OREF ORTHOPAEDIC RESEARCH AND EDUCATION FOUNDATION
9400 West Higgins Road, Suite 215 • Rosemont, IL 60018-4261
(847) 698-9980

The Orthopaedic Research and Education Foundation (OREF)

and

The Orthopaedic Trauma Association (OTA)

ORTHOPAEDIC TRAUMA ASSOCIATION

Trauma Research Grant

With funding provided by Arthrex, Inc.

Request for Applications

Application Deadline: June 15, 2022

TRAUMA RESEARCH GRANT

ADMINISTRATIVE POLICIES AND PROCEDURES

1. **Objective:**
   This Funding Opportunity Announcement solicits investigator-initiated research proposals focusing on Orthopaedic Trauma. Although orthopaedic trauma results in significant disability and substantial financial cost, comprehensive research aimed at addressing these issues are limited. Investigators who have demonstrated a sustained interest in orthopaedic trauma research are encouraged to apply.

   The focus of the research proposal should be:
   - ***Enhancing recovery from soft-tissue injury occurring in conjunction with skeletal trauma***
   - *Proposals that address recovery from muscle, tendon and/or ligamentous challenges associated with pilon fractures, proximal tibial fractures or patella fractures will be particularly interesting.*

   - 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. Proposals will be adjudicated on scientific merit, feasibility, and ability to have a significant impact.
   - The goal is to fund science that ultimately improves clinical expertise and patient outcomes.
   - All proposed projects are expected to generate results that will likely lead to 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 the area of research.

   Maximum funding will be a total of $150,000 over a two-year grant period, conditional upon periodic progress reports and annual review.

2. **Eligibility:** See page 3

3. **Deadline for Application:** **June 15, 2022 by 10:59 pm CST.** This is the DUE date.

4. **Period of Grant:** - 2 years: study to begin approximately September 2022 following the signed Letter of Agreement (LOA) and the appropriate documentation of compliance with IRB and/or IACUC.

5. **Amount:** Up to $150,000 ($75,000 per year)

6. **Items 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 - *applicable to full proposals only.***

   Please direct application questions to:

   The OREF Grants Staff
   grants@oref.org
   Phone: (847) 430-5109

PROGRAM INFORMATION

1. **Eligibility**:

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

   B. An orthopaedic surgeon principal investigator (PI) must be licensed to practice in the United States and working in an institution in the U.S. or Canada. PhDs or DVMs working in or holding a primary appointment at an institution/orthopaedic department in the U.S. or Canada may serve as the PI. A letter from the department chair confirming the appointment is also 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 time will be spent.

   D. 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.

   Orthopaedic Relevance:

   It is important that the research topic clearly contain relevance to orthopaedic practice. Ultimately, applications are evaluated on whether or not the potential exists for clinical advancements resulting from the knowledge gained at the conclusion of the proposed study.

2. **Application Procedure**:

   A. The proposal must be single-spaced. 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, and 1 inch for top and bottom.

   B. The Research Plan is **not to exceed six (6) pages**. See instructions for further clarification.

3. **Award and Declination Notices**:

   Applicants will be notified about the status of grant awards through proposalCENTRAL in September 2022.

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.

   Please review the FAQ's (Frequently Asked Questions) on the OREF 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 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 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 and 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 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. 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. **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.

4. 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.

B. Key Personnel Section:

1. Provide contact information for all key personnel listed in the application. Key Personnel are defined as Principal Investigator (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**: 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 and use of time.

2. **Career Goals**: 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 Society 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, if applicable, address diversity issues in the proposal to include racial and ethnic groups, gender and age, disabilities, and disadvantaged backgrounds.

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. **Categories that Relate to the Project:** Please prioritize the 3 categories that relate to the project in order of relevance. In addition, please note all other relevant categories.

E. Budget and Budget Justification:

1. **Budget:** Enter budgets for the initial budget period. Enter budget for all the years for which funds are requested on the Budget for Entire Proposed Period of Support Page. At bottom of this page, provide justification for *each* expense and category for each year. For example, in a 2- year grant, each year is limited to one-half of the total budget (for a $150,000 budget, the limit is $75,000 for each year).

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 the budget justification page state what each person will be doing. Funds of up to 50% of grant may be budgeted each year for salaries.

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, lab supplies, and all expendable materials may be grouped in this category under appropriate subheading.

5. **Travel Expenses:** If the applicant is an early stage or new investigator who has not secured independent funding in the role of PI, such as an NIH RO1, it is a requirement that he or she 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 to attend a grant writing workshop. Applicants may include up to $2000 in their budget for expenses related to participation in the workshop, including registration, travel, and housing. The PI or Co-PI is 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 the **Grant Writing Workshop** is a required condition for receiving the obligated grant funds as well as future OREF grant awards.

   B. Recipients of previous OREF grants, who attended a Grant Writing Workshop **within the last 3 years as a result of that funding, do not need to attend a second workshop**. Please indicate the year you attended the workshop in your justification so that OREF may verify this account.

   C. Include the information about your participation in a grant writing workshop in your progress report/deliverables in a verifiable format.

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

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, carrying the credit line "Aided by a Grant from the Orthopaedic Research and Education and the Orthopaedic Trauma Association" 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 of your existing Other Support. For each Other Support entry, indicate 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.

G. Proposal Attachments

1. **Conflict of Interest:** In order 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.

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 adopted and should be followed as stated. See sample bio on next page**.

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:

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, informative and avoid redundancies.

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 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. **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.

Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.

Explain how the proposed project will improve scientific knowledge, technical capability and/or clinical practice in one or more broad fields.

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 interventions.

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 the 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 project's specific aims, demonstrating progress expected at 6, 12, 24, and 36 months. (Not included in 6-page research plan page limit.)

Products: All products used in the study must be "on label" and approved by OREF ahead of time.

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. Potential risks and complications to human subjects
2. Adequacy of protection against risk
3. Potential benefits of the proposed research to human subjects and others
4. Allowance for non-prejudicial withdrawal from investigation
5. Importance of knowledge to be gained

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 ensuring 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.

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 secretarial personnel
        (7) All travel expenses of personnel working under the grant, except travel to the Grant Writing Workshop
        (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:

2-Year Grants. Two-year research grant payments are disbursed over multiple payments as specified in the Letter of Agreement at the time of the award.

1. 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.

2. Fifty percent (50%) of most recently released OREF funds must be expended before the next grant payment will be released.

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 all final 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. As applicable, the Principal or Co-Principal Investigator are required to attend the Grant Writing Workshop in Year 1 as a condition for receiving grant funds in the subsequent project year(s).

7. 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.

8. 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.

9. 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.

10. 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 unallowable.

11. 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 where the Grantee has not submitted the 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 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 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 progress and final reports must use the templates provided****

I. Progress Reports

1. Grantees must submit a progress at the completion of twelve months. This allows time to set up the project and report on the progress to date. The Grantee should pay close attention to the established milestones of what is to be accomplished by the sixth and twelfth months. It is extremely important that the Grantee report these accomplishments because the criteria established in the proposal will be used by the Committee **to determine if funding should be continued**.

2. Upon receipt of acceptable reports through Proposal Central, the Grantee will be notified as to the availability of subsequent funding.

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 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 or the unobligated balance 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 used as a footnote on the first page of the text:

AIDED BY A GRANT FROM THE
ORTHOPAEDIC RESEARCH AND EDUCATION FOUNDATION
and
THE ORTHOPAEDIC TRAUMA ASSOCIATION
WITH FUNDING PROVIDED BY Arthrex, Inc

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.

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.

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