



ADMINISTRATIVE POLICES AND PROCEDURES FOR FOT RESEARCH GRANTS

(status November 2011)

I. GENERAL ADMINISTRATION

1. **Objective:** The objective of Research Grants is to encourage investigators by providing seed and start-up funding for promising research projects in the field of orthopedic trauma surgery through Grants of up to US\$30,000 for a research project extending over a maximum of 3 years. Both laboratory and clinical projects are suitable, but in either case clinical relevance must be explicitly and clearly described.
2. **Eligibility:**
 - An orthopedic surgeon, FOT member must serve as either the principal or co-principal investigator. Non-trauma/orthopedic surgeon, M.D.'s, Ph.D.'s or D.V.M.'s may serve as the principal or co-principal investigator, as long as they are affiliated with a trauma/orthopedic department with an FOT member orthopedic surgeon as the co-principal investigator.
 - Candidate may not submit a grant application if a grant awarded previously has not been completed.
 - Candidate may receive only one FOT Grant per institution in each year.
3. **Deadline for Application: June 1, 2012.**
4. **Period of Grant:** August/September 2012, through July/August 2014, maximum two years.
5. **Amount:** Up to US\$20,000 for single institution grants and up to US\$30,000 for multicenter grants during Period of Grant.

6. **Application Procedure:**

-Two copies of the application, an electronic copy and an "original" paper copy, are necessary for the application to be considered by the FOT Research Committee.

-Electronic application (e-mail) must arrive by the **June 1, 2012** deadline.

-The original application must be clipped, not stapled; original signatures should be in blue or black ink. The original must be single sided. Total **Research Plan is not to exceed four (4) pages.**

7. -Application is available at: http://www.fotnorthamerica.org/multi-center_studies.asp

- Provide Animal IACUC application or acceptance, or equivalent according to your national regulations, if applicable.
- Provide Human IRB / Ethics Committee application or acceptance, or equivalent according to your national regulations, if applicable.

8. **Selection Criteria for Awarding Grants:**

- The Research committee will strive to minimize the possibility of bias in the selection process. All applications will be blinded to the committee. A scoring system will be used by the Research Committee similar to those used by the OTA and OREF. This is available as an attachment on the FOT website. Each study will be evaluated based on 1) relative importance to the field, 2) research design, and 3) budget. The number and amounts of grants funded will be given at the discretion of the research committee based on merit and budgetary constraints.
- The Research Committee will be made up of 5-6 actively practicing Orthopedic Trauma surgeons and FOT members with an interest and experience in basic science and clinical research. Conflicts of interest, if any, will be kept on file with the FOT and made apparent as part of all Research Committee meetings.
- Any study will be disqualified for the following reasons: 1) lack of blinding of the application, 2) an incomplete application, including budget, 3) the Primary investigator or Co-primary investigator has another study funded by the FOT that is incomplete. 4) off label use of any drug, technology, or device used in the study.

9. **Notification of Award and Contracts:** The FOT Research Committee will notify each applicant by email by **August 30, 2012**. Contracts will be offered by end-September, 2012.

10. **Submission Instructions:** Complete applications should be submitted via email to: LeeAnn Finno, Administrator, Foundation for Orthopedic Trauma administrator@fotnorthamerica.org

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

II. GUIDELINES

A. 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 trauma and orthopedic 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 the FOT, 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, FOT funds may not be used for remodeling or building construction costs.
3. Ownership of the Equipment - Equipment purchased under FOT Grants becomes the property of the institution, unless otherwise specified by the FOT before termination of the Grant or its extensions.
4. Awarding of grant will be subject to background check of the PI
5. Awarding of grant will be subject to medical license verification of the PI

B. Budget Policies and Reports

1. Grant Term: Upon notification of Grant award, grantees must send in the signed grant letter and a fully signed signoff sheet within ninety (90) days. All Grants must be disbursed within one year of award of the Grant. Further, all research activities must be completed within two years of award of the

Grant.

2. If approved budget is less than that requested, budget forms will be sent to Grantee when notification of award is made. These forms must be completed, signed by the principal investigator and financial officer of the institution, and returned to the FOT for approval, within thirty (30) days after notification.
3. Financial Report: Reports of expenditures must be prepared every twelve months, be signed by the responsible financial officer, and submitted to the FOT for approval with accompanying documents. The approved financial report is returned to the financial officer. Expenses must be submitted by category, i.e., Salary and Wages, Equipment, Supplies, Animals, Other.
4. Ten percent (10%) of Grant funds will be withheld until the final report of expenses and the final report of the research are received at the FOT. Upon receipt of both reports, withheld funds will be sent to the Grantee institution. In case of Grants with more than one year Grant period, the same will apply to each individual year of the Grant period.
5. At expiration of Grant, any unexpended fund of US\$100 or more less any uncancellable obligations which have been subject to FOT prior approval and do not exceed the budget, must be refunded to the FOT within sixty (60) days together with the final report of expenditures and accompanying documentation, properly submitted.
6. Grantee must request permission and receive written approval from the FOT prior to making any changes to approved budget.
7. Grantee may terminate a Grant prior to normal expiration date by notifying the FOT in writing and stating the reasons for termination. Unexpended funds must be returned to the FOT within sixty (60) days, together with a final report of expenditures.

C. Policy on Delinquent Financial/Research Reports

The FOT reserves the right to deny additional Grants to any institution where after proper notification, an investigator has not submitted his/her final reports, and/or the financial officer has not submitted the final report of expenses, as required by FOT. This policy will be enforced when reports are six (6) months past the final due date. Upon receipt of these reports, the institution shall again become eligible for FOT Grants.

D. Policy on Animals in Research

1. Use of animals and institution must justify number requested for project. If applicable, provide IACUC approval or equivalent according to your national regulations, regarding use of and number of animals requested for project.
2. All animals used in research supported by FOT Grants must be acquired lawfully and be transported, cared for, treated and used in accordance with existing laws, regulations and guidelines. Scientists and institutions must make decisions as to the kind and sources of animals that are most appropriate for particular studies. FOT 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 or equivalent according to your national regulations, governing the use of animals are followed.

E. Policy on Human Subjects in Research

1. Use of human subjects and sample size must be justified. If applicable, IRB statements or equivalent according to Grantee's national regulations, from institution's human subjects committee must be provided. IRB approval is required for use of any material (e.g., radiographs, laboratory results), which could lead to identification of individual patients; some institutions allow expedited review.
2. FOT Grantees are entrusted to assure adequate protection of human subjects. NIH regulations or equivalent according to your national regulations regarding human subjects should be followed.

F. Policy on Transfer of Grant

If the principal investigator moves to a new institution, he/she must submit a letter detailing resources, personnel and curriculum vitae of investigators at the new institution. The FOT Research Committee shall review the request to determine whether the change in institution is approved, and respond to the principal investigator.

G. Policy on Changing Aims of Grant

If the principal investigator 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 principal investigator must write to FOT, requesting permission to change the procedure and state the reasons for the change. The FOT Research Committee will respond to the principal investigator.

H. Progress Report

1. Grantees must submit a brief progress report at the completion of 12 months past contract sign-off. This allows time to set up the project and report on the progress to date.
2. In case of Grant periods of more than one year, annual progress reports must be submitted sixty days after termination of one and two years past sign-off.
3. Progress reports should be sent to the FOT by e-mail.
4. This Progress Report must detail the specific research work and activities undertaken to date with the Grant funding. This Progress Report must also detail all related expenditures of Grant funding acc. to section 7.

I. Final Reports

1. Grantees are required to submit the Final Report to the FOT sixty days after termination of the Grant or they may submit a preliminary report in sixty days followed by the Final Report four months later, giving the investigator six months to complete the report. The scientific report of the Final 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.

2. The FOT reserves the right to deny additional Grants to any institution where the Final Reports have not been submitted within six months.
3. This Final Report should include details of all results, conclusions, discoveries and related information from research activities, and should expand upon the details set forth in your Progress Report. This Final Report must detail all related expenditures of Grant funding.

J. Output updates

Grantees are required to submit any scientific output related to the project during two years after completion of the project. The output update should include details on presentations, publications (including published abstracts) and obtained funding based on the work performed under the grant.

K. Confidentiality

During the period of your research activities hereunder and for a period of One (1) year following receipt of your Final Report, the Research Grant Recipient and FOT undertake mutually that they shall neither give nor make available Confidential Information to any third-party. FOT reserves the right to communicate under confidentiality to the Grant donator(s) a copy of the Progress, Final and Financial Report in order to ensure and document proper use of the Grant money.

Confidential Information as used herein means any technical or non-technical information in written, oral or tangible form, relating to potential patent applications that accrue from your work supported by Grants funded by FOT. Without limitation the reports mentioned above shall be deemed Confidential Information.

You will be free to publish papers to the extent they are consistent with the protection of Confidential Information.

L. Patents

If any patents accrue from investigations supported by Grants funded by the FOT, the FOT reserves the right to negotiate a proportionate interest in the royalties.

M. Publication

1. The FOT encourages free publication of research findings by Grantees but requires that the following acknowledgement be used as a footnote on the first page of the text:
"AIDED BY A GRANT FROM FOUNDATION FOR ORTHOPEDIC TRAUMA (FOT)"
2. Also, when a Grantee presents a paper or Power Point presentation at a professional scientific meeting, the above credit line must be included.
3. The FOT 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.

N. Authorization

In the performance of his research activities hereunder the Principal Investigator agrees to comply with all professional standards and guidelines and all applicable laws, rules and regulations of any government or governmental body or board having jurisdiction. In this regard, the Principal Investigator represents and warrants to FOT that, whenever necessary, he has obtained and will maintain, at his own cost, (i) any permits, licenses, registrations, governmental approval and any relevant tax certificate when necessary, in order to perform his research activities hereunder and as an independent contractor (ii) any necessary authorizations required under law or by contract to perform his research activities hereunder.

Grant Acceptance:

As an FOT Grant supported recipient I hereby affirm that I have read and understand the FOT Research Administrative Policies and Procedures.

Print Name

Signature and date