



Study Proposal Review Process

Phase 1: Proposal Submission

- The **Principal Investigator (PI)** completes the **Multi-Site Research Study Proposal Form** [available [HERE](#)].
- Ideally, proposals should be submitted **at least two months before** the planned Proposal Overview & Presentation (POP) Session to be considered. The ROC *may make exceptions* if it determines that there is sufficient time to complete Phase 2.
- The **Research Oversight Committee (ROC)** reviews each submission for completeness and readiness for formal review (Phase 2).
- ☒ If the proposal is judged to be **detailed** and **complete**, it moves to Phase 2. The PI will receive feedback in Phase 2 in order to present the proposal (or be presented by a designated representative) at an upcoming **A+PTRN Quarterly POP Session** (two held in person, two via Zoom) as determined by the ROC and as the schedule allows – Phase 3.

Phase 2: Proposal Review (Formal Review by the ROC)

- Each proposal is assigned **three reviewers**: two clinicians and one data scientist (methodologist, biostatistician, or epidemiologist).
- Reviewers assess the scientific merit, methodology, and alignment with A+PTRN's mission.
- Reviews are due to the ROC by these assigned reviewers **two weeks after assignment**.
- The ROC meets within one to two weeks of review completion to determine:
 - Whether the primary investigator will be invited to respond to reviewer feedback and revise
 - Whether the proposal will be presented at the next Quarterly POP Session

- *Note: the ROC will either (1) move a proposal forward to full membership, (2) send it back to the PI for revisions, or (3) reject.*
 - PIs are notified of the decision within a few days and receive the compiled reviews (including specific comments, if any).
 - If invited to revise, the PI must:
 - Submit a **revised proposal** within two weeks using the **Multi-Site Research Study Proposal Form**
 - Use the provided standard A+PTRN **presentation template**
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Phase 3: Proposal Refinement

Stage A: Proposal Distribution to All Members and POP Presentation

- Before the POP Session, revised proposals are sent to all A+PTRN members for review.
- Proposals are presented at the **POP Session** using the **standard A+PTRN slide template**.
- Each presentation is allotted **30-45 minutes**, including time for Q&A. Members will receive **oral feedback** during the POP Session.

Stage B: Member Scoring, Written Feedback, and Site Participation Poll

- Within 24 hours of the POP Session, a **poll is sent to all members**, asking them to:
 - Provide **written comments** (optional and may be shared with PI)
 - Score the **current proposal**:
 - Yes/No: "Like the concept for A+/"Do not like the concept for A+"
 - Proposal Strength: 1 = Insufficient, 5 = Excellent
 - *Note: A "Yes" vote does not mandate participation by the voting center*
 - Indicate whether their site would **participate** if approved
 - Any other items at the discretion of the ROC
 - *Note: There will only be one vote per member (Center) as per the Membership Agreement*

- Proposal advancement to the Development Phase requires, at minimum:
 - **Simple majority of members with a “Yes” vote**
 - **Sufficient sites willing to participate**
- The **ROC breaks ties** and may **veto proposals** (regardless of scores—see Step 5) in collaboration with the Board.
- **Data Coordinating Center** (DCC) participates ex-officio and may submit comments.
- Important participation rules:
 - Centers must vote consistently to maintain **active member status**
 - Centers that agree to participate must adhere to the study timeline (e.g., 3 months to IRB, 5 months of data collection)
 - Failure to meet timelines may result in **loss of authorship**
- If member comments indicate that a vote could change based on revisions, at the ROC’s discretion, the PI will have **one week** to revise the proposal. A **re-vote may be required**.
- All scores and written comments are compiled and sent to the ROC within 1–2 days.

Stage C: Final Review & Study Selection by ROC

- The ROC meets within **one to two weeks of receiving scores**.
- Final decisions consider:
 - Overall scores
 - Study balance (e.g., not selecting three RCTs exclusively if other study types are valuable)
- Selected PIs are notified within **one week** of the decision.

Phase 4: Study Development

- Selected proposals enter the Development Phase and will continue to utilize **MAP Meetings** to modify and fine-tune study materials.
- PIs refine:
 - Final proposal (as needed) and initial study abstract.
 - **Dataset**
 - **Manual of Procedures**
 - **Test data** from their Center (if applicable)

Final stage: Prior to moving to the In-Progress (Active) Phase

- To move to the **In-Progress (Active) Phase**:
 - ROC must approve study materials and help assign a “**Resource Intensity Score**” (e.g., *high, medium, low*) to each project
 - Lead Center must obtain initial **IRB approval** as a model for other centers to use for their respective IRBs
 - ***All RedCap data collection forms should be submitted to the DCC, which is REQUIRED for any multi-center data collection efforts***
 - Once ready for multi-site participation, a **survey is sent to all members** to reassess and confirm participation commitments and communicate the Resource Intensity Score.
 - Each site will need to determine if it has the necessary resources to participate.
 - Only studies with **sufficient site participation** are moved to the **In-Progress (Active) Phase**.
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Phase 5: Study In-Progress (Active) (Study Begins)

Stages

- **Enrollment and Data Collection**
 - Enrollment begins at the discretion of the Study PI.
- **Data Analysis**
 - Details regarding time frames are in the A+ Membership Agreement.
- **Writing and Manuscript Preparation**
 - Details regarding time frames are in the A+ Membership Agreement.

Edited August 7, 2025 (Reviewed by Regan Williams, Karla Lawson, David Notrica)