PittPRO | Pitt Protocol Review Online

Scientific Review Responsibilities and Approval Process

Introduction

This guide covers information and tasks relevant to individuals who serve as a Scientific Reviewer.

Scientific Review

All proposed human subject research is required to undergo scientific review prior to submission for IRB review, with the exception of (i) research qualifying for "exempt" review status; and (ii) research reviewed by a peer scientific review committee as a condition of research funding (e.g., NIH/NSF sponsored research). Detailed information is available in the Human Research Protection Office Policies and Procedures, Chapter 8, Required Ancillary Reviews.

Each department, school, or center has designated individuals responsible for oversight of the scientific review process. These scientific approvers can conduct the review or assign specific individuals to review for scientific merit. Only the designated scientific approvers can approve the application or request clarifications.

Read Only Access for Reviewers

The designated scientific approver may assign another person with expertise in the field of study to perform the scientific review. This might occur if 1) the listed scientific approver is also a part of the study team or 2) the listed scientific approver does not have appropriate expertise in the area being studied. The assigned reviewer will provide comments to the designated scientific approver who can request clarifications or approve the study for scientific merit. Once the study is approved for scientific merit, read only access is removed. If an individual is given read only access due to a conflict of the scientific approver, a note should be included when the scientific approver hits the approval button indicating s/he did not participate in the review.

Responsibilities of Scientific Reviewer

Scientific reviewers should consider the following when determining whether to move the study forward to the IRB:

- **Sound Scientific Basis and Rationale**
  - The protocol should be scientifically sound and based on well-established scientific principles.
  - There should be convincing clinical and/or preclinical evidence that the study will have valuable results.
  - Preclinical studies should have demonstrated promising results regarding safety and potential efficacy.

- **Appropriateness of the Proposed Study Design**
  - The primary and secondary objectives should be scientifically sound.
  - The study should be designed to meet the objectives.
  - The study should distinguish between standard and/or routine care and research.
  - The subject populations and associated criteria for inclusion/exclusion should be well defined.
  - Sample size should be appropriate.
  - Statistical Design should be appropriate.
  - Endpoints should be clearly defined.

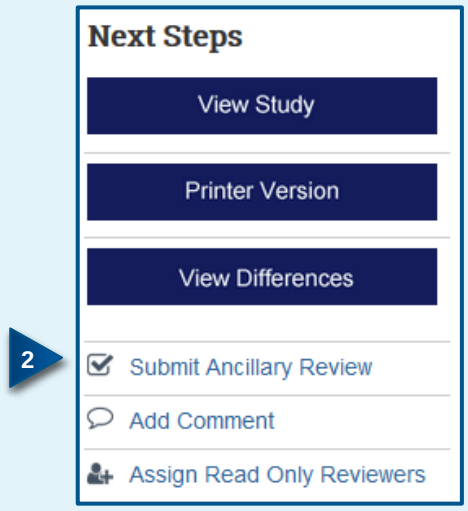
- **Competency of Personnel and Adequacy of Proposed Resources**
  - The principal investigator has the appropriate expertise and experience to conduct the study.
  - The study team brings sufficient expertise to the project.
  - There are sufficient resources (appropriate personnel, equipment, facilities) for the successful and safe conduct of the study.

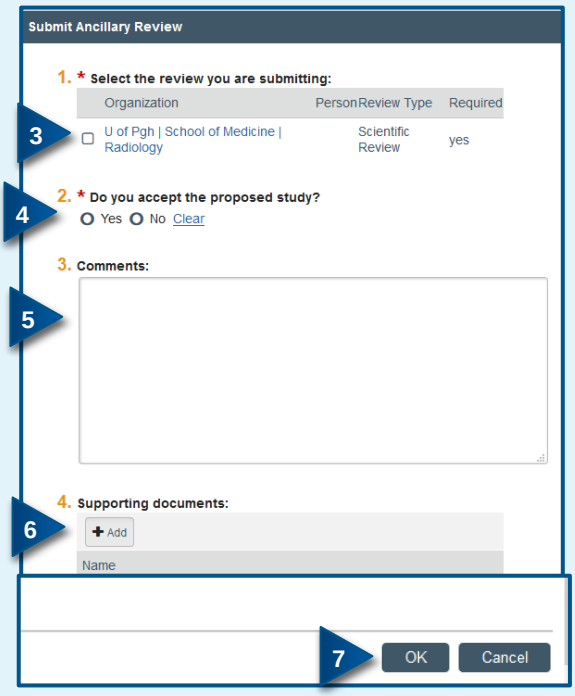
Scientific Review Process

The PI will designate the scientific review entity on the Study Design page of the application. Department, schools, and centers have previously designated individuals who will serve as the scientific approvers. Since not all scientific approvers will conduct the review for scientific merit, the approver can provide Read Only Access to an individual with appropriate expertise to conduct the review. This individual will submit their approval or comments to be addressed to the designated scientific approver who will either approve for scientific merit or request clarifications.

If the scientific approver does not participate in the scientific review, indicate in the Comment section:

- Who conducted the review?
- Reviewer's decision
- State that you did not participate in the review process.
- Upload documentation from the reviewer





Submit Scientific Review Decision

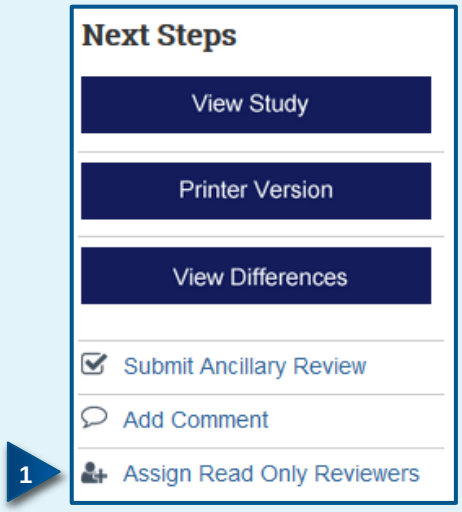
1. Email notification is sent to the designated Scientific Approver. They can either review or assign Read Only Access.
2. When ready to approve for scientific merit or to request changes, click on **Submit Ancillary Review**
3. **Q1** – click on the checkbox
4. **Q2** – Click **Yes** if ready to approve

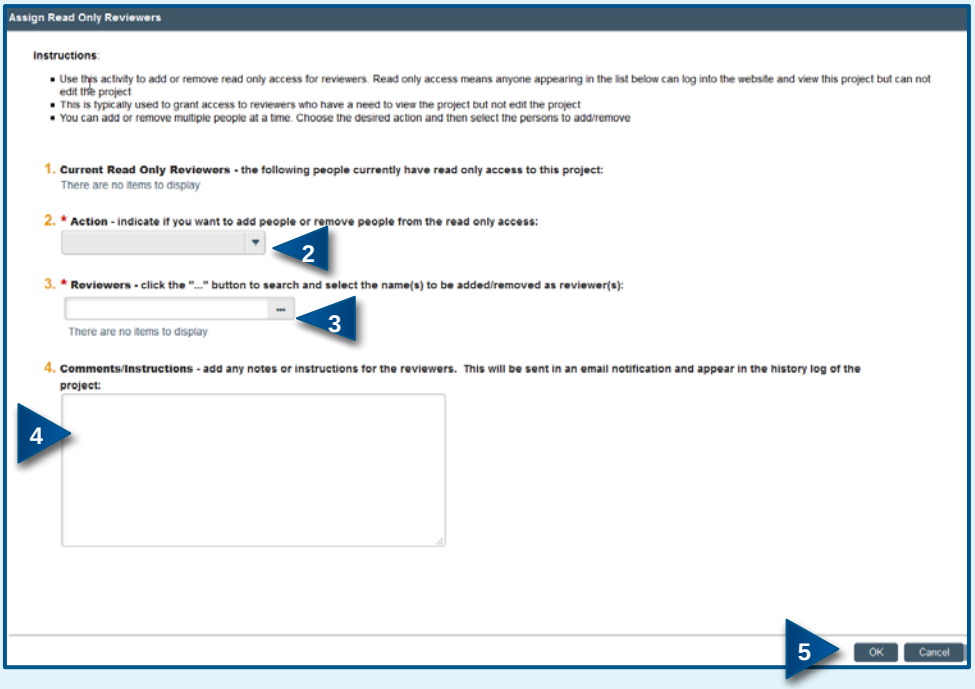
   Q2 – click **No** if changes are requested.
5. Enter your Comments
6. Upload any documents if applicable.
7. Click **OK**.

The reviewer will receive an email about the review and the study will also appear in the reviewer's IRB Inbox.

Assign Read Only Access for Scientific Reviewer

You can provide Read Only Access to an individual with appropriate expertise to conduct the scientific review. This individual will submit their approval or comments to be addressed to the designated scientific approver who will either approve for scientific merit or request clarifications.





Assign Read Only Access

1. Click **Assign Read Only Reviewers**
2. **Q2** – Click the down arrow and select **Add**
3. **Q3** – Click ... to select the reviewer. Use the **Advanced** search to enter the first and last name
4. **Q4** – Provide instructions for the reviewer
   - Request review for scientific merit
   - Name and email of contact person to send the comments.
5. Click **OK**

The details will appear on the IRB Assignment Details tab.