



ACT Systems Transformation Committee

Single National REB RFA Update

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Funded by the Canadian government, the Accelerated Clinical Trials (ACT) Consortium has a national mandate and responsibility to establish a single Research Ethics Board (REB) review and approval process for multicentre RCTs.

Updates on Process

- Development of RFA – Mar to May 2024
- RFA launched May 2024 and closed Aug 2024
- Adjudication process established and underway
 - External Review Committee (ERC) to score written submissions, distinct from ACT leadership
 - Selection Committee (SC) to undertake interviews of successful submissions and make final selection
- Decision - pending

RFA for Single national REB process

Objective:

- Open competition to select a group to set up and run a sustainable Pan-Canadian, **distributive, single Research Ethics Board (REB) review** and approval process for the initiation and conduct of multicentre RCTs
- A **distributive model** will utilize qualified Canadian REBs and will distribute multicentre trial submissions to one qualified Canadian REBs, which will act as the REB of record. If a qualified Canadian REB approves a trial, other Canadian centres should then accept this REB of record's approval of the ethics and methodology of the trial, without the need for re-evaluation.
- To achieve the goal of efficiency, this new system must set and achieve internationally competitive timelines regarding the review process.

RFA Proposal Review Criteria

1. Governance and operational considerations: [15% of the score]
2. General description of proposed process and system: [10% of the score]
 - Structures and processes for submitting, tracking, and evaluating an REB submissions as well as process for appeals
3. Critical performance metrics of the proposed system: [10% of the score]
 - Review timelines and public reporting
4. Approach to stakeholder engagement [5% of the score]
 - Avoid re-evaluation of ethics in local site approval processes
5. Details on workflows and system requirements [15% of the score]
 - e.g. process for assigning qualified REBs
6. Sustainability and funding model: [15% of the score]
7. Approach to REB selection and qualification/accreditation: [5% of the score]
8. Legislative issues and approaches to address: [5% of the score]
9. Experience with REB processes: [10% of the score]
10. Implementation plan with timelines and deliverables: [10% of the score]

RFA Adjudication

Two-stage review process:

Stage 1: Eligible applications forwarded to an unbiased External Review Committee (ERC). Reviewers required to confirm that they have no conflicts with the applications. Reviewers provide a score out of 100 for each application. Applications with an average score <70 will be excluded. Any applications with a score ≥ 70 will be invited to undergo an interview.

Stage 2: Applicants invited to an interview give a 20-minute presentation on their proposal. After the presentation, the Selection Committee will ask structured questions. After all interviews are completed, Selection Committee Members will select the successful application.

External Review Committee (ERC) & Selection Committee (SC)

Co-Chairs of ERC and SC: Megan Singleton (Hopkins) & Matt Westmore (UK Research Authority)

ERC: Megan Singleton (Hopkins), Matt Westmore (UK Research Authority), Chris MacKnight (Nova Scotia Health), Deborah Cook (McMaster), John Cairns (UBC), Gordon Bernard (Vanderbilt IRB), John Alexander (Duke), Mike Linke (Cincinnati, StrokeNet REB), Marion Campbell (UK)

SC: Megan Singleton (Hopkins), Matt Westmore (UK Research Authority), Chris MacKnight (Nova Scotia Health), Deborah Cook (McMaster), Adeera Levin (UBC), Gordon Bernard (Vanderbilt IRB), and John Alexander (Duke)

Timelines

Announcement of RFA: Friday May 24th, 2024

Deadline for proposals: Friday August 16th, 2024

Inform applicants about score on written applications and whether invited for interview: Friday September 13th, 2024

Complete interviews: October 4th, 2024

Successful group to be announced: Friday October 18th, 2024