What Happens After an New Application Is Submitted to the Health Sciences or Minimal Risk IRB: IRB Administrative Review and IRB Pre-Review

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All applications that will be considered by the convened IRB undergo an administrative review and pre-review process by IRB staff. After an initial review application is received by the HS-IRBs Office, it undergoes administrative review. This involves a review of funding information and other administrative portions (e.g., ensuring study team members have completed human subjects research training) of the IRB application. Administrative review is typically conducted within 1 day of receipt of an application. If the HS-IRBs Office identifies any issues during administrative review, these are sent to the study team as reviewer notes in ARROW and must be addressed before an application is assigned for IRB pre-review.

What is IRB pre-review?

The HS-IRBs use a pre-review process for all IRB applications. This means that applications are reviewed in detail by an IRB staff member – typically an IRB staff reviewer – before being reviewed by the full IRB. Exemption and non-exempt medical records applications (NEMR) also undergo pre-review before exemptions are granted or NEMR applications are approved by an IRB member.

If an IRB staff reviewer identifies any issues with an application during pre-review, these are sent to the study team as reviewer notes in ARROW. To address issues raised during pre-review, a study team may need to provide additional information as well as revise the application and supporting materials.

What is the purpose of IRB pre-review?

IRB pre-review is a service the HS-IRBs office provides to study teams. The goals of pre-review are to:

- Provide study teams with expert assistance with understanding the regulatory and other requirements for conducting human subjects research
- Guide study teams in revising IRB application and supporting documents (e.g., protocol, consent forms) to ensure these materials meet regulatory and other IRB requirements
- For studies requiring review by the full IRB, increase the number of applications that receive approval (rather than modifications or a deferral) at the IRB meeting
With the implementation of this comprehensive pre-review process, the number of studies deferred by the IRB was significantly reduced and the number approved by the IRB as submitted significantly increased.

What if I have questions about the pre-review comments I have received?

During the review process, study teams may receive questions or requests from IRB staff that are unclear to them or with which they may disagree. The review process is intended to work as a dialog between the IRB and study teams, involving a collaborative effort to arrive at an agreement regarding how to ensure the protection of human subjects participating in a research study.

- If an IRB request is unclear or the study team is uncertain why the request is being made, contact the staff reviewer assigned to that study. Staff reviewers can explain the rationale behind the request, which can be helpful to study teams as they craft their responses.

- If a study team disagrees with a request, please contact the staff reviewer assigned to the study to discuss the proposed response. As the liaisons between the IRB and study teams, the staff reviewer can then provide guidance as to whether the response would address the IRB’s concerns as well as any additional information that can be provided as part of the request for reconsideration. There are many cases where the staff reviewer or IRB have dropped or modified a request because of clarifications provided by the study team.

If you have questions about the pre-review comments you have received, please contact the IRB staff reviewer who conducted the pre-review of your application for assistance. Please see HS IRBs Office: Contact Information for specific contact information.

When are applications scheduled for an IRB meeting?

The HS and MR IRBs do not use a deadline-based scheduling system. Rather, applications requiring review by the full IRB are scheduled for a meeting only after pre-review is complete or when any outstanding issues with an application cannot be resolved during pre-review. NOTE: Studies that fall under the purview of the Madison VA Hospital must receive endorsement from the VA Research and Development Committee before being scheduled for an IRB meeting.

How long does the IRB pre-review process take?

How long the pre-review process takes depends on several factors, including the quality of the application and the responsiveness of study teams to the issues raised during pre-review. Some applications not requiring review by the full IRB can complete pre-review and receive approval within a couple weeks of the application being received by
the HS-IRBs. The pre-review and approval process is frequently longer for applications reviewed by the full IRB and/or projects which are especially complex or raise certain regulatory concerns.

**What can I do to make the IRB review process go smoothly?**

The best way to ensure the IRB review process goes as smoothly as possible is to submit a very well prepared IRB application and to respond quickly and thoroughly to issues raised during the pre-review process. The HS-IRBs Office offers a variety of resources to assist investigators including:

- Comprehensive guidance for study teams on the [HS-IRBs website](#), including instructions for completing the IRB application as well as FAQs on using ARROW
- Complete the [HS IRBs Presentation Request Form](#) for study teams to obtain expert assistance and advice regarding the IRB submission and review process
- Expert IRB point of contact available by phone every business day to answer general IRB questions (263-2362)

**See Also:**

- [What Happens After an Application Is Submitted to the Health Sciences or Minimal Risk IRB: Scientific Review](#)
- [Working with Reviewer Notes](#)