

INITIATIVE FOR MULTICENTER PRAGMATIC ANESTHESIOLOGY CLINICAL TRIALS' (IMPACT) AWARD LETTER OF INTENT GUIDELINES

INTRODUCTION

In an initial attempt to advance clinical trial infrastructure in the United States, a consortium of academic anesthesiology organizations launched an initiative in 2018 in collaboration with our colleagues in Canada (PACT) and elsewhere. This effort was conceptualized and endorsed by a few key organizations, which have as a common goal the advancement of knowledge in anesthesiology and the enhancement of care in perioperative medicine, critical care, pain management, and peri- and post-partum care.

These organizations included:

- [Association of University Anesthesiologists \(AUA\)](#)
- [Early-Stage Anesthesiology Scholars \(eSAS\)](#)
- [Foundation for Anesthesia Education and Research \(FAER\)](#)
- [International Anesthesia Research Society \(IARS\)](#)
- [Society of Critical Care Anesthesiologists \(SOCCA\)](#)
- [Multicenter Perioperative Outcomes Group \(MPOG\)](#)
- [Canadian Perioperative Anesthesia Clinical Trials Group \(PACT\)](#)

OBJECTIVE

Now in its third year, IMPACT has awarded six promising projects the seed funding (\$15,000 USD each) to develop a formal proposal for large scale trials. These projects are in various stages of grant preparation, review, or pilot work. For 2020, we would like to reshape the IMPACT award based upon learnings from the initial award cycles and the context of pragmatic trials in anesthesiology medicine.

Three major changes are occurring in the IMPACT award criteria for 2020, with an increased focus on:

- 1) early and mid-career principal investigators;**
- 2) enabling a pilot / feasibility study essential for the successful planning and funding of pragmatic trials;**
- 3) clear prioritization of pragmatic rather than explanatory trials.**

First, applicant principal investigators must be clinically active anesthesiologists within ten years of their initial faculty appointment to a Department of Anesthesiology. Next, rather than distributing funds to three different projects to enable grant preparation, a single award in the amount of \$50,000 USD will be made to enable a pilot or feasibility trial in preparation for the design of a multicenter pragmatic clinical trial. Finally, while the value of explanatory randomized controlled trials is clear, the focus for IMPACT is clearly on pragmatic trials, as assessed by the PRECIS-2 tool (<https://www.precis-2.org/>).

The clinical trials should focus on any or all of the following areas: Intraoperative Anesthesiology Care, Pain Management, Peri- and Postpartum Care, Perioperative Critical Care, Postoperative Management, Preoperative Care/Optimization.

INITIATIVE FOR MULTICENTER PRAGMATIC ANESTHESIOLOGY CLINICAL TRIALS' (IMPACT) AWARD LETTER OF INTENT GUIDELINES

APPLICATION PROCESS

Applicants must submit a letter of intent (LOI) as stage 1 of the application process. All applicants will receive an e-mail during the week of January 20, 2020 notifying them if they have been selected to move forward with stage 2 of the process. Those invited to stage 2 will submit a full proposal, due by March 23, 2020. Full proposals will be reviewed and a single awardee will be announced at the IARS 2020 meeting. Awardees will receive \$50,000 USD to be spent over 12 calendar months for the planning and successful completion of a pilot pragmatic clinical trial. Knowledge gained from the pilot trial should enable the design and submission of a grant proposal. Proposals must have a high probability of receiving support from the National Institutes of Health (NIH) or another funding agency. The IMPACT Award grant applications are conducted through Proposal Central.

Submission instructions:

1. Log into: <https://proposalcentral.altum.com/>
2. Click on the "Grant Opportunities Tab"
3. Look under Grant Maker look for "International Anesthesia Research Society" and under Programs look for "AUA IMPACT Award."
4. Click on "Apply Now" to begin the application.

CRITERIA

- Significance (Is this an important problem? Can it be solved? Is there clinical equipoise?)
- Innovation (Is novel infrastructure being considered? Is the intervention widely available?)
- Approach (Is this approach "pragmatic" rather than "explanatory"? Is the approach feasible and realistic? Will this result in pilot data that informs a successful pragmatic trial grant submission?)
- Investigator and Environment (Does the team have the experience, resources, and expertise?)

LETTER OF INTENT GUIDELINES

The letters of intent should be no more than 2 pages in length, with 1 page being the Specific Aims page. They should be single spacing, minimum of size 11 font (Arial or Times New Roman) with borders of 0.5"

The letter of Intent should include:

- Descriptive title of proposed research
- Name, address, email & telephone number of the Principal Investigator(s), and names of key personnel
- Participating institutions for the pilot / feasibility study
- Number and title of the funding opportunity
- Specific Aims
- PRECIS-2 assessment

The LOI is due on December 16, 2019. Access to the application will be closed at 11:59 pm ET.

If you have questions or concerns, please contact Tricia Brazil, at tbrazil@iars.org.