UNIVERSITY OF MICHIGAN CLINICAL RESEARCH

CALENDAR REVIEW ANALYSIS OFFICE

Process for Ancillary Committee Review

Study Team Submits IRB Application

- Yes
  - CRAO Review Required
    - Study team uploads the Draft Billing Calendar into Section 14-1.3
    - CRAO retrieves the core documents for review from eRRM and eRPM
    - CRAO conducts the Billing Calendar Review and Medicare Coverage Analysis (MCA)
    - CRAO produces proposed FINAL version of the Billing Calendar
    - The FINAL Billing Calendar is uploaded by PI in Section 14-1.3
    - CRAO issues Ancillary Approval

- No
  - Study moves forward in review process

CRAO receives the study for review at the same time as the other Ancillary Committees

Study moves forward in review process
1. Study Team submits the IRB application and Ancillary Committees are notified if their review is required.

2. The CRAO is alerted at the same time other Ancillary Committees are notified (for example, IDS and CRAO receive notification at the same time). The reviews are conducted concurrently.

3. The alert that CRAO receives is an eResearch generated e-mail in Outlook. The study will also appear in the CRAO “Inbox” within eResearch. This is the CRAO’s queue of work/studies to be reviewed.

4. Whether or not CRAO is alerted for review depends on the answers in Section 14-1.1.
   a. If Section 14-1.1 was answered with one of the following choices available then a DRAFT Billing Calendar will need to be uploaded into Section 14-1.3.
      • A Health Plan
      • External Sponsor
      • Internal Award
      • Subject or Legal Guardian
      • RMRN account
   b. If 14-1.1 was answered with “None of the above” the Study Team has “exempted” the study from Billing Calendar review and CRAO will NOT be alerted.
   c. A study is exempt from Billing Calendar review if none of the choices in 14-1.1 applies, but instead one or more of the following choices from 14-1.2 describe the study. Note that 14-1.2 must be filled out when “None of the above” is chosen.
      • Retrospective or Prospective Chart Review
      • Specimens Used in Research
      • Questionnaire/Survey
      • Research-Only Space Used
      • Other

5. Once the CRAO receives the study and has all of the core documents (Protocol, Informed Consent, Billing Calendar, Budget(s) and Contracts, as applicable), the review can begin.
   a. All documents are acceptable in DRAFT form.
6. If a Billing Calendar is not uploaded in Section 14-1.3 at the time the application is submitted, the CRAO’s first step is to send it back to the study team via “Changes Requested by Ancillary Committee”. When CRAO chooses this option, an auto generated e-mail will be sent in Outlook to ALL persons listed as Study Team members in eResearch. A full review cannot be completed until the Billing Calendar has been uploaded for CRAO review.

7. Once the Billing Calendar is uploaded in Section 14-1.3, the application will need to be submitted back to the CRAO. The CRAO will then be notified (within eResearch and by an auto-generated email in Outlook) and can begin the review. Further questions and clarifications will be sent via “Posted Correspondence” or “Changes Requested by Ancillary Committee” in eResearch.

8. Once the CRAO review is complete, and the Billing Calendar is believed to be FINAL, CRAO will ask for approval from the PI. If the application is with CRAO, the calendar will be sent via “Changes Requested by Ancillary Committee”. If the application is with the study team, the calendar will be sent via “Posted Correspondence”.

9. CRAO will include this comment: The CRAO review is complete and we believe this to be the final version of the billing calendar. If the PI agrees, please upload the attached in Section 14-1.3 as your FINAL calendar. This calendar, with an added header and footer, will serve as the PI signature on the billing calendar.
   a. A written signature is not needed.

10. The steps taken to obtain the PI’s approval of the FINAL Billing Calendar, is an INTERNAL PROCESS. The Study Team should decide how to best achieve this and upload the approved FINAL version.

11. If the PI does not agree with the proposed FINAL version, then the Study Team should revise the calendar within MBECT and then alert the CRAO Analyst. When the revisions are complete “Post Correspondence” to the Analyst with the Billing Calendar attached so they can re-finalize.
   a. Do not upload the calendar to Section 14-1.3 as the FINAL version until there is agreement.

12. When the FINAL version of the Billing Calendar is uploaded in 14-1.3 and the Study Team has “Submit Requested Changes to Ancillary Committee”, CRAO will be notified within eResearch.
and by an auto-generated email in Outlook. CRAO can then complete the process and “Issue Ancillary Committee Approval”. This will move the study forward in the review process. The approval letter will be attached in eResearch.

a. Please note that if this is a device study then CRAO will “Issue Ancillary Committee Conditional Approval” if Medicare requirements are required. Please see the CRAO Device Study Procedure Flow as a reference for these studies.