



## **Policy on Exam 5 Ancillary Concept Proposal Review and Management of Conflicts of Interest**

### **Purpose**

This policy establishes procedures for the objective and rigorous review of Exam 5 ancillary concept proposals and defines standards for identifying, disclosing, and managing conflicts of interest (COI) among reviewers and decision-makers.

### **Scope**

This policy applies to all individuals involved in the review, scoring, discussion, or recommendation of Exam 5 concept proposals.

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### **Proposal Review Policy**

#### **Principles**

The review process shall be conducted in a manner that ensures:

- Scientific merit and feasibility is assessed objectively and consistently
- Equity, fairness, and transparency in decision-making
- Protection of confidential and proprietary information
- Independence of judgment, free from improper influence

#### **Review Process**

##### **1. Reviewer Selection**

The Executive Committee will be responsible for the review and ultimate selection of approved concept proposals for Exam 5, with consultation from the Scientific Advisory Board as appropriate. At least two reviewers shall be assigned to each proposal based on relevant subject-matter expertise, methodological knowledge, and the absence of disqualifying conflicts of interest.

##### **2. Confidentiality**

All proposal materials, reviewer discussions, preliminary scores, and recommendations are confidential and may not be disclosed or used outside the formal review process.

##### **3. Evaluation Criteria**

Proposals shall be evaluated according to standardized review criteria, including



overall impact, significance & innovation, rigor and feasibility, participant and clinical burden, ethical considerations, and potential risks (including unintended negative consequences, where applicable). After initial scoring, the top 50% of concept proposals (or 20, whichever is larger) will advance for full consideration.

#### 4. **Documentation**

Reviewers are expected to provide written critiques that clearly articulate strengths, weaknesses, and the rationale for scores or recommendations. Written critiques shall serve as the primary basis for proposal discussions and the subsequent selection of proposals.

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### **Conflict of Interest Policy**

#### **Definition of Conflict of Interest**

A conflict of interest exists when a reviewer's objectivity could be compromised—or reasonably perceived to be compromised—by personal, professional, or financial relationships related to a proposal or applicant.

For the purposes of concept proposals, conflicts include, but are not limited to:

- **Professional conflicts**
  - Scientific involvement with concept proposal development
- **Personal conflicts**
  - Family, close personal, or adversarial relationships with the applicant
- **Financial conflicts**
  - Direct financial interest in the outcome of the proposal
  - Employment, consulting, equity, or honoraria related to the applicant or project
- **Potential conflicts**
  - Current or recent collaboration with the applicant
  - Mentor/mentee or supervisory relationships
  - Institutional affiliation with the applicant organization



## **Disclosure Requirements**

- All reviewers must disclose any actual or perceived conflicts of interest as soon as they become known.
- Disclosed potential conflicts will be reviewed by the Executive Committee on a case-by-case basis to determine appropriate mitigation measures.
- Disclosures must be updated if circumstances change during the review process.

## **Conflict Management Procedures**

Upon disclosure, conflicts will be evaluated and managed as follows:

### **1. Recusal**

The conflicted reviewer will not:

- Access the proposal
- Participate in discussions or scoring of the proposal
- Be present during deliberations regarding the conflicted proposal

### **2. Limited Participation (if appropriate)**

In rare cases, and with approval from review leadership, a reviewer with a manageable conflict may provide factual or technical input without scoring or voting.

### **3. Documentation**

All disclosed conflicts and management actions will be documented to ensure transparency and accountability.