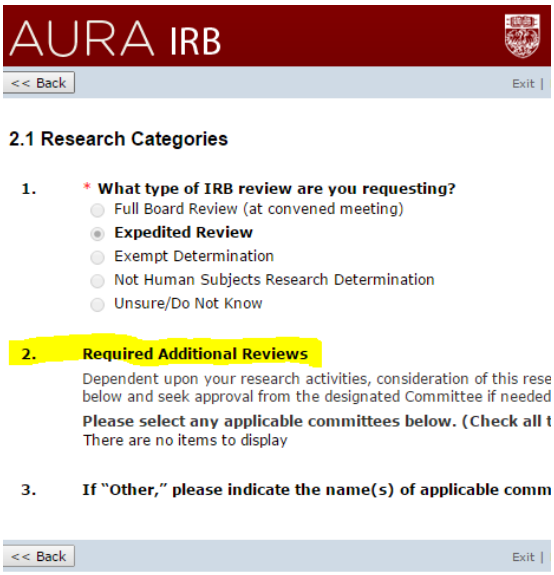
Clinical Resources Center
Application for CRC Services and Review Process

Thank you for your interest in the ITM's Clinical Resources Center. Our goal is to make the process of applying to the CRC as easy and straightforward as possible. Please follow the instructions below to make your application to the CRC, and if you have any questions about the application or review process, contact Sonya Redmond-Head at srhead@bsd.uchicago.edu or (773) 834-3810.

To complete a CRC application:

1. When submitting your IRB application in AURA, list the CRC as a site under "Required Additional Reviews (question 2.1.2 of the AURA application form). If you already have an existing IRB application in AURA, you will need to submit a study amendment to change the answer to this question.



2. Add Gerald Stacy as a guest e-mail for each of their protocols
3. Complete the budget page of the CRSO Workbook, listing the specific services requested from the CRC, for each visit.
4. Complete the DSMP form.
5. Send an e-mail to ClinicalResearchCenter@uchicago.edu and include in the e-mail:
    a. The AURA-IRB number
    b. The protocol title
    c. Attach the CRSO budget workbook and DSMP form to the e-mail.
    d. The name and information of the person we should contact with questions or concerns, if other than the person sending the e-mail.

Pre-Review

After the ITM receives your application, we may contact you if we have any questions about your application or need clarification about the CRC resources that you need.

CRC Review

The level of review that your application will receive is determined by the CRC Director and the chair of the CRC review committee:

a. All applications will receive a CRC feasibility and safety review
b. Applications that have already received a substantive scientific review, where it is highly unlikely that changes/improvements to the study can be made, may not receive a CRC scientific review. Examples include:
    i. Industry-initiated multi national or multicenter studies
    ii. Multi-center clinical trials written by a protocol committee (e.g., ACTG, ECOG, etc.)
c. Applications that have already received a substantive scientific review, but where it is possible for changes/improvements to be made, may receive a more abbreviated scientific review from a single member of the review committee
d. Applications that have not had a scientific review before will receive a full scientific review by two reviewers. Examples of these types of applications include:
    i. Pilot studies
    ii. Single-center investigator-initiated studies
    iii. Studies without external funding
    iv. KL2/K12 Scholar applications
e. **PLEASE NOTE:** The CRC reserves the right to review ANY application, for any reason. If questions are raised by any of the other reviewers, they may recommend that an application receive a full scientific review as well.

Post Review

After your application is reviewed, the ITM will e-mail the study PI and primary contact for the study:

1. A letter with either a protocol approval, reviewer questions/concerns, requests for protocol modifications, or an application denial.
2. A CRC budget for the study, based on the provided orders and the CRC price list

The study PI will need to respond back to the ITM, based on the outcome of the review:

1. Please respond to any questions/concerns/requests by e-mailing a reply to ClinicalResearchCenter@uchicago.edu
2. If the application is approved, please e-mail ClinicalResearchCenter@uchicago.edu with an acceptance/approval of the study budget and provide financial contact information for invoicing
3. Once the application is approved, you will be contacted by the CRC staff within two weeks to schedule a protocol in-service.