consent**
  - When appropriate, the study includes an informed consent, or requests a waiver of informed consent



## CSEC Review Categories, cont'd

The complete CSEC Reviewer checklist is available on the JCTO website:

<http://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/navigating-the-csec-and-irb>





## Types of Outcomes

The PI and Administrative Contact will receive the committee outcome via email within 24-48 hours after the review.

- **APPROVED:** No response required; the CSEC approval letter will be uploaded to eIRB, and the NTRP section will be completed.
- **APPROVED WITH CONDITIONAL CHANGES:** you will be asked to provide a point-by-point response via email to the committee's inquiries, comments or requests and to update Part B of your CSEC application in REDCap if necessary. Your responses will not need to be presented at a meeting and will generally be reviewed within 48 hours.



## Types of Outcomes, cont'd

- **REVISIONS REQUIRED:** you will be required to make changes per the committee's request to Part B of your CSEC application in REDCap, the study protocol and/or informed consent. You will need to provide a point-by-point response to the committee's inquiries, comments or requests by email, as well as provide tracked changes versions of any revised study materials. Once complete, your study will be scheduled for a re-review at the next committee meeting.



# Contacting the CSEC

- Cancer CSEC
  - [CancerCSEC@med.cornell.edu](mailto:CancerCSEC@med.cornell.edu)
- General CSEC
  - [GeneralCSEC@med.cornell.edu](mailto:GeneralCSEC@med.cornell.edu)
- CSEC Information, Guidelines, and Forms:
  - <http://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/navigating-the-csec-and-irb>



# Upcoming Workshops

- **October 19<sup>th</sup> @ 10am:** Constructing an ICF & eIRB Submissions - Approvals, Deferrals & Everything in-between
- **November 18<sup>th</sup> @ 2pm:** The Clinical and Translational Science Center (CTSC) - A Treasury of Resources
- **December 21<sup>st</sup> @ 10am:** Developing an Effective Data and Safety Monitoring Plan and Utilizing the WCMC Data and Safety Monitoring Board