AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
1 of 16

Editing Parameters:
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Be succinct and address only the information requested.

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Application deadline: November 9, 2017, 11:59 CST

Research Plan

Cover Letter

Attach an optional cover letter.

Limitations: No longer than one page of single-spaced text with the head: Cover Letter and the Name of the PI (Last Name, First Name) as a single file using Editing Parameters.

Project Summary in Lay Language

Summarize the proposed project for dissemination to the public. State the project's broad, long-term objectives and specific aims, design, methods, including how the project relates to occupational therapy and the Intervention Research Grant objectives. The summary should be understandable when read separate from the Application. (Avoid describing supporting literature and past projects and use of the first person.

Limitations: No more than 200 words of single-spaced text with the head: Project Summary in Lay Language and the name of the PI (Last Name, First Name) attached as a single file using Editing Parameters. Do not include the head in the word count.

Specific Aims

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s). List succinctly the specific objectives of the research proposed.

Limitations: No longer than one page using the head: Specific Aims and the name of the PI (Last Name, First Name) attached as a single file using Editing Parameters.

Plan for Future Studies and Funding

State how the proposed research lays the necessary groundwork for larger intervention studies and identify specific funding opportunities/notices and sources that will be pursued upon completion of an AOTF Intervention Research Grant Award.

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AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
2 of 16

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Research Strategy Plan

Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section heading: SIGNIFICANCE, INNOVATION, APPROACH.

Cite published literature that supports the Research Strategy using APA Style http://blog.apastyle.org/apastyle/2011/01/writing-in-text-citations-in-apa-style.html.
Provide full references in the **References and Literature Cited** section below.

Limitations: SIX pages, single-spaced text with the head: Research Strategy Plan and the name of the PI (Last Name, First Name) attached as a single file using Editing Parameters.

A. SIGNIFICANCE:

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
- Discuss how the proposed research addresses an AOTF Research Priority

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
- Healthcare experience: access, care coordination, utilization

B. INNOVATION:

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
3 of 16

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C. APPROACH:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 5.5.15, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

Within the research strategy plan:
Discuss how the proposed research addresses other AOTF Research Objectives. (Note: A project does not have to address all objectives).

AOTF Research Objectives – Please use these.

- 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.
- Mentor new investigators and researchers.

Resources Available

Describe facilities, special equipment, consultative services and other relevant resources available for project and directly applicable to the proposed work. Describe other in kind or matching support for this project. This information is important in determining whether resources available are capable of supporting successful completion of proposed project.

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESIs project, and availability of organized peer groups; logistical support such

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as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.

If any of these resources are to be obtained through collaborative arrangements, letters confirming arrangements must be included in Application.

Limitations: There are no page limitations for this section but be succinct and do not use this section to circumvent the page limitations of the Research Strategy Plan. Use the head: Resources Available and the name of the PI (Last Name, First Name) and upload as a single file using Editing Parameters.

Consortium, Contractual, Consulting Arrangements

Summarize and explain any programmatic, fiscal, and administrative arrangements to be made between applicant's organization and consortium organization(s), contractual services, and consultants. If consortium/ contractual/consultant activities represent a significant portion of overall project, explain why applicant organization, rather than ultimate performer of activities, should be grantee.

Limitations: There is no page limitation for this section but be succinct and do not use this section to circumvent the page limitations of the Research Strategy Plan. Use the head Consortium, Contractual, consulting Arrangements.

***See Appendices for more required information regarding Consortium, Contractual, and/or Consulting Arrangements.**

References and Literature Cited

List all references cited in the Research Plan using APA style.
Each reference must include title, names of all authors, title of book or article, name of journal and volume number and page numbers, and year of publication. References should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research.

Limitations: There are no page limitations for this section. Use the head: References and Literature Cited and the name of the PI (Last Name, First Name). For assistance in using APA style, see the Purdue Online Writing Lab.
http://owl.english.purdue.edu/owl/resource/560/07/

Letters of Support

Provide institutional Letters of Support for facilities, equipment, and personnel release time.
Letters should be attached as a single file with a cover letter listing letters attached.

AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
5 of 16

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To SAVE your work, select NEXT PAGE before you LOG OFF.

Budget – Under Budget Justification provide a rationale for each item listed in Budget.	
To SAVE your work, select NEXT PAGE before you LOG OFF.	
Direct Costs -- The research mentor can receive no compensation from this grant.	
Co-Investigators	Identify the PI and all co-investigators regardless of whether salary will be requested. Identify role on project, type of appointment, total percent effort spent working on the project, organization base salary, salary requested, fringe benefits requested, and total support requested. In the Budget Justification, describe the specific role of each individual on the project regardless of whether salary will be requested. Tuition is not a direct cost.
Click Add Another Row to add more Co-Investigators	
Other Key Personnel	Identify all Other Key Personnel regardless of whether salary will be requested. Identify role on project, type of appointment, total percent effort spent working on the project, organization base salary, salary requested, fringe benefits requested, and total support requested. In the Budget Justification, describe the specific role of each individual on the project regardless of whether salary will be requested. Tuition is not a direct cost.
Click Add Another Row to add more Key Personnel	
Consultants	Identify all consultants, regardless of whether salary will be requested. Consultants should not exceed 10% of total award. In the Budget Justification, identify all consultants for the project. Describe services and costs.
Click Add Another Row to add more Consultant	
Equipment	Itemize all equipment requested. Equipment is limited to 20% of total award and does not include computers or major software. In the Budget Justification, identify all equipment.

AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
6 of 16

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Click Add Another Row to add more Equipment	
Travel	Itemize all travel money requested. In the Budget Justification, provide a thorough explanation of travel supports needed.
Click Add Another Row to add more Travel	
Subject/Participant Costs	In the Budget Justification, itemize by category (not individually).
Click Add Another Row to add more Subject/Participant Costs	
Other Costs including supplies	
Click Add Another Row to add more Other Costs	
Indirect Costs – Indirect costs requested cannot exceed 10% of direct costs. The research mentor can receive no compensation from this grant.	
Cost Category	Tuition expenses are not allowed.
Click Add Another Row to add more Indirect Costs	
Subtotal Direct Costs	
Subtotal Indirect Costs	Not to exceed 10% of direct costs
Total Budget Requested	**Not to exceed $50,000**
To SAVE your work, select NEXT PAGE before you LOG OFF.	

AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
7 of 16

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AOTF Intervention Research Grant
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8 of 16

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Assurances	
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Applicant Organization	
Type of Non-Profit Organization	What is the type of non-profit organization?
Tax-Exempt Status	Does the applicant organization have tax-exempt status?
Employer/Federal Tax ID Number	What is the applicant organization's employer/federal/tax ID number?
Applicant Organization Verification	
Verification by Application Organization	Click here for the request form that will be sent electronically to the applicant organization at the email address listed below for verification. Administrative Official Authorized to Act for Applicant (required) Title (required) Email address of Administrative Official (required) Alternate Official Financial Officer (required) Make checks payable to (required) Mailing address of checks OR Electronic Transfer Information) (required)
Human Subject Assurance	What is the Human Subject Assurance Type? Number? Expiration date?
Human Subjects Research Training Certificates for ALL co-investigators	Are certificates of completion for human subjects protection training attached for ALL co-investigators in the appendix?
Human Subjects Data	Will the study include human subjects' data?
IRB Approval	If yes, identify date of Institutional Review Board Approval if completed. (IRB approval is not required at time of application submission. If award is

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	made, payment will not be issued until IRB approval is received by AOTF.)
Vertebrate Animals	Will the study include vertebrate animals (nonhuman)?
Animal Welfare Assurance	If yes, identify the institution's animal welfare assurance number.
IACUC Approval	If yes, identify date of approval by Institutional Animal Care Use Committee if complete. (IACUC approval is not required at time of application submission. If award is made, payment will not be issued until IACUC approval is received by AOTF.)
To SAVE your work, select NEXT PAGE before you LOG OFF.	

Protections	
To SAVE your work, select NEXT PAGE before you LOG OFF.	
Protection of Human Subjects Plan	**Limitations: There are no page limitations for this section but be succinct and do not use this section to circumvent the page limitations of the Research Strategy Plan. Use the head: Protection of Human Subjects Plan and the name of the PI (Last Name, First Name) and upload as a single file using Editing Parameters.** **Address each item within your Protection of Human Subject Plan.** If no human subjects are involved and your research has been determined to be EXEMPT by your Institutional Review Board (IRB), please state so. If research involving human subjects is determined by your Institutional Review Board (IRB) to be NON-EXEMPT and your institution has determined that IRB Approval is necessary, then you must provide sufficient information for reviewers to determine that the proposed research meets 1) the requirements of the DHHS regulations to protect human subjects from research risks and 2) the requirements of Foundation policy on inclusion of women, minorities, and children. The Foundation does not provide IRB review or make a determination regarding whether IRB Approval is necessary.

AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
10 of 16

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	A. Risks to Human Subjects. 1. **Human Subjects Involvement, Characteristics, and Design:** Describe the proposed involvement of human subjects outlined in the Research Strategy section. Describe and justify the characteristics of the subject populations, including their anticipated numbers, age range, and health status if relevant. Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that "prisoners" includes all subjects involuntarily incarcerated (for example, detention centers) as well as subjects who become incarcerated after the study begins. If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention's dose, frequency, and administration. List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data will be obtained, managed, and protected. 2. **Sources of Materials:** Describe the research material obtained from living individuals in the form of specimens, records, or data. Describe any data that will be collected from human subjects for the project(s) described in the application. Indicate who will have access to individually identifiable private information about human subjects. Provide information about how the specimens records, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project. 3. **Potential Risks**: Describe the potential risks to subjects (physical, psychological, financial, legal, or other) and assess their likelihood and seriousness to the human subjects. Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of alternative treatments and procedures, to participants in the proposed research. **B. Adequacy of Protection Against Risks.**

AOTF Intervention Research Grant
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11 of 16

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1. **Recruitment and Informed Consent:** Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed study will include children, describe the process for meeting requirements for parental permission and child assent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent documents need not be submitted unless requested.

2. **Protections Against Risk:** Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness. Research involving vulnerable populations must include additional protections must include additional protections. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in case of adverse effects to the subjects. Studies that involve clinical trials must include a general description of the plan for data and safety monitoring of clinical trials and adverse event reporting to the IRB and others as appropriate to ensure safety of subjects.

C. **Potential Benefits of the Proposed Research to Human Subjects and Others:** Discuss the potential benefits of the research to research participants and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

D. **Importance of Knowledge to Be Gained**. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

E. Data and Safety Monitoring Plan: If the proposed research includes a clinical trial, include a Data and Safety Monitoring Plan. Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the

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	entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported. Be succinct. The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a: Primary Investigator (required); IRB (required); independent individual/safety officer; designated medical monitor; Internal Committee or Board with explicit guidelines; data and Safety Monitoring Board (see NIH requirements). A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and for approval prior to the accrual of human subjects.
Inclusion of Women, Minorities, Children	**Limitations: There are no page limitations for this section but be succinct and do not use this section to circumvent the page limitations of the Research Strategy Plan. Use the head: Inclusion of Women, Minorities, Children and the name of the PI (Last Name, First Name) and upload as a single file using Editing Parameters.** **Address each item within your Inclusion of Women, Minorities,Children.** If the project does NOT include human subjects for research, please state so. **A. Inclusion of Human Subjects**: If the project includes human subjects for research, please summarize the following. **Address, at a minimum, the following four (4) points.** **1**. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups. If using existing specimens and/or data without access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion cannot be described. Alternatively, describe the gender and minority composition of the population base from whom the specimens and/or data will be obtained. **2.** A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.

AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
13 of 16

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	3. A compelling rationale for proposed outreach programs for recruiting sex/gender or racial/ethnic group. 4. A description of proposed outreach programs for equitable recruitment of members of sex/gender and racial/ethnic group as subjects. **B. Inclusion of Children: Address, at a minimum, the following four (4) points.** **1.** Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, application, or proposal, present an acceptable justification for the exclusion. **2.** If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan must also include a description of the expertise of the investigative team for working with children, the ages included, of the appropriateness of the available facilities to accommodate the children and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. **3.** When children are involved in research, please address additional protections to children involved as subjects in research under Protections Against Risk. **4**. Address any exclusion of any specific age group and justify the exclusion.
Vertebrate Animal Protections	**Address each item within Vertebrate Animals Protections.** **Limitations: There is no page limitation for this section but be succinct and do not use this section to circumvent the page limits of the Research Strategy Plan. This section should be attached as a single file using the head Vertebrate Animal Protections and the name of the PI (Last Name, First Name) using the Editing Parameters.** If the project does NOT include research on vertebrate animals, please state so.

AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
14 of 16

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	If the project includes research on vertebrate animals, please address the following areas. Research protocols on animal subjects must be reviewed by Institutional Animal Care Use Committee (IACUC) and approval is required at time of application submission. If vertebrate animals are involved in the project, address each of the five (5) points below. If all or part of the proposed research involving vertebrate animals will take place at alternate sites, identify those sites and describe the activities at those locations. Failure to address the following points will result in the application being designated as incomplete. **A. Use of Animals.** Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy Plan section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. **B. Justification.** Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers. **C. Veterinary Care.** Provide information on the veterinary care of the animals involved. **D. Procedures.** Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. **E. Euthanasia.** Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations. If involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used.
Practice Settings	Identify all practice settings that will be used to recruit participants (subjects/clients, practitioners, researchers) for inclusion or involvement in the research project
Hospital	Yes or No

AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
15 of 16

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To be used for all documents (except for documents submitted by other entities (i.e. Letters of Support, IRB)
All documents must be created in a text editor of your choice (i.e Microsoft Word) using Times New Roman font, no smaller than size 12, single spaced, with ½ inch borders and then saved in an acceptable file format.
The only acceptable file formats are: .pdf, .tif, .png, .gif, .jpeg, .bmp, and .zip. Any other file formats will not be reviewed.

Be succinct and address only the information requested.

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Application deadline: November 9, 2017, 11:59 CST

SNF/ECF/ECF	Yes or No
Home/Home care	Yes or No
Community-based program	Yes or No
School system	Yes or No
Health and wellness facility	Yes or No
Academic or research center	Yes or No
Industry	Yes or No
Other	
To SAVE your work, select NEXT PAGE before you LOG OFF.	

Appendices	
To SAVE your work, select NEXT PAGE before you LOG OFF.	
Human Subjects Research Training Certificates	Human Subjects Research Training Certificates are required for all **co-investigators and Other Key Personnel.** **Co-investigators** must submit their certificates with this application. **Other Key Personnel** may submit their certificates at a later time but grants will not be awarded until all certificates are submitted.
Consortium, Contractual, Consultant Letters	
IRB Approval Letter/IACUC Approval	
Surveys, questionnaires, data collection instruments, clinical protocols	
Additional Information	
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AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
16 of 16

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Biosketches **Biographical sketches must be completed for all co-investigators on your own document or use the NIH Biographical Sketch Form found on http://grants.nih.gov/grants/funding/phs398/phs398.html**	
To SAVE your work, select NEXT PAGE before you LOG OFF.	
Biosketch	The NIH Biographical Sketch Format Page – Forms Version D must be submitted. A Word version of the biosketch, instructions and a biosketch sample are also on the AOTF website: http://www.aotf.org/scholarshipsgrants/aotfinterventionresearchgrantprogram Or the NIH website: http://grants.nih.gov/grants/forms/biosketch.htm
Name	
eRA Commons User Name	Leave blank
Position Title	Current position or title
Education/Training	List sites of education/training beginning with bachelor's.
Institution and Location	
A. Personal Statement	Instructions for these sections and a biosketch sample are also on the AOTF website: http://www.aotf.org/scholarshipsgrants/aotfinterventionresearchgrantprogram Or the NIH website: http://grants.nih.gov/grants/forms/biosketch.htm Use additional pages as needed. The Biosketch may not exceed five (5) pages. Do not use a font smaller than 12.
B. Positions and Honors	
C. Contribution to Science	
D. Research Support	
Save document at a pdf.	
Upload .pdf of NIH Biosketches including parts A-D for each co-investigator. **If there is more than 1 co-investigator, combine them into 1 pdf OR create a .zip file. Only 1 upload is permitted.**	Biosketch may not exceed five (5) pages for each co-investigator.
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AOTF Intervention Research Grant
Application Instructions – updated 9/15/2017
17 of 16

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Optional Data Form – to be used for statistical tracking only.	
To SAVE your work, select NEXT PAGE before you LOG OFF.	
Principal Investigator	
Gender	.
Race	
Ethnic Origin	
Co-Investigators	
Gender	
Race	
Ethnic Origin	
Click Add Another Row to add more Co-Investigators	
To SAVE your work, select NEXT PAGE before you LOG OFF.	

Application Saved
Do NOT hit Submit until your application is finished and all supplements including required documents are attached. **Once submitted, no changes may be made.**

Application must be submitted by November 9, 2017, 11:59 CST to be eligible.