OREF ORTHOPAEDIC RESEARCH AND EDUCATION FOUNDATION®
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The Orthopaedic Research and Education Foundation (OREF)

& J. Robert Gladden Orthopaedic Society (JRGOS)

Orthopaedic Health Disparities Resident Research Grant

Request for Applications

Application Deadline: March 4, 2019

ADMINISTRATIVE POLICIES AND PROCEDURES FOR
OREF/JRGOS ORTHOPAEDIC HEALTH DISPARITIES RESIDENT RESEARCH GRANT

2018 Resident Research Project Grant
Revised December 2018

1. **Objective:**
   The J. Robert Gladden Society in partnership with the OREF encourage investigators to conduct research in the area of health disparities and diversity in the Orthopaedic Surgery field. Residents who have demonstrated a sustained interest in research and excellence in their training are encouraged to apply.

   Highlighted areas of research focus include the following, although other areas of disparity in orthopaedic practice will be considered:
   - Strategies to reduce racial/ethnic inequities in Orthopaedic treatment
   - Disproportionate outcomes/access to care for minority Orthopaedic patients
   - Diversity in Orthopaedic Surgical Training

   OREF and JRGOS strongly encourage the submission of well-crafted clinical, translational, and epidemiologic studies.
   The clinical relevance of all proposals must be clearly noted in the abstract and specific aims and be obvious from the title and the study design. All proposed projects are expected to generate results that have a practical application. It is expected that upon completion of the proposed project, the principal investigator will be well poised to pursue NIH/DOD or the equivalent large-scale funding to continue to advance this area of research.

   Maximum funding will be a total of $5,000 over a one-year grant period, conditional upon periodic progress reports and annual review.

2. **Eligibility:** See page 3

3. **Deadline for Application:** March 4, 2019

4. **Period of Grant:** 1- year (study commencing July)

5. **Total Amount: up to** $5,000 (no indirect costs are allowed).

6. **Required:**
   - ❖ Applicant must submit application electronically through proposalCENTRAL.
   - ❖ Application Face Pages (with signatures) should be printed, signed with institutional signatures and uploaded as an attachment.
   - ❖ Minimum of two letters of reference/support from the following:
     a. Resident Program Director
     b. Mentor
   - ❖ See Applications Instructions, Section I for details.

Please direct application questions to: The OREF Grants Team
grants@oref.org
(847) 430-5109

PROGRAM INFORMATION

A. Eligibility:

1. Applications may be submitted by domestic non-profit, public and private institutions of higher education, such as hospitals, medical schools, universities, and colleges.

2. The resident applicant (PI) must be an orthopaedic surgery resident in an ACGME-Accredited orthopaedic program in the United States.

3. Applicants that wish to be eligible for this grant, resident ***must*** be a Gladden member in good-standing at the time of application. If a Gladden member, please state in specialty society relevance section Membership will be confirmed before the issuance of an award.

4. Applicants are limited to one submission per individual, regardless of category, per year. The same project may not be submitted in multiple grant categories, even if the PI is different. The investigator may receive only one OREF grant of each type during his/her lifetime.

B. **Application Procedure:**

1. The proposal must be single-spaced. Prepare the application using Arial 11 typeface in black font color. Minimum margins must be 1/2 inch for left and right, 1 inch for top and bottom.

2. The Research Plan cannot exceed **five (5) pages**.

C. **Letters of Reference:**

Each applicant must have a minimum of two (2) letters of reference stating the specific project the resident will be working on and the specific time committed to the project. Letters are required from:

1. **Resident Program Director**, confirming a specific plan to ensure adequate time for the resident to complete the project within the timeframe of the funding.

2. A **mentor** confirming the specific relationship with the resident and a plan for mentoring. The mentor should be listed as the Co-PI on the application. This letter should include the following:

    - The work should clearly be achievable by the resident as a free-standing project. The resident's role must be clearly defined.
    - The mentor is responsible for ensuring that the clinical relevance of the work is explicitly, specifically, and clearly highlighted.

For applicants whose eligibility is based on a future position, the letter of reference must verify that the future position is confirmed, and the title of the new position and start date must be stated.

Instructions for submitting letter(s) of reference are addressed in Section I of the Application Instructions.

D. **Award and Declination Notices:**

Applicants will be notified about the status of grant awards through proposalCENTRAL in June 2019.

***Submissions failing to follow the guidelines or instructions may not be considered. ***

INSTRUCTIONS FOR COMPLETING THE GRANT APPLICATION

A. Title Page:

1. The project title must contain a reference to the clinical relevance of your project.

2. Please indicate the type of project (basic, clinical or health services).

3. Please indicate if this proposal is a resubmission.

******Applicants must download and complete all required templates. Applications with missing attachments cannot progress to the review stage.

Applicant/PI & Institutional Contacts Fields:

1. Please complete all sections in the Applicant/PI fields. This information auto populates to Face Pages 1 & 2, which are the cover sheets for the entire application.

2. Face Page 2 requires information about the institution's Financial and Authorized Signing Officials.

3. Please enter specific titles, departments, addresses, telephone and e-mail addresses, where requested.

4. Signatures are required for the principal investigator, department chair, the authorized financial officer and the authorized institutional official. No "per" signatures permitted.

B. Key Personnel Section:

1. Provide contact information for all key personnel listed in the application. Key Personnel is defined as Principal Investigator (PI), Co-Principal (Co-PI), Co-Investigators (Co-I), Mentors/Advisors and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation.

2. Include investigators' National Provider Identification Number (if applicable) to enable OREF to comply with Sunshine Act reporting regulations. If not applicable, please enter zeros into the field.

3. Biographical sketches *must* be submitted for all investigators listed in the Key Personnel section.

C. Other Key Information Section:

1. **Role of Orthopaedic Surgeon**: The **Resident** must provide a statement, clarifying his/her responsibility on the project, the expected duration of the project, and how the project will be completed in that time.

2. **Career Goals**: **Resident** must state the reasons for their interest in orthopaedic research. The statement must describe their objectives, clinical and research interests and person goals, and how these can best be accomplished by receiving this grant. Please indicate what you would like to be doing in five to 10 years.

3. **Relevance of the Project to the Mission of OREF:** Provide a statement describing the relevance of the project to OREF's mission.

4. **Specialty Society Relevance**: Please describe how your research applies to and ultimately benefits the Gladden Society. Provide answers to *both* questions.

5. **Statement on Diversity**: OREF recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences research community. We encourage efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; to improve the quality of the educational and training environment; to balance and broaden the perspective in setting research priorities; to improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and to improve the capacity to address and eliminate health disparities.

The application should address diversity issues in the proposal to include racial and ethnic groups, gender and age, disabilities, and disadvantaged backgrounds, if applicable.

D. Abstract Section:

1. **Abstract of Research Plan**: Provide a 200-word executive summary. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This description is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

2. **Statement of Clinical Relevance**: Provide one statement (200-word limit) that explicitly and clearly describes how your research project will impact the clinical practice of orthopaedics (including how the information could be used to develop strategies for treating a specified targeted patient population). Describe how your project will change the way we think about clinical problems or how we treat them.

3. Please prioritize the 3 categories that relate to the project in order of relevance. In addition, please identify all other relevant categories.

E. Budget and Budget Justification:

1. Enter budgets for the proposed budget period. At the bottom of the Budget Summary & Justification page provide justification for each expense and category.

2. **Salaries and Wages**: Enter the name, percent of time on project and salary requested, as well as normal fringe benefits, i.e., pay for vacation, sick days, and holidays charged to the grant. On budget justification page state what each person will be doing. Funds may not be used to augment the salary or stipend of the resident.

   ❖ **Resident Level of Effort:**
   - The Resident PI should propose and expend the level of effort required to accomplish his/her specific aims.
   - OREF defers to the institution to track PI effort and confirm he/she attests to the level of effort being expended on the project, if awarded.

3. **Permanent equipment**: Any major piece of equipment or apparatus costing more than $500 should be itemized, and justifications made.

4. **Consumable supplies**: Glassware, chemicals, supplies and all expendable materials may be grouped in this category under appropriate subheading. Rent for use of the Institution's computers may be charged against this grant.

5. **No travel expenses** are allowed on this grant.

6. **All other expenses**: Retirement plan and Federal Insurance Compensation Act employer contributions may be charged to grants, when such contributions are made as part of the normal practice of the institution. The percentage of such costs charged on behalf of a given individual must be calculated based on the percentage of that individual's salary charged to the grant. These expenditures must be shown in this category for approval.

   Publication costs, carrying the credit line "Aided by a Grant from the Orthopaedic Research and Education" may be charged against the grant if the principal investigator desires.

****No overhead or indirect costs can be charged against the grant.**

7. **Other Support**: Please add all your existing Other Support. For each Other Support entry, select if there is overlap with this application and if so, provide a description of the overlap.

F. Organizational Assurances

1. All sections marked with an asterisk must be completed. Any research involving a living individual by whom an investigator obtains data through interaction or Identifiable, private information requires a documented approval from the institutions IRB to comply with the requirements set forth in 45 CFR 46.
2. Research involving live vertebrate animals, including: animals obtained or euthanized for tissue harvest, or generation of custom antibodies must be approved by the institutions IACUC.
3. In order to avoid duplication of the effort, Grantees are authorized to use a single IRB of record for multiple sites that are conducting the same protocol (Protocols that address the same research questions, involve the same methodologies, and evaluate the same outcomes). The single IRB will be accountable for compliance with regulatory requirements, such as providing initial and continuing review of the research. All participating sites will be responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of approved protocols, and reporting unanticipated problems and adverse events to the single IRB of record.
4. Alternatively, site investigators may choose to work with their individual IRBs to obtain ethical approvals of the human subjects work performed at the respective sites.

G. Proposal Attachments

1. **Conflict of Interest:** To assure that all OREF funded research is free from bias resulting from investigator financial conflicts of interest, key personnel in the roles of Principal Investigator and Mentor/Co-PI must attest to COI on the disclosure form in every application submitted for funding consideration.
2. **Biographical Sketch:** Biographical sketches **must** be submitted for all investigators listed in the Key Personnel section of the application.

   Be sure to include information relevant to the project. ***The newest NIH format has been adapted*** and should be followed as stated. ***See sample bio on next page.***

SAMPLE

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES**.

NAME: Jane Doe

POSITION TITLE: Associate Professor of Pediatric Orthopaedics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/1990	Chemistry
University of Vermont	M.D.	05/1996	Oncology
University of California, Berkeley	Residency	08/1998	Orthopedic Oncology

A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

1. Merryle, R.J. & Doe, J.L. (2004). Independent living, physical disability and substance abuse among the elderly. Psychology and Aging, 23(4), 10-22.
2. Doe, J., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
3. Doe, J.L., Wiechelt, S.A. & Merryle, R. (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292
4. Doe, J.L., Hunt, M.C., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.

B. Positions and Honors

Positions and Employment

1998-2000	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001-	Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2007-	Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995-	Member, Orthopaedic Research Society
1998-	Member, POSNA
1998-	Member, American Geriatrics Society
2000-	Associate Editor, Psychology and Aging
2003-	Board of Advisors, Senior Services of Eastern Missouri
2003-2005	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-2011	NIH Risk, Adult Addictions Study Section, members

Honors

2003	Outstanding Young Faculty Award, Washington University, St. Louis, MO
2004	Excellence in Teaching, Washington University, St. Louis, MO
2009	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Contribution to Science

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.

    a. Gryczynski, J., Shaft, B.M., Doe, J.L.., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.

    b. Doe, J.L., Hunt, M.C., Merryle, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. International Journal of Drug Policy, 30(5), 46-58.

    c. Doe, J.L., Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. Journal of Applied Gerontology, 28(2), 26-37.

    d. Doe, J.L., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. Addiction, 104(9), 1436-1606. PMCID: PMC9000292

2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment.

    a. Doe, J.L., Merryle, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. Journal of the American Geriatrics Society, 57(4), 15-23.

    b. Hunt, M.C., Doe, J.L., Marks, A.E., Merryle, R. & Jensen, J.L. (2005). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.

3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.

    a. Doe, J.L., & Jensen, J.L. (2003). Morbidity among elderly substance abusers. Journal of the Geriatrics, 60(4), 45-61.
    b. Doe, J.L., & Pour, B. (2004). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.
    c. Doe, J.L., & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. Journal of Ageing, 54(1), 24-41. PMCID: PMC9112304

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PgT7IEFIAJBtGMRDdWFmjWAO/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

R01 DA942367 Doe (PI) 09/01/08-08/31/16
Health trajectories and behavioral interventions among older substance abusers
The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.
Role: PI

R01 MH922731 Bao (PI) 12/15/07-11/30/15
Physical disability, depression and substance abuse in the elderly
The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.
Role: Co-Investigator

Faculty Resources Grant, Washington University 08/15/09-08/14/15
Opiate Addiction Database
The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.
Role: PI

Completed Research Support

R21 AA998075 Doe (PI) 01/01/11-12/31/13
Community-based intervention for alcohol abuse
The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.
Role: PI

H. Research Plan Format:

Complete this section, giving details following the outline below**.** The research plan should be self-contained and include sufficient information to evaluate the project, independent of any other document (e.g., previous application). Be specific and informative and avoid redundancies.

If this is a resubmission, an introduction **(1-page limit)** must summarize the substantial additions, deletions, and changes to the application including a response to the criticism raised in the critique(s).

Begin each section of the research plan with a section header (e.g., Specific Aims, Research Strategy, etc.) The Research Strategy is composed of three distinct sections: Significance, Innovation, and Approach. Note the Approach section also includes Preliminary Studies for new applications and a Progress Report for resubmitted applications. **The total proposal (research strategy only) must not exceed five (5) pages.**

Specific Aims (1-page limit): 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) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Research Strategy (5-page limit): 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 experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

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.

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.

Approach: Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

Discuss potential problems, alternative strategies to achieve the aims, and benchmarks for success.

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.

Explain how relevant biological variables, such as sex, are factored into the research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.

Refer to the NIH Guide on Sex as Biological Variable for further consideration as needed.
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html

If an application has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all the Specific Aims collectively.

The following sections are not included in 5-page research plan page limit.

Sub-Award Policy: The prime institution must submit sub-award paperwork with the proposal that contains the biosketch of the sub-PI, a letter of intent endorsed by an Authorized Institutional Official that includes a scope of work (representing programmatic effort), sub-recipient budget, and budget justification. The sub-awardee must adhere to the terms and conditions of the agreement between OREF and the prime institution; this is typically referred to as "flow-down".

Project Timeline: Prepare a proposed timeline for each of the projects specific aims, demonstrating progress expected at 6 and 12 months.

Human Subjects: Attach an IRB approval, if applicable. This documentation must come from your Institutional Review Board. The IRB approval is required for any studies including patients or patient material. If approval is pending at the time of application, please note that in the application. If the project is funded, final IRB approval will be required before funding begins.

Please address the following in the human subjects section:

1. Description of study
2. Potential risks and complications
3. Statement of confidentiality
4. Allowance for non-prejudicial withdrawal from investigation
5. Liability and hold harmless clause

Vertebrate Animals: Attach an IACUC approval, if applicable. This documentation must come from your Institutional Animal Care and Use Committee. The IACUC oversees the university's animal programs, facilities and procedures insuring the appropriate care, use and humane treatments of animals being used for research. IACUC approval is required for any studies including animals. If approval is pending at the time of application, please note that in the application. If the project is funded, final IACUC approval will be required before funding begins.

Please address the following in the animal section:

1. Description of proposed use of animals, provide species, strains, ages, sex, and numbers to be used.
2. Justify the use of animals, the choice of species, and number specified. If animals are in short supply, costly, or to be used in large numbers, provide additional rationale for the selection and numbers.
3. Provide information on veterinary care of the animals involved.
4. Describe procedures for ensuring discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize distress, pain, and injury.
5. Describe and provide a rationale for any method of euthanasia to be used. State whether this method is consistent with recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include justification for not following the AVMA recommendations.

****Appendix**: (i.e. preliminary reports, time line for planned investigation, planned data acquisition instruments, power analysis, database layout, letters of support, plans for dissemination of findings).

Resources: List facilities available at your institution and other sites where the research will be performed. Include laboratory space, office, and major equipment available for use with this investigation.

Bibliography and References Cited: Provide a bibliography of any references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application. The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

I. Letters of Reference

The letters of reference are uploaded directly from the nominator to the proposalCENTRAL application. To do so, please enter into the proposalCENTRAL system the e-mail address of the nominator submitting a letter of reference. Enter the e-mail address again to confirm and click "Add." If the nominator's e-mail address is in the proposalCENTRAL system, you will be prompted to "Send E-mail" to the nominator. If the nominator's e-mail address is not in the proposalCENTRAL system, you will be prompted to enter the nominator's first and last name before being prompted to "Send E-mail." **The e-mail to the nominator will contain instructions and a link to upload the letter of reference directly to the application**.

A minimum of two (2) letters of support are required, stating the specific project the resident will work on and the specific time committed to the project. Letters are required from:

- **Resident's Program Director** confirming a specific plan to ensure adequate time for the resident to complete the project within the time frame of the funding.

- A **Mentor** confirming the specific relationship with the resident and a plan for mentoring. The mentor should be listed as the Co-PI for the grant. This letter should include:
    - The work should clearly be achievable by the resident as a free-standing project even when it is a part of a larger work. The resident's role on the project must be clearly defined.
    - The mentor is responsible for ensuring that the clinical relevance of the work is explicitly, specifically, and clearly highlighted.
    - The mentor should note previous residents that he/she has successfully mentored.

- If necessary, Chair letters can be placed in the appendix section of the research plan.

GUIDELINES

A. Fiscal Procedures and Policies:

1. Facilities to be provided by Grantee Institution:

   a. Grantee institution is expected to provide all necessary, basic facilities and services. These include the facilities and services that normally could be expected to exist in any institution qualified to undertake orthopaedic research.

   b. In particular, it is expected that the grantee institution will provide, whether from its own funds or from grant funds other than those of OREF, the following, unless otherwise specifically agreed upon:

      (1) Laboratory space
      (2) Maintenance service, including maintenance, supplies and service contracts
      (3) Telephone services
      (4) Library service, including subscriptions to periodicals and the purchase of books
      (5) Laboratory furniture
      (6) Salary of principal investigator, co-principal investigator/mentor and of secretarial personnel
      (7) All travel expenses of personnel working under the grant
      (8) Worker's compensation, public liability or other hazard and special insurance
      (9) Office equipment
      (10) Employee group life, disability, medical expense or hospitalization insurance
      (11) Lantern slides, color plates, etc.
      (12) Hospital bed expense, nursing or related services, even though used for research studies.
      (13) Indirect Costs
      (14) Tuition expenses of personnel on grant.

2. As a matter of policy, OREF funds may not be used for remodeling or building construction costs.

3. Ownership of the Equipment - Equipment purchased under OREF grants become the property of the institution, unless otherwise specified by OREF before termination of the grant or its extensions.

B. Fiscal Policies and Reports:

1. There will be two (2) grant payments. The first payment of 90% will be sent in December, the final payment (10%) will be released after the project has ended and all final reports have been submitted in accordance to the schedule. .

2. Reports of expenditures must be prepared every six (6) months, be signed by the responsible and authorized financial officer, and submitted to OREF for approval with accompanying documents. Accompanying documents include a detailed, itemized list of expenses by category, i.e., Salary and Wages, Equipment, Supplies, Other. **Your report is deemed unacceptable without this detailed documentation.**

3. Ten percent (10%) of grant funds will be withheld until the final report of expenses and the two (2) final reports of the research are received at OREF. Upon receipt of both reports *that strictly adhere to the reporting schedule*, withheld funds will be sent to the grantee institution.

4. At expiration of grant, any unexpended balance of $100 or more must be refunded to OREF within sixty (60) days together with the report of expenditures and accompanying documentation, properly submitted.

5. Separate accounts must be maintained for each grant. These accounts, with substantiating invoices and payrolls, must be available at all times to representatives of OREF.

6. Grantee must use the budget revision form to request permission prior to making any changes to approved budget and/or moving funds between budget categories. The form should be signed by the PI and an official at their institution prior to submission. The request will be reviewed and if approved, Grantee will receive written approval from OREF Grants Committee.

7. Grantee may terminate a grant prior to normal expiration date by notifying OREF in writing and stating the reasons for termination. Unexpended funds must be returned to OREF within sixty (60) days, together with a final report of expenditures.

8. OREF reserves the right to terminate a grant upon written notice to Grantee for any reason or no reason at OREF's sole discretion. In addition, OREF may terminate a grant immediately for any one of the following reasons:

   a. Grantee provides false or misleading information in the Grantee's application,

   b. Grantee fails to meet any of the eligibility criteria for receiving the grant,

   c. Grantee commits any act of misconduct in connection with the use of the grant or breaches the terms of these Guidelines.

   d. Grant funds cannot reasonably be spent in accordance with the budget.

9. If Grantee receives NIH or other funding for this project before or during the term of the grant, he or she is required to notify OREF of such funding immediately. Grantee is also required to submit a financial report of expenses for monies already expended and return the remaining funds to OREF. OREF will then cancel the grant.

C. Policy on Delinquent Financial/Research Reports

OREF reserves the right to deny additional grants and any unobligated funds to any Grantee and/or institution where the Grantee has not submitted his/her required reports, and/or the financial officer has not submitted the required report of expenses on a timely basis.

D. Policy on Human Subjects in Research

1. Use of human subjects and sample size must be justified.

2. If applicable, IRB approvals from Grantee' IRB must be provided. IRB approval is required for patients' x-rays, laboratory results or the use of any material which could lead to identification of individual patients. Some institutions allow expedited review. If approval is not obtained prior to the effective date of the grant, OREF reserves the right to withhold disbursement of funds until a copy of the approval is provided. If approval is not obtained or revoked by the Grantee's Institution for any reason, Grantee must notify OREF immediately, all funds previously disbursed must be returned within sixty (60) days of the notification, and grant will be terminated by OREF. If proof of approval is submitted within the sixty (60) day period, Grantee will be permitted to continue their research.

3. OREF Grantees are entrusted to assure adequate protection of human subjects. NIH regulations regarding human subjects should be followed.

E. Policy on Animals in Research

1. Use of animals and the number requested for project must be justified.

2. If applicable, provide IACUC approval regarding use of and number of animals requested for project. If IACUC approval is not obtained prior to the effective date of the grant, OREF reserves the right to withhold disbursement of funds until a copy of the approval is provided. If approval is not obtained or revoked by the Grantee Institution for any reason, Grantee must notify OREF immediately, all funds previously disbursed must be returned within sixty (60) days of the notification, and the grant will be terminated by OREF. If proof of approval is submitted within the sixty (60) day period, Grantee will be permitted to continue their research.

3. All animals used in research supported by OREF grants must be acquired lawfully and be transported, cared for, treated and used in accordance with existing laws, regulations, and guidelines. Decisions as to the type and sources of animals most appropriate for particular studies must be made by scientists and institutions. OREF policy requires that such decisions be subject to institutional and peer review for scientific, merit, and ethical concerns and that appropriate assurances be given that NIH principles governing the use of animals are followed.

F. Policy on Transfer of Grant

1. If Grantee moves to a new institution, the Authorized Institutional Official representing the Grantee at the original institution must submit a formal transfer request 60 day prior to the transfer using the OREF Relinquishment Statement form indicating the willingness to release all rights and interests in the grant. The institution is also required to submit a final financial report not to exceed 30 days following the date the grant terminates.

2. The new institution must facilitate the completion of the new application to include IRB and IACUC approvals as applicable.

3. OREF's Research Grants Committee will consider the request and make a final decision as to whether the change should be approved, or the grant terminated.

G. Policy on Changing Aims of Grant

If the Grantee and collaborators find that the original aims of the grant cannot be accomplished, and that to continue the project substantial changes in aims or methodology must be considered, the Grantee must write to the OREF contact listed on the application, requesting permission to change the procedure and state the reasons for the change. The OREF Grants Committee will approve or deny all requested changes.

H. Policy on Changing Original PI of Grant

Grantees must seek approval to change from the original PI of the grant to a new PI. The OREF Research Grants Committee can approve this change without peer review of the proposed PI as long as there are not changes to the research plan. To request a change in PI, a letter or email must be sent to the Vice President of Grants, signed by an authorized institution official from the Sponsored Research Office, and must include the following information:

1. Reason for change of PI.

2. Biographical sketch of the proposed new PI.

3. Certification of human subjects training if the proposed new PI will be working with human subjects.

4. Any budget changes resulting from the change in PI, using the budget revision form.

If the Research Grants Committee denies the request, justification for the rejection is given. In the event that an acceptable replacement is not named, OREF will terminate the grant. Alternatively, if the change is approved, OREF will issue a revised Notice of Award with a project period end date that coincides with the original PI's departure date and the start date of the newly named PI.

****All final reports must use the templates provided****

I. Final Reports

1. Grantees are required to submit two (2) versions of the final report to OREF. The Grantee has sixty (60) days from the project end date to complete the reports.

   a. One version is the scientific report of the project. This report should refer to the original proposal so the reviewer can determine whether or not the goals of the research were accomplished. This mechanism will assure continuance of a quality control program that meets the highest scientific and academic standards.

   b. The second version of the final report is to be written in lay language and giving a broad overview of the project and would, similar to a media release, state what was accomplished during the period of the grant.

2. OREF reserves the right to deny additional grants to any institution where the final reports have not been submitted on a timely basis. (See Section C above).

J. Publication

1. OREF encourages free publication of research findings by grantees but requires that the following acknowledgment be used as a footnote on the first page of the text:

   AIDED BY A GRANT FROM THE
   ORTHOPAEDIC RESEARCH AND EDUCATION FOUNDATION
   AND
   THE J. ROBERT GLADDEN ORTHOPAEDIC SOCIETY
   FUNDING PROVIDED BY -
   J Robert Gladden Society

2. When Grantee presents a paper at a professional scientific meeting, the above credit line must be included.

3. OREF should be sent reprints of all papers and publications resulting from work done under a grant, even those that appear after the grant has been terminated.

4. OREF imposes no restrictions on copyrighting publication by Grantee.

K. Intellectual Property

As a non-profit, Section 501(c)(3) charitable and educational organization, OREF grants funds to individuals and institutions to perform research, which frequently results in intellectual property susceptible to copyright or patent. OREF

has determined that it does not generally wish to seek compensation from the use of copyright or patents arising from research funded by it.

1. General Provisions:

    a. OREF will not include provisions in research grants requiring compensation to OREF for use of copyright, patent, or other intellectual property rights arising from research funded by OREF.

    b. Research grants shall require grantees to report to OREF on the commercialization of products or intellectual property developed from the research grant, and the grantee shall grant permission to OREF to publicize the practical applications of the funded research.

2. Exceptions:

    a. OREF may determine to make exceptions to its general policy in its sole discretion.

    b. Any exceptions will be clearly set forth in individual grant agreements.

***Submissions failing to follow the above guidelines or instructions may not be considered. ***