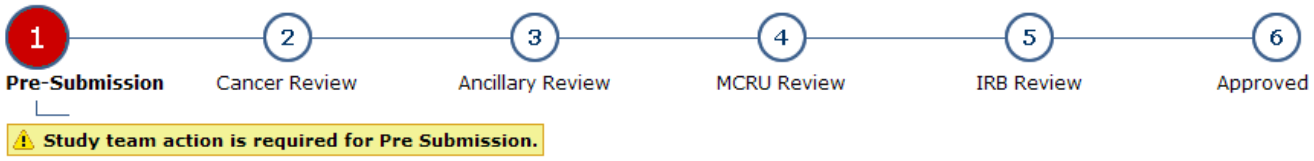
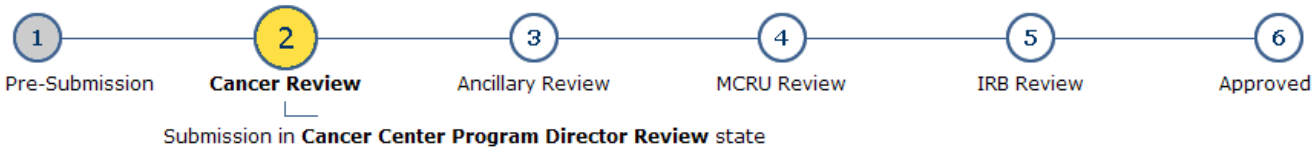
Ceding IRBMED Review Process Changes, July 2013

This document will highlight just the changes made to the IRBMED Ceding IRB application and approval process. If not otherwise noted here, assume the process is unchanged. This document is divided into sections based on the status meter in the eResearch system.



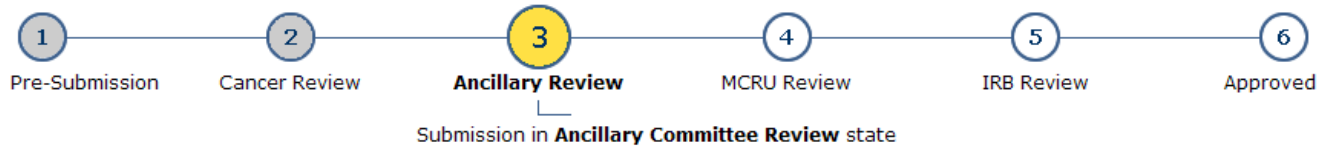
Changes applying to **Pre-Submission** while the study is in the hands of the study team:

- For applications that have IRBMED selected in question 1.9 and have application type "Requesting Review by a **Non-UM IRB"** selected in question 1-1.1, the smartform path has been changed. See the *IRBMED Ceding IRB Application Smartform Changes* document for details.
- On Ceding IRB applications with IRBMED selected in question 1.9 and require PRC review because question 1-2.5 has been answered "Yes", the study team will submit the application after all sections are filled out. Not after filling out sections 1 through 3-2.

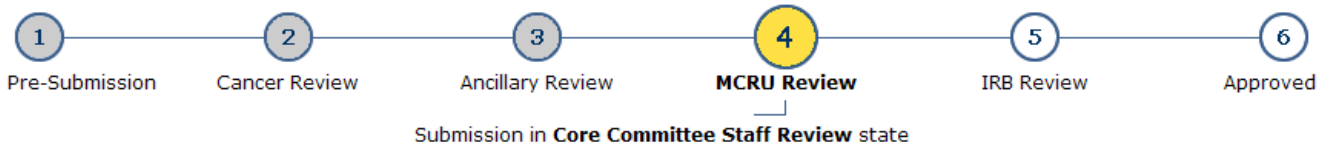


Changes applying to studies in **Cancer Center Program Director Review** and **PRC Review**:

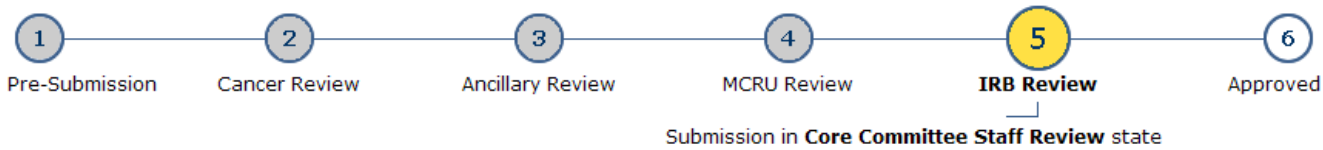
- Ceding IRB applications that require CCPD and PRC review are completely filled out before being submitted for review.
- After PRC approval is given, the study does not automatically return to the study team. The next required committee (Ancillary, MCRU, or IRB) receives the application for review.



There are no changes that apply directly to the **Ancillary Committee** review process. Application sections requiring Ancillary Committee approval in standard applications are now also filled out and reviewed for ceding IRB applications with IRBMED selected in question 1.9.

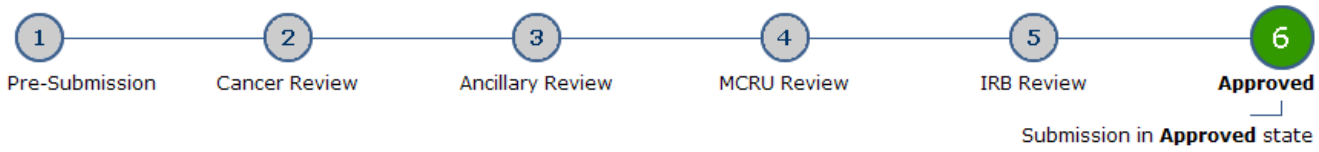


There are no changes that apply directly to the **MCRU** review process. Application sections requiring MCRU approval in standard applications are now also filled out and reviewed for ceding IRB applications with IRBMED selected in question 1.9 and MCRU selected in question 1-2.4.



Changes applying to studies in **IRBMED** review:

- Reviewer checklists are populated with new "Requesting Review by a Non-UM IRB" sections.
- Full Committee and Expedited Reviewer checklists will now have two recommendations available
    - Acknowledged for Ceding Oversight to a Non-UM IRB
    - Action Deferred Pending Core Committee
- Full Committee and Expedited reviewers will answer a revised attestation statement when the "Acknowledged for Ceding Oversight to a Non-UM IRB" recommendation is selected. *"I certify that the research meets applicable University of Michigan criteria for ceding to an external IRB."*



Changes applying to studies that have been **Approved**:

- Approval period will need to be manually overwritten by IRBMED staff using the "Edit Approval Period" activity with the approval period from outside IRB.
- No retroactive data conversion will happen on previously approved ceding IRBMED applications. When amended, the study team will be required to fill out the new required sections.
- ***Amendments*** to approved ceding IRBMED applications will use this new review process and will be reviewed by the appropriate committees (based on answered given in the required sections).
- Full Committee and Expedited reviewer checklists for ***Scheduled Continuing Reviews*** will have the new recommendation set for IRBMED ceding IRB applications.
    - Acknowledged for Ceding Oversight to a Non-UM IRB
    - Action Deferred Pending Core Committee