VCU IRB Review Process

Purpose

The purpose of this document is to illustrate the VCU IRB review process, from the moment the PI submits a new study in RAM-IRB, all the way through to IRB decisions. This information is also communicated in a visual format using a flowchart. This document provides an alternative means of communicating the information.

Initial procedures for all new studies submitted to the IRB

This section covers the procedures for all new studies submitted to the IRB. Later in this document, procedures will be described based on the determined review level of the study (exempt/expedited or full board).

Step 1: PI submits a new study in RAMS-IRB

Using the electronic IRB management system, RAMS-IRB, the PI submits a new study to the IRB.

Step 2: Department review (expedited and full board submissions only)

Before being routed to the IRB, the new study is sent to a department approver, who reviews the study in a limited capacity, looking specifically at the following:

- PI eligibility
- Adequacy of resources to conduct the research (including financial, personnel, and equipment/space)
- Scientific merit

This step is only required for expedited and full board submissions. Studies submitted as exempt will skip this step; however, PIs are instructed to select a department approver upon submitting an exempt study, in the event that the study is upgraded to expedited or full board review, at which point, it will be routed to that department approver for review.

At this time, department approvers may send the study back to the PI with change requests. The PI addresses these requests and then resubmits the study to the department approver, who either sends it back to the PI for more changes, or issues department approval. Once department approval is granted, the study moves to the next step.

Step 3: Scientific review committee (Only full board clinical trials that have not already received scientific review by sponsor, funder, or Massey PRMC)

Studies are next forwarded to the scientific review committee (SRC), only if they meet certain criteria. Studies are sent to SRC review only if they meet the following criteria:

- Are a full board submission
- Are a clinical trial
- Have not already received scientific review by a sponsor, funder, or the Massey PRMC

If studies do not meet these criteria, they skip this step and go directly to Step 4.

If SRC review is required, the SRC may send the study back to the PI with change requests. The PI addresses these requests and then resubmits the study to the SRC. The SRC reviews changes, and may either send the study back to the PI for more changes, or will issue SRC approval. Once SRC approval is granted, the study moves to the next step.

Step 4: Study is received by the VCU HRPP for completeness check and review type determination

After department review and SRC review, if applicable, all studies are then routed to the IRB for an initial screening by IRB staff. The purpose of this screening is to check the submission for completeness (i.e.: missing documents or information, etc.) and to make a final determination of review level. While investigators make an initial review level request of exempt, expedited, or full board, the IRB makes the final determination of what review level is appropriate.

What happens after this step is determined by the review level. Procedures for exempt and expedited studies are covered first, followed by procedures for full board studies.

Exempt/expedited procedures

This section of the document describes the review process for exempt/expedited studies, which both receive review by a single IRB member (usually an “in-house” review conducted by IRB staff who are also IRB members).

Step 1: Pre-screening by IRB Analyst for complete submission

In this step, an IRB Analyst (who is an IRB staff member) will conduct an administrative review of the submission to check for completeness. During this step, the IRB Analyst may return the study to the PI with change requests. Once the PI provides additional information/makes requested changes, the IRB Analyst reviews the changes and may either send the study back with more change requests, or will move the study to the next step.

Step 2: Review by a single IRB member (usually an in-house IRB Analyst)

Once a submission is considered complete, the actual IRB review begins. Usually, the reviewer assigned to an exempt/expedited submission is an IRB Analyst who is also an IRB member. At this point, the Turn Around Time (TAT) calculation begins.

TAT is defined by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) as the time between the start date of IRB review and the end date of IRB review. The start date is considered to be the date the study is first assigned to the reviewer or committee, and the end date is considered to be the official IRB approval date. TAT excludes days in pre-review/pre-screening and days with ancillary committees prior to receipt by the IRB.

During review, there are several different decisions that can be made by the IRB reviewer. Only the four most common decisions are covered below.

Review decision 1: IRB Reviewer requests additional information

If the study does not meet the criteria for exemption or the criteria for expedited approval as it is written, the IRB reviewer will send the submission back to the PI to gather additional information or to request changes in order to bring the study in line with the criteria for exemption or the criteria for expedited approval.

Once the PI submits changes/additional information, the reviewer may either send the study back for another round of changes, or may issue one of the other possible review decisions.

Review decision 2: IRB Reviewer determines study meets exemption criteria

If the study meets the criteria for exemption, the IRB reviewer will approve the study as exempt. At this time, the PI will receive an electronic approval letter via email.

Review decision 3: IRB Reviewer determines study meets expedited review criteria

If the study meets the criteria for approval for an expedited study, the IRB reviewer will approve the study as expedited. At this time, the PI will receive an electronic approval letter via email.

Review Decision 4: Study does not qualify for exempt or expedited review

If the study does not actually qualify for exempt or expedited review (i.e.: the study is greater than minimal risk, and/or the study does not fall into the exempt/expedited categories), the single IRB reviewer will refer the study to the full board for review. The study will transition to full board review, and the procedures under the Full Board Procedures heading will be followed.

Full board procedures

This section of the document describes the review process for full board studies, which receive review from the convened IRB committee.

Step 1: Pre-review by IRB Administrator for complete submission

In this step, an IRB Administrator (who is an IRB staff member) will conduct an administrative review of the submission to check for completeness. During this step, the IRB Administrator may return the study to the PI with change requests. Once the PI provides additional information/makes requested changes, the IRB Administrator reviews the changes and may either send the study back with more change requests, or will move the study to the next step.

Step 2: Full board review by the convened committee

Once a submission is considered complete, the actual IRB review begins. Usually, a full board study is assigned two lead reviewers, who conduct thorough reviews of the study, and then present findings at the full board meeting for discussion. At this point, the Turn Around Time (TAT) calculation begins.

TAT is defined by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) as the time between the start date of IRB review and the end date of IRB review. The start date is considered to be the date the study is first assigned to the reviewer or committee, and the end date is considered to be the official IRB approval date. TAT excludes days in pre-review/pre-screening and days with ancillary committees prior to receipt by the IRB.

During review, there are several different decisions that can be made by the IRB committee. Only the four most common decisions are covered below.

Review decision 1: Study does not require full board review

If the committee determines that the study does not require full board review (i.e.: because the study is minimal risk), the study is referred to single IRB member review. At this point, the procedures under the Exempt/Expedited Procedures heading above are followed.

Review decision 2: IRB determines study meets review criteria

If the study meets the criteria for approval for a full board study, the IRB committee will approve the study. At this time, the PI will receive an electronic approval letter via email.

Review decision 3: Conditional approval

This decision is made when the IRB committee determines that a study will meet the criteria for approval, provided specific, directed changes are made by the PI. At this point, the study will be sent back to the PI with specific change requests.

Once the study is resubmitted with the changes made, an IRB reviewer will review the changes to ensure they were made accurately and completely, with no additional changes beyond what was requested. If the changes were made to the letter, then the study will be approved, and the PI will receive an electronic approval letter via email.

If the changes were not made satisfactorily, or additional changes were made beyond what was requested, the study will be assigned to the next available IRB meeting where the changes can be reviewed by the convened IRB committee (return to step 2 in this section).

Review decision 4: Tabled

If the IRB determines that substantive changes are needed in order for the study to meet the criteria for approval, the study will be sent back to the PI with requests for changes and/or requests for more information. The PI will address those requests, and then return the study to the IRB. The study will be assigned to the next available meeting, and changes will be reviewed by the convened IRB committee (return to step 2 in this section).