

Research Review Committee (RRC) Department of Psychiatry Policy on Review of Grant Applications

A. Goals of Research Review Committee Review

- To ensure that research applications prepared by Department of Psychiatry investigators are highly competitive and meet the highest scientific and ethical standards.
- To promote a departmental culture of collaboration and shared mission in research endeavors.
- In the case of pilot projects, to ensure that all research conducted by Department of Psychiatry investigators has received some peer review.

B. Policy Statement

The major function of the Research Review Committee (RRC) is to provide timely, high-quality peer review of research proposals prepared by investigators in the Department of Psychiatry. The RRC evaluates the scientific and technical merits of all federal and foundation research proposals prior to submission to external funding agencies. RRC review is conducted for applications submitted by Department faculty, fellows, students, and staff. During its review, the RRC also provides a preliminary evaluation of potential risks and benefits to human participants and of the welfare of animal subjects. RRC reviewers provide written evaluation comments for submitted applications, and investigators provide a written response to RRC reviews.

With this process, the Department of Psychiatry strives to enhance the scientific quality of research proposals and to promote collaboration and peer review among faculty members. The goals of the RRC are facilitated by investigators submitting proposals for review well in advance of internal and external deadlines, and by working proactively with the RRC throughout the review process, especially when questions or special circumstances arise.

C. Research Review Committee Personnel

RRC Co-Directors: Daniel J. Buysse, MD: buyssej@upmc.edu; Judy Cameron, PhD: jcameron@pitt.edu

RRC Co-Chairs: David Brent, MD, MPH: brentda@upmc.edu; William Klunk, MD, PhD: klunkwe@upmc.edu; Paul Pilkonis, PhD: pilkonspa@upmc.edu

Administrative Coordinators: Melissa (Missy) DeVito: mszycoml@upmc.edu; Nathan Rockcastle: rockcasn@pitt.edu

RRC e-mail service account: psychiatryrrc@upmc.edu

D. Requirements for RRC Review

1. Which applications need to be submitted to the RRC?

- All applications to NIH, PCORI, AHRQ, and other federal agencies on which the PI and Multiple PIs are from the Department of Psychiatry.
- All applications to NARSAD/BBRF, Klingenstein, and other foundations on which the PI is from the Department of Psychiatry.
- Federal and Foundation applications on which a Co-Investigator from the Department of Psychiatry provides >10% effort (regardless of whether salary support is requested on the application). These applications may be eligible for Expedited (Type B) Review, depending on the particular circumstances, as detailed below:
 - Applications reviewed in other Schools/Departments at the University of Pittsburgh using a process similar to that of the RRC. These applications may be eligible for Expedited (Type B) Review, depending on the particular circumstances, as detailed below.
- IRB and IACUC protocols for unfunded studies. These applications are eligible for Expedited (Type B) Review, if the protocol used has been previously reviewed.

2. Which applications DO NOT need to be submitted to the RRC?

- Applications for Quality Improvement projects funded by UPMC or other agencies.
- Federal and Foundation applications on which a Co-Investigator from the Department of Psychiatry receives $\leq 10\%$ effort (regardless of whether salary support is requested on the application).

3. Which applications MAY be submitted to the RRC at the Investigator's discretion?

- Federal or foundation applications on which a Co-Investigator from the Department of Psychiatry provides $\leq 10\%$ effort (regardless of whether salary support is requested on the application). These applications typically have a PI from another Department, School or Institution.

E. Research Review Committee Process

Two types of review are used by the RRC, Standard (Type A) Review and Expedited (Type B) Review.

1. Standard (Type A) Review

a. What is Standard (Type A) Review?

- Standard Review involves written reviews of an application from 3 faculty members.
- Standard (Type A) Review is the default review type, and is appropriate for the majority of submissions.

b. Which applications require Type A Review?

- All new (AO) and revised (A1) applications to NIH, PCORI, AHRQ, and other federal agencies on which the PI or Multiple PIs are from the Department of Psychiatry.
- All applications to foundations on which the PI is from the Department of Psychiatry.
- Federal and foundation applications on which a Co-Investigator from the Department of Psychiatry provides >10% effort (regardless of whether salary support is requested on the application). Note: Some of these applications may qualify for Type B review, as described below.

c. Materials to be submitted. If you have any questions about what should be submitted, please contact the RRC Coordinators at psychiatryrrc@upmc.edu.

- New applications (e.g., AO applications to NIH)
 - RRC Cover Sheet (available at http://www.psychiatry.pitt.edu/sites/default/files/Documents/research_committee/2016Forms/Cover%20Sheet%20For%20Grant%20Proposals.docx)
 - For Research Project Applications (R series grants): Current draft of the following:
 - Research Plan (Specific Aims, Research Strategy [Significance, Innovation, Approach])
 - Progress Report (if applicable)
 - Human Subjects Section (or equivalent)
 - Individual Post-Doctoral Fellowship Applications (F32): Current draft of the following:
 - Fellowship Applicant Section (Applicant's Background and Goals for Fellowship Training)

- Research Training Plan Section (Specific Aims, Research Strategy, Respective Contributions, Selection of Sponsor and Institution, Training in Responsible Conduct of Research)
 - Sponsors, Collaborators, and Consultants Section (Sponsor and Co-Sponsor Statements, Letters of support from Collaborators, Contributors, and Consultants)
 - Institutional Environment and Commitment to Training Section
- Institutional Training Grants (T32): Current draft of the following:
 - Program Plan: Background, Program Plan (Program Administration, Program Faculty, Proposed Training, Training Program Evaluation, Trainee Candidates, Institutional Environment and Commitment to Training, Qualifications of Trainee Candidates), Recruitment Plan to Enhance Diversity
 - Plan for Instruction in the Responsible Conduct of Research
 - Plans for Instruction in Methods for Enhancing Reproducibility
- Resubmission applications (e.g., A1 applications to NIH)
 - RRC Cover Sheet
 - NIH summary statement from the previous review (or equivalent, for non-NIH applications)
 - Introduction to the revised application
 - All other applicable sections, as described above for AO applications
- NIH AO applications based on a previously twice-reviewed submission. *These applications require prior approval from Dr. Lewis. Please see Section G below. Once approval is obtained, submit the following:*
 - RRC Cover Sheet
 - NIH summary statement from the immediately previous review
 - All other applicable sections, as described above for AO applications
- Foundation grant applications
 - RRC Cover Sheet
 - Text sections of application (equivalent to research plan and, if applicable, training plans)
 - Funding announcement, if available
 - Review criteria, if available

d. Procedure

- Prior to submission, the Principal Investigator should *identify 3 faculty reviewers and determine their ability and willingness to review in a timely fashion*. In most cases, reviewers are faculty members in the Department of Psychiatry. However, reviewers from other departments, schools and universities may also serve as reviewers if their specialized expertise is required. The PI should ensure that outside reviewers understand the requirement to provide written comments in a timely fashion, typically within 5 business days. In certain cases, advanced post-doctoral fellows may also be appropriate reviewers. PIs may also consult with the assigned RRC Chair (see below) if they need help identifying appropriate reviewers.
- To initiate a review, submit the proposal to the RRC via psychiatryrrc@upmc.edu *at least one month prior to the internal deadline* at the Office of Grants and Contracts (OGC).
- Applications are assigned to an RRC Chair (Dr. Buysse, Cameron, Brent, or Klunk) who oversee the review process. The Committee Chair reviews the suggested reviewers. Additional or alternative reviewers may be selected by the RRC Chair, in consultation with the PI.
- Reviewers who have confirmed willingness to review the grant are sent the application and the appropriate RRC Scoring Form.
- Reviewers are asked to complete their written review within 5 business days and return the completed Scoring Form to the RRC. Upon receiving the Scoring Form, the Committee Coordinator sends an update to the PI and the RRC Co-Chair via e-mail regarding the current status of the grant review.
- The application and 3 Scoring Forms are forwarded to the Committee Chair for his/her review. The RRC Chair contacts the PI to request a written response to the review, and to provide any additional recommendations. The RRC Chair also grades the quality of the reviews.
- The PI prepares a written response to the reviews and suggestions from the reviewers, and returns this to the RRC.
- The RRC Chair reviews the PI's response, addresses any final concerns with the PI, then recommends action to the Department Chair, Dr. Lewis.
- The Committee Coordinator sends the Scoring Forms and the PI's Response to the assigned reviewers for their information.
- Dr. Lewis conducts a final review and recommends a final action for the application (Approved, Not Approved, or Approved Pending Further Information).
- The Committee Coordinator sends a formal approval letter to the PI and notifies the Office of Grants and Contracts.

2. Expedited (Type B) Review

a. What is Expedited (Type B) Review?

- Expedited Review involves a brief review of the application by one of the RRC Chairs. No reviews are solicited from other faculty members. Written review comments are not required.

b. Which applications require Type B Review?

- The application includes a Co-Investigator from the Department of Psychiatry who contributes >10% effort (regardless of whether salary support is requested on the application), but the application has been reviewed and approved by a different department or center in the University. If such a review has been conducted, the investigators must submit the written reviews from the other department/center. An RRC Co-Chair will determine whether these reviews are consistent with RRC procedures; if so, then Type B review is permitted. If reviews from the other department/center are not deemed sufficiently rigorous by the RRC Co-Chair, then Type A review may be required.
- The application has been approved previously by the RRC via Type A Review, has no major scientific changes, and is now being submitted in essentially unchanged form to a different funding agency.
- The application is being submitted for IRB or IACUC approval purposes only. Typically, these are small pilot grants supported by internal funds. Type B review is appropriate if all of the protocols proposed have received previous scientific review by the RRC or another review body. If new protocols are proposed but have NOT received previous scientific review, the application is NOT eligible for Type B review. The RRC Co-Chair assigned to a specific Type B RRC application will determine, based on the nature and scope of the proposed study and prior reviews, whether Type A review should be obtained. This decision will rest with the RRC Co-Chair, and not with the investigator(s).
- Applications for administrative supplements.

c. Materials to be submitted. If you have any questions about what should be submitted, please contact the RRC administrators at psychiatryrrc@upmc.edu.

- RRC Coversheet.
- Current version of the application/protocol.
- E-mail with a brief explanation for requesting Type B review.
- Written reviews from another department/center, if applicable.

d. Procedure

- Submit the above materials to RRC psychiatryrrc@upmc.edu.
- One of the RRC Chairs will be assigned to make a determination of whether Type B review is appropriate.
- If Type B review is deemed appropriate, the RRC Chair will briefly review the application and request clarifications or provide comments as appropriate.

- After comments are resolved with the PI, the RRC Chair will provide a recommendation for approval.
- Dr. Lewis conducts a final review and recommends a final action for the application (Approved, Not Approved, or Approved Pending Further Information).
- The Committee Coordinator sends a formal approval letter to the PI and notifies the Office of Grants and Contracts.

F. Compliance with IRB and IACUC Requirements

The University of Pittsburgh IRB and IACUC require written notification from the RRC that proposals submitted for review have been approved for scientific merit. Therefore, a copy of the RRC approval letter must accompany any submission to the IRB or IACUC. The approval letter may be scanned and entered into the OSIRIS system for electronic submissions used by the IRB. Small pilot studies that do not have external funding may enter the RRC process at this stage, either a Type A or Type B review as explained above in section E.2.b.

G. Department of Psychiatry Policy for Submitting Previously Twice Reviewed Grants as New Grants (in response to NIH Policy Change announced on April 22, 2014 [NOT-OD-14-074])

The resubmission of a previously twice-reviewed application as a new AO application requires approval from the Department Chair, Dr. Lewis.

Investigators who wish to submit a twice-reviewed application as a new AO should first submit an e-mail to Dr. Lewis, (cc Hermi Woodward, Assistant Director of Research). The e-mail should explain your rationale for resubmitting the new AO application, and should include the following materials as attachments:

- Summary statements for the AO and A1 submissions of the application
- A brief summary of how feedback from the A1 submission will be integrated in improving the new application. This summary is similar to the introduction to a revised application.

Neither the RRC nor the OGC can accept “twice-reviewed” AO applications without prior approval from Dr. Lewis. Once approval is obtained, follow the procedures described above for Type A submission of a twice-reviewed AO application (Section E.1.b)

H. Withdrawal or Postponed Submission

- Please notify the assigned Research Review Chair and Coordinator if you decide to either not submit your application or, to submit at a later date.

Date: July, 2019