

## **AOTF Intervention Research Grant 2018-2019 Request For Application**

The AOTF Intervention Research Grant (IRG) is targeted to principal investigators who do not currently have substantial extramural research awards as an independent principal investigator (e.g., NIH, R01, PCORI, Research Program Project Grant, Veterans Administration Merit Award, and Field-Initiated Project). Typically, the principal investigator (PI) will have a funding history associated with early stage, emerging, or early midcareer investigators that may include small research grants and training-related or mentored career awards. The PI must also have a commitment from an experienced research mentor who has an established record of substantial extramural grant funding, peer-reviewed publications, and supervision and mentoring of researchers.

Contact AOTF ([research@aotf.org](mailto:research@aotf.org)) if you have any questions.

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### **Grant Eligibility Form and Letter of Intent will open July 16, 2018.**

#### **I. ABOUT THE 2018-2019 FUNDING PRIORITIES FOR INTERVENTION RESEARCH**

##### **A. What are the research priorities for the 2018-2019 funding cycle?**

The [AOTF Research Priorities](#) were used to establish the funding priorities.

The AOTF Research Priorities:

- Health behaviors to prevent and manage chronic conditions
- Functional cognition
- Safety and injury prevention in home, clinical and community settings
- Technology and environmental supports in home and community
- Development and transitions for individuals and families
- Emotional and physiological influences
- Family and caregiver needs
- Health care experience: access, care coordination, utilization

##### **B. What are the objectives of the AOTF Intervention Research Grant?**

- Lay the necessary groundwork for larger studies to evaluate the effectiveness of occupational therapy interventions on occupation, participation, and health.
- Align with future funding priorities and intended sources of funding.
- Develop interventions that are client-centered, occupation-based, theory-driven, and manualized.
- Lead to efficacy (research under tightly controlled conditions) or effectiveness (research under real-world conditions) trials.
- Cultivate interdisciplinary research teams and partner with communities.
- Include underserved and diverse populations in research.

## II. ABOUT THE APPROACHES: PILOT/FEASIBILITY/PLANNING GRANT DESCRIPTIONS

### A. Approaches that lay the necessary groundwork for larger intervention studies include:

- Pilot studies

“A Pilot Study is a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Alternatively at the end of the pilot study the data may be analysed and set aside, a so-called external pilot.” (p. 5)

Pilot studies are characterized by:

- “rigorous methodological components like sample size estimation, randomization and control group selection” (p. 5)
- an explicit purpose (e.g., “to test a new procedure in preparation for a clinical trial”) and “the criteria which lead to further studies being abandoned.” (p. 6)
- reporting of results are “interpreted with caution” (p. 6) or as “inconclusive, with the intention of conducting a further, larger study” (p. 5)
- results that “provide information to enable a sample size calculation in a subsequent main study.” (p. 6)

- Feasibility studies

“Feasibility Studies are pieces of research done before a main study. They are used to estimate important parameters that are needed to design the main study. For instance:

- standard deviation of the outcome measure, which is needed in some cases to estimate sample size,
- willingness of participants to be randomised,
- willingness of clinicians to recruit participants,
- number of eligible patients,
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure,
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.

Feasibility studies for randomised controlled trials may not themselves be randomised. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main study.....If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.” (p. 5)

In general, feasibility studies are “conducted with more flexible methodology compared to those labeled 'pilot'. For example the term 'feasibility' has been used for large scale studies such as a screening programme applied at a population level to determine the initial feasibility of the programme.” (p. 5)

Arain, M., Campbell, M. J., Cooper, C. L., & Lancaster, G. A. (2010). What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC medical research methodology*, 10(1), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2912920/>

- Intervention research planning grants

An intervention research planning grant allows a new community (typically multi-disciplinary) of experienced investigators to form and share knowledge and ideas around a shared problem prior to attempting to undertake collaborative intervention research. The planning grant period allows the PI to determine who is committed to working together in a true collaborative spirit. The “product” of the planning grant should be a detailed plan for going forward with clearly identified goals for intervention research, a work agenda with defined roles for participants, and a plan for obtaining the needed resources to allow the program to go forward.

What are the key elements for success in a planning grant?

- A driver – the one person who has the passion and vision and takes a leadership role
- A team committed to working together with a deep appreciation for why traditional approaches will not solve the problem.
- Duration – long enough for true planning and collaboration – but short enough to drive a product.
- A structure that allows for both a focused working group and casting a wide net.
- An opportunity to involve individuals across the career span – but especially junior people who will then internalize a new model for successful research.
- A problem that cannot be solved without a novel approach calling on combined expertise
- A commitment to developing a “common currency” or a shared language – this means developing a respect for other “kinds” of knowledge and for recognizing why a particular, dogmatic approach will not succeed. This takes time and some discomfort.
- An atmosphere of trust – individuals must be comfortable pushing one another.
- A project that has both practical outcomes while contributing the further development of theory.

A planning grant should include goals to:

- Yield a program of intervention research with real growth potential
- Yield operational success – so a component of the application should include a plan for how the program of intervention research identified during the planning process would be supported by identifying pertinent RFAs.
- Demonstrate why occupational therapy is central to the intervention research program and its likelihood of success.
- Provide a true training component to strengthen capacity for intervention research.

James S. McDonnell Foundation, personal communication <http://www.jsmf.org/about/s/preface-gauthier.pdf>

### III. ABOUT THE AVAILABLE AWARDS FOR THIS INTERVENTION RESEARCH INITIATIVE

- One year non-renewable proposals for up to \$50K (including indirect costs) will be considered.
- Indirect expenses will be funded up to the level of 10%.
- Funds will be released in 2018 on a payment schedule identified by AOTF. The grant cycle will begin on July 1 pending IRB receipt by AOTF.

#### IV. ABOUT THE ELIGIBILITY CRITERIA FOR INVESTIGATORS

##### A. What are the eligibility criteria for the principal investigator (PI)?

###### General Personal Criteria

- The PI has a terminal research degree or has an OTD with advanced research training (such as completion of a research fellowship).
- The PI is employed by a U.S. domestic, public or private, non-profit organization/institution that is eligible to receive Foundation research grants and will provide assurance of its accountability and support for the project.
- The PI is a U.S. citizen or non-citizen national of the United States OR admitted for permanent residence OR applied for permanent residence. (For non-citizens, the applicant organization must have policies in place to determine whether residence status or visa status will allow completion of the research.)
- The PI is a credentialed occupational therapist with a faculty appointment or an equivalent research position OR a non-OT investigator with a primary academic appointment in an occupational therapy department.

###### Research and Proposed Project Criteria

- The PI has a track record of achievements and career goals related to the proposed project that includes peer-reviewed publications.
- The PI does not currently have any substantial extramural research awards (e.g. RO1, PCORI, Research Program Project Grant, Veterans Administration Merit Award, Field-Initiated Project). Typically, the PI will have a funding history associated with early stage, emerging, or early midcareer investigators that may include small research grants and training-related or mentored career awards.
- The PI has a commitment from an experienced research mentor who has an established record of substantial extramural grant funding, peer-reviewed publications and supervision and research mentoring experience.
- The PI does not have any conflicts of interest. The PI is not:
  - An AOTF or AOTA board or staff member
  - An AOTF Scientific Advisory Council member
  - A board or staff member of an IRG sponsor

#### V. ABOUT THE PROCESS AND TIMELINE FOR 2017-2018 APPLICATIONS

##### A. What is the process for submitting an application for 2017-2018 Intervention Research funding?

Applying for the grant involves several steps:

- The principal investigator reviews the eligibility criteria and completes the online Grant Eligibility Form. The online site for the AOTF Intervention Research Grant **opens July 16, 2018**.
- If the principal investigator meets all eligibility criteria on the online Grant Eligibility Form, immediate access will be given to the Letter of Intent (LOI). The LOI must be submitted **by August 23, 2018, 11:59 CDT**.
- The LOI is reviewed by AOTF. If the PI meets all eligibility criteria and the LOI is accepted by AOTF, applicants will be provided with a link to the application. Principal investigators who are granted permission to submit an application will be notified by **September 21, 2018**.
- Application deadline: **November 13, 2018, 11:59 CDT**.

Applicants are responsible for all deadlines. Deadline extensions will NOT be granted.

B. What is the timeline for the 2018-2019 Intervention Research Grant project?

July 2018

- Review the research priorities, objectives, approaches, and eligibility criteria.
- Begin developing the initial framework for a Letter of Intent and Application using information and instructions on the AOTF website.
- Contact AOTF if you have questions regarding the Intervention Research Grant program. (AOTF Scientific Programs Officer, [research@aotf.org](mailto:research@aotf.org)).
- **July 16, 2018** -- Online submission site for Letter of Intent opens.

August 2018

- **August 24, 2018** -- Letter of Intent deadline 11:59 p.m. CDT.

September 2018

- **September 21, 2018** -- Invitations to submit an Application are extended to principal investigators who meet all eligibility criteria and have submitted an LOI that is accepted by AOTF.
- **September 21, 2018** – Online Application site opens. Begin Application.

November 2018

- **November 13, 2017** -- Application due 11:59 p.m. CST.

February 2019

- Summary statements and award notifications are sent to applicants.

VI. ABOUT THE COMPONENTS OF THE 2018-2019 LETTER OF INTENT AND APPLICATION

A. What are the components of the Letter of Intent (LOI)?

- Principal investigator: personal information and biosketch
- Information about the applicant organization
- Research mentor: personal information, letter of commitment, biosketch, and mentor training table
- Description of the proposed research project

B. What are the components of the Application?

- Principal investigator and project information.
- Sponsoring institution information.
- Research Plan.
- Project summary in lay language.
- Budget and budget justification.
- Specific aims.
- Research plan strategy:
  - Significance.
  - Innovation.
  - Approach.
- Letters of support.
- Literature cited.

- Protection of human subjects plan.
- Inclusion of women, minorities, and children.
- Consortium/contractual/consulting arrangements.
- IRB approval letter/IACUC approval (required but may be submitted at a later date. Grant will not begin until AOTF receives IRB).
- Human subjects research training certification for key personnel.
- Appendices.
- Available resources.
- Biographical sketches of co-investigators and other key personnel.
- Practice settings.

VII. ABOUT THE KEY REVIEW CRITERIA FOR 2018-2019 APPLICATIONS

A. What are the key review criteria for the 2018-2019 applications?

- Overall impact score
- Significance
- Innovation
- Approach
- Environment
- Investigator(s)
- Protections for human subjects
- Potential for subsequent funding -- lays the necessary groundwork for larger intervention studies and subsequent funding.
- Budget