9400 West Higgins Road, Suite 215 • Rosemont, IL 60018-4261
(847) 698-9980 • FAX (847) 698-7806

THE ORTHOPAEDIC RESEARCH AND EDUCATION FOUNDATION (OREF)

PREVENTION OF MUSCULOSKELETAL YOUTH SPORTS INJURIES

RESEARCH GRANT

In HONOR OF JAMES R. ANDREWS, MD

Request for Applications

Application Deadline: **February 8, 2024**

ADMINISTRATIVE POLICIES AND PROCEDURES FOR OREF PREVENTION OF MUSCULOSKELETAL YOUTH SPORTS INJURIES GRANT

1. **Objective:**

   The objective of this grant is to provide startup funding or seed money for a new investigator conducting clinical and/or social research on the prevention of musculoskeletal youth sports injuries. Clinical relevance 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 practical application. OREF will fund only one Prevention of Musculoskeletal Youth Sports Injuries Grant per institution per year. *Please note: Although the potential for concussions and their harmful impact on young athletes is a major issue for the field of pediatrics and sports medicine, this topic is not within the scope of this grant program.* Accordingly, no proposed projects regarding youth concussions will be considered.

2. **Eligibility:** See page 3

3. **Deadline for Application: February 8, 2024 via proposalCENTRAL by 10:59 p.m. CST.** This is the **DUE** date without exception for invited applications.

4. **Period of Grant: One Year Grant** (study commencing **May 2024**)

5. **Amount: $25,000** .

6. **Items Required:**
   - **Applicant must submit application electronically through Proposal Central.**
   - **Application Face Pages (with signatures) are required and must be uploaded in the application.**

Please direct application questions to:

OREF Grants Staff
9400 West Higgins Road, Suite 215
Rosemont, IL 60018-4975
Phone: (847) 430-5109
grants@oref.org

PROGRAM INFORMATION

1. Eligibility:

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

   B. An orthopaedic surgeon licensed to practice in the United States may serve as Principal Investigator (PI) or co-PI. Multidisciplinary research activity is always encouraged. PhDs and DVMs may serve as the principal investigator (PI) if S/he has a primary or secondary faculty appointment in an orthopaedic department. A letter from the department chair confirming this appointment is required.

   C. The orthopaedic surgeon must provide a statement on time to be allocated to the project indicating percent of average time allocated and how the time will be spent.

   D. The PI must be a new investigator. A new investigator is classified as an individual who has not received an R01 National Institutes of Health (NIH) grant or its equivalent (e.g., VA, DOD, NSF) in the role of PI.

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

2. Application Procedure:

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

   B. The complete Research Plan is not to exceed **six (6) pages**.

3. Notification of Award:

   OREF will notify each applicant via proposalCENTRAL.

4: Mentoring:

   OREF recognizes the importance of mentoring relationships for the professional development of orthopaedic investigations. Mentors provide direction, support and inspiration. Applicants should highlight his/her mentoring relationship and discuss any activities relevant to the proposed research project. The Orthopaedic Research Society (ORS) is committed to the development of the New Investigator, both professionally and scientifically. For more information on ORS programs and resources, please visit the website at www.ors.org.

   Please review the FAQs (Frequently Asked Questions) on OREF's website for additional assistance.

   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 description of the clinical relevance of the project.
2. Please indicate the type of project (translational or clinical).

**Applicants must download and complete all templates. Applications with missing attachments cannot progress to the review stage. Please complete resubmission and sub award templates only if applicable.

Enable Other Users to Access Proposal

Add the names, email addresses and assign the permission level to any of the individuals you would like to grant "view only" or "edit" rights to your proposal.

Applicant/PI & Institutional Contacts Fields:

1. Please complete all sections marked with an asterisk in the Applicant/PI fields. This information auto populates to Face Pages 1 & 2, which are the cover sheets for the entire application. ***If applicable, Chair letters should be placed in the appendix section of the research plan.***

2. Please enter specific titles, departments, addresses, telephone numbers and email addresses, where requested. NPI: **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. Signatures are **required** for the principal investigator, department chair, the authorized financial officer and the authorized institutional official. No "per" signatures permitted. Face pages should be submitted electronically with the application loaded at the bac k of the research plan.

B. Key Personnel Section:

1. Provide contact information for all key personnel listed in the application. Key Personnel is defined as the Principal Investigator (PI), Co-Principal (Co-PI), Co-Investigators (Co-I) 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. Biographical sketches ***must*** be submitted for all investigators listed in the Key Personnel section. The newest NIH format has been adopted and should be followed as stated.

C. Other Key Information Section:

1. **Role of the Orthopaedic Surgeon**: Please provide a statement clarifying the role of the orthopaedic surgeon, stating the significant part taken in the planning and/or execution of the design and analysis of data and time to be allocated to the project each week during the grant period, including percent of time dedicated to research vs clinical duties.

2. **Career Goals:** Because the PI or co-PI is a new investigator, please provide a statement describing your career goals, including a summary of past accomplishments in research, citing future research goals and how successful completion of this Research Grant will enhance your potential for future NIH or other large-scale funding.

3. **Specialty Relevance:** Please describe how your research *applies to* and *ultimately benefits* any orthopaedic specialty or specialties. Provide answers to *both* questions.

4. **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 maximum 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 field of youth musculoskeletal sports injuries research as it is specifically relevant of 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 (basic, clinical or health services). In addition, please note all other relevant categories.

E. Budget and Budget Justification

1. **Budget**: Enter budgets for the initial budget period. At bottom of this page, provide justification for *each* expense and category.

2. **Salaries and Wages:** Enter the name, role, 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 the budget justification page, state what ***each*** person will be doing. **No salary can be requested for principal investigator or co-principal investigators.**

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.

5. **Tuition**: Graduate student tuition up to $5,000 is allowable and may be charged to this grant.

5. **Travel Expenses:** As an early stage or new investigator who has *not* secured independent funding in the role of PI, such as an NIH R01, it is a requirement that the PI or Co-PI participate in a Grant Writing Workshop to learn strategies for success in competing for NIH or other large-scale funding. ***The Art of Grantsmanship*** course from the Orthopaedic Research Society (ORS), as well as other grant writing workshops, can satisfy this requirement.
Here is the link: https://www.ors.org/learnors-grant-writing/

   As applicable, the budget must include travel costs for the grant writing workshop. Applicants may include **up to $2000** in their budget for expenses related to participation in the workshop, including registration, travel, and/or housing. The PI or Co-PI is typically required to prepare a grant proposal that will be critiqued during the workshop. ***Workshop attendees may not have been awarded an NIH R01 grant or its equivalent in the role of PI.***

   a. As applicable, attendance at a **Grant Writing Workshop** is a *required condition for being eligible to receive future OREF grant awards.*

   Recipients who have attended a grant writing workshop within the **last 3 years do not need to attend a second workshop.** Please indicate the year and the workshop you attended in your justification so that OREF may verify this account.

Please review the FAQs (Frequently Asked Questions) on the OREF website for additional assistance.

7. **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 of any paper carrying the credit line "Aided by a Grant from Orthopaedic Research and Education Foundation in honor Dr. James Andrews, MD" may be charged against the grant if the principal investigator desires.

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

8. **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. This section ***has*** *to* be completed in the Applicant Professional Profile Section.

F. Organizational Assurances

1. All sections marked with an asterisk must be completed. Any research involving a living individual from whom an investigator obtains data through interaction or identifiable, private information requires a documented commitment by the institution to comply with the requirements set forth in 45 CFR 46 with an approval from the institution's IRB. Assurance approvals are required for all work proposed at every performance site. However, the prime institution may elect to model the NIH's Single IRB mechanism provided the human subjects work is the same at each performance site.

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. Assurance approvals are required for all work proposed at every performance site.

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 Co-Principal Investigator **must** attest to COI on the disclosure form in every application submitted for funding consideration.

1. **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 the next page***.

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

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: Hunt, Morgan Casey

eRA COMMONS USER NAME (credential, e.g., agency login): huntmc1

POSITION TITLE: Associate Professor of Psychology

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	BS	05/2003	Psychology
University of Vermont	PHD	05/2009	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/2013	Public Health and Epidemiology

A. Personal Statement

I am an Associate Professor of Psychology, and my research is focused on neuropsychological changes associated with substance use disorders. 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 substance use disorders. 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 older people with substance use disorders, 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 2015-2016, 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. In summary, I have the expertise, leadership, training, expertise, and motivation necessary to successfully carry out the proposed research project.

Ongoing and recently completed projects that I would like to highlight include:

R01 DA942367
Hunt (PI)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older people with substance use disorders

R01 MH922731
Merryle (PI), Role: co-investigator
12/15/17-11/30/22

Physical disability, depression, and substance use among older adults
R21 AA998075
Hunt (PI)
01/01/19-12/31/21
Community-based intervention for alcohol abuse

Citations:

1. Merryle, R.J. & Hunt, M.C. (2015). Independent living, physical disability and substance use among older adults. Psychology and Aging, 23(4), 10-22.
2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2018). Substance use and mental health among community-dwelling older adults. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
3. Hunt, M.C., Wiechelt, S.A. & Merryle, R. (2019). Predicting the substance use treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292
4. Merryle, R. & Hunt, M.C. (2020). Randomized clinical trial of cotinine in older people with nicotine use disorder. Age and Aging, 38(2), 9-23. PMCID: PMC9002364

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2021– Present Associate Professor, Department of Psychology, Washington University, St. Louis, MO
2020 – Present Adjunct Professor, **McGill University Department of Psychology, Montreal, Quebec, Canada**
2018 – Present NIH Risk, Adult Substance Use Disorder Study Section, member
2015 – 2017 Consultant, Coastal Psychological Services, San Francisco, CA
2014 – 2021 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2014 – 2015 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2014 – Present Board of Advisors, Senior Services of Eastern Missouri
2013 – 2014 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2011 – Present Associate Editor, Psychology and Aging
2009 – Present Member, American Geriatrics Society
2009 – Present Member, Gerontological Society of America
2009 – 2013 Fellow, Intramural Research Program, National Institute on Drug Abuse, Baltimore, MD
2006 – Present Member, American Psychological Association

Honors

2020 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society
2019 Excellence in Teaching, Washington University, St. Louis, MO
2018 Outstanding Young Faculty Award, Washington University, St. Louis, MO

C. Contributions to Science

1. My early publications directly addressed the fact that substance use 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 concerns about a substance use disorder. These publications document this emerging concern and guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the behavior, and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for older adults with substance use disorders 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., Merryle, R., & Hunt, M.C. (2013). Community based participatory research with late-life substance use disorder. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.
b. Shaft, B.M., Hunt, M.C., Merryle, R., & Venturi, R. (2014). Policy implications of genetic transmission of alcohol and drug use in women who do not use drugs. International Journal of Drug Policy, 30(5), 46-58.
c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2015). Early-life family and community characteristics and late-life substance use. Journal of Applied Gerontology, 28(2),26-37.
d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2018). Community-based intervention strategies for reducing alcohol and drug use in older adults. 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 people with substance use disorders and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of substance use disorders and the disruptive potential of networks in substance use treatment. This body of work also discusses the prevalence of alcohol and amphetamine use in older adults and how networking approaches can be used to mitigate the effects of these disorders.

a. Hunt, M.C., Merryle, R. & Jensen, J.L. (2015). The effect of social support networks on morbidity among older adults with substance use disorders. Journal of the American Geriatrics Society, 57(4), 15-23.
b. Hunt, M.C., Pour, B., Marks, A.E., Merryle, R. & Jensen, J.L. (2018). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.
c. Merryle, R. & Hunt, M.C. (2020). Randomized clinical trial of cotinine in older people with nicotine use disorders. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364

3. Methadone maintenance has been used to treat people with substance use disorder 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. Older adults 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. Hunt, M.C. & Jensen, J.L. (2013). Morbidity among older adults with substance use disorders. Journal of the Geriatrics, 60(4), 45-61.
b. Hunt, M.C. & Pour, B. (2015). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.
c. Merryle, R. & Hunt, M.C. (2018). The use of various nicotine delivery systems by older people with nicotine use disorder. Journal of Aging, 54(1), 24-41. PMCID: PMC9112304
d. Hunt, M.C., Jensen, J.L. & Merryle, R. (2020). Aging and substance use disorder: ethnographic profiles of older people with substance use disorder. NY, NY: W. W. Norton & Company.

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1lCifFFV4VYQZE/bibliography/public/

H. Research Plan Format:

If this is a resubmission, an Introduction page **(1-page limit)** must summarize the substantial additions, deletions and changes to the application including a response to the criticism raised in the reviewer critique(s). The Introduction is a preface to the research plan and will not count against the page limits.

Complete this section, 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.

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, as applicable. **The total proposal (research strategy only) must not exceed six (6) 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 (6-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 the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to support your application.

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.
Describe the experimental design and methods proposed and how they will achieve robust, unbiased results.

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.

Highlight any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

Include information on preliminary studies briefly describing any work you have done that is particularly pertinent.

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.

If appropriate, please address the following:

- Did you state the goal, objectives and the full hypotheses in the introduction?
- How will you assure generalizability of this investigation to clinical practice (e.g., clinical relevance, university to community practice, US to other international sites, etc.)?
- Complications - Which complications will be explored? How will complications be identified?
- Will a structured tool be utilized (e.g.: Greenfield)?
- What other approaches will be used to assure quality of this investigation (e.g., study oversight committee, blinding of the analyses, data completion, protocol violations, etc.)?
- What ethical concerns are present and how are these to be reconciled?
- If this investigation is successful, how will it provide a foundation for future investigations?

Significance:

- What are the anticipated benefits from this study?
- What is the expected magnitude of the benefit(s)?
- What clinical complications might be reduced?
- What is the potential economic impact of the planned research endeavor (to the individual and/or to society at large)?
- What party or parties will receive direct or indirect benefits from this investigation?

Project Timeline: Prepare a proposed timeline for each of the project's specific aims, demonstrating progress expected at **6** and **12** months. (Not included in the 6-page research plan page limit.)

Human Subjects: Attach an IRB approval, if applicable. This documentation must come from your Institutional Review Board and MATCH the title of the proposal being submitted to OREF. 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. A single IRB approval is acceptable for the same protocol carried out at multiple sites. Visit the OREF website, FAQ section for additional information.

Please address the following in the human subject's 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 treatment 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:

- Description of proposed use of animals, provide species, strains, ages, sex, and numbers to be used
- 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 number.
- Provide information on veterinary care of the animals involved.
- 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.
- 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's (AVMA) Guidelines on Euthanasia. If not, include justification for not following the AVMA recommendations.

****Appendix****: Please do not use this section to circumvent the research plan page limit. The following attachments would be deemed acceptable to include in the appendix section: preliminary reports, timeline for planned investigation, planned data acquisition instruments, power analysis, database layout**, letters of support**, plans for dissemination of findings. Please upload the appendices in the back of the research plan and include a page break with the title "Appendix". This will NOT count against the research plan page limits.

Sub-Award: The prime institution must submit sub-award paperwork (as applicable) 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". Sub recipients outside of the U. S. or Canada are not allowed.

Resources: List facilities available at your institution and any 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.

GUIDELINES

A. Fiscal Procedures and Policies:

1. Facilities to be provided by Grantee:

   a) Grantee 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. In particular, it is expected that the grantee 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 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 becomes the property of the institution, unless otherwise specified by OREF before termination of the grant or its extensions.

B. Fiscal Policies and Reports:

1. 1-Year Grants. One-year research grant payments are disbursed over three payments. The first payment of 50% of the grant funds awarded will be paid at the start of the grant. Upon submission of the 6-month financial report, the second payment equaling 40% of the grant funds awarded will be paid. The third and final payment will be paid upon receipt of all final reports (financial, scientific, and lay reports) *that strictly adhere to the reporting schedule* and equals 10% of the total grant awarded.

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2. Reports of expenditures must be prepared every six (6) months, must be signed by the authorized financial officer, and submitted to OREF for approval with supporting documentation.

3. The supporting documents must include a detailed, itemized list of expenses by category, date, i.e., Salary and Wages, Equipment, Supplies, Other.

4. Fifty percent (50%) of the last OREF disbursement must be expended before the next grant payment will be released.

5. Ten percent (10%) of grant funds will be withheld until the final report of expenses, the final scientific and lay reports are received by OREF. If all final reports strictly adhere to the reporting schedule, withheld funds will be sent to the Grantee.

6. 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.

7. 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.

8. The Principal or Co-Principal Investigator classified as a New Investigator (has not received NIH or other large-scale funding in the role of PI) is required to participate in a Grant Writing Workshop as a condition for receiving all grant funds.

9. 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 the Authorized Institutional Official prior to submission. The request will be reviewed by the OREF Research Grants Committee, and if approved, Grantee will receive written approval from a member of the OREF Grants staff.

10. 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 thirty (30) days, together with a final report of expenditures.

11. 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.

12. If grantee has not completed the project prior to expiration and would like to initiate a ***one-time*** extension of the expiration date not to exceed 12 months, OREF must be notified **in writing** at least **30 days prior** to the original expiration date of the grant. The extension may not be exercised merely for the purpose of using an unobligated balance and the request must contain:

    a) Detailed justification explaining the reason the No Cost Extension is being requested and a scientific justification for keeping the funds

    b) Request must be signed by the authorized institutional official and countersigned by the PI

    c) An itemized budget of the unobligated balance and budget justification detailing how funds will be used if the extension is awarded. Second NCEs are not allowed.

    d) Note that No Cost Extension (NCE) is not automatic and the request will be reviewed and adjudicated.

13. 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. 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 as dictated by the FE Agreement.

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's Internal Review Board 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 is 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 his/her 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 the 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 is 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 be 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 days *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 no later than 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 grant staff at grants@oref.org 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, which must be approved by the OREF Research Grants Committee. 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 and unexpended funds must be returned to OREF. 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 progress and final reports must use the templates provided****

I. Progress Reports

1. Grantees must submit progress reports. The Grantee should pay close attention to the established milestones of what is to be accomplished by the sixth and ninth months. It is extremely important that the Grantee report these accomplishments, because the criteria established in the proposal will be used by the Research Committee to determine if funding should be continued as applicable.

2. Electronic submissions are required through proposalCENTRAL.

J. Final Reports

1. Grantees are required to submit two (2) versions of the final report to OREF. The Grantee has three (3) months 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 Research Committee 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; give a broad overview of the project and would, similar to a media release, state what was accomplished during the period of the grant.
   c) Upon receipt of acceptable reports through proposalCentral, the Grantee will be notified as to the availability of subsequent funding.

   OREF reserves the right to deny additional grants and any unobligated balances to any institution where the final reports have not been submitted within three (3) months. (See Section C above.)

K. Publication

1. OREF encourages free publication of research findings by grantees but requires that the following acknowledgment be included:

   SUPPORTED BY A GRANT FROM
   ORTHOPAEDIC RESEARCH AND EDUCATION FOUNDATION (OREF)
   IN HONOR OF DR. JAMES R. ANDREWS, MD

2. When Grantee presents a paper at a professional scientific meeting, the above credit line must be included. All presentations based on the funded research should be listed in the Deliverables section of proposalCentral.

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. These should be uploaded to proposalCentral in the Deliverables section.

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

L. 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.

3. Rights to Publication
   a) OREF may use abstracts, scientific reports, and other deliverables for promotion on website, annual reports, or other publications.

   b) OREF retains the right to publish a description of the research in a searchable database.

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

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