Osteosynthesis & Trauma Care Foundation

Research

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CH-4528 Zuchwil
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ADMINISTRATIVE POLICES AND PROCEDURES FOR OTC RESEARCH GRANTS 2017

(status November 2016)

I. GENERAL ADMINISTRATION

1. **Objective:** The objective of Research Grants is to encourage orthopedic trauma surgeons and basic scientists by providing seed and start-up funding for promising research projects in the field of orthopedic trauma surgery through Grants of up to US$ 50,000 for a research project extending over a maximum of two years. Both laboratory and clinical projects are suitable, but in either case clinical relevance must be explicitly and clearly described.

2. **Eligibility:**

   - A trauma or orthopedic surgeon 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 orthopedic surgeon as the co-principal investigator.
   - Candidate may not submit a proposal if a grant awarded previously has not been completed.
   - Candidate may receive only one OTC Grant per institution in each year.

3. **Deadline** for submission of Application Form: **April 15, 2017**. This is the **DUE date**, not the postmark date.

4. **Period of Grant:** September 2017, through August 2019, maximum two years.

5. **Amount:** Up to US$ 50,000 during Period of Grant.

6. **Application Procedure:** The original application must be clipped, not stapled; original signatures should be in blue ink. The original must be single sided. Total **Research Plan is not to exceed four (4) pages.** Margins must be 1 inch. The application must also be submitted to OTC Research Committee electronically. The main form and optional supplement as Word file, the signature page as PDF.

7. **Application Items Required:**
   - Electronic application (e-mail) must arrive by the **April 15, 2017** deadline. Original application (**with all signatures**) must arrive in the OTC office by **May 15, 2017**.
   - Provide Animal IACUC approval, or equivalent according to your national regulations, if applicable.
   - Provide Human IRB / Ethical Committee statement, or equivalent according to your national regulations, if applicable.
   - Provide statement clarifying the role of the orthopedic surgeon in the project.

8. **Notification of Award and Contracts:** The OTC Foundation will notify each applicant by email until **July 15, 2017**. Contracts will be offered immediately thereafter.

9. **Submission Instructions:** Complete applications should be submitted to:
   OTC Foundation
   Emmenholzweg 1
   CH-4528 Zuchwil
   Switzerland
   An electronic copy (application form as Word file; signature page as PDF) should be sent to research.grants@otcfoundation.org

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

II. INSTRUCTIONS FOR COMPLETING FULL-LENGTH RESEARCH GRANT APPLICATION

A. Sections 1 and 7:

1. Section 1 is the cover sheet for the entire application. Please complete all sections.

2. The principal investigator or co-principal investigator must be a trauma or orthopedic surgeon.

3. Please enter specific titles, departments, addresses, telephone and fax numbers, where requested.

4. Signatures are required for principal and co-principal investigator (section 7). Please use blue ink for all required signatures; no per signatures are permitted. **No Grant money will be transferred without a fully completed sign-off sheet.**

B. Section 2:

1. Provide a Curriculum Vitae of the Principal and Co-principal investigator (section 3). Do not exceed 1 page per biosketch.

C. Research Plan (Section 3):

1. Complete this section on continuation pages, giving details following the outline below. **The total proposal (section 3.1 through 3.9) may not exceed four (4) pages. One page containing only Tables and/or Figures may be submitted as supplement**.

   a. Project Title (section 3.1): provide a clear project title (max. 200 characters).

   b. Executive Summary (section 3.2): Provide a maximum 2,500 characters abstract for project summary. State the application's broad, long-term objectives and specific aims, making reference to the trauma care relatedness of the project. Describe concisely the research design and methods for achieving these goals. A timeline should be provided. 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. This summary will be released to the public (OTC website or research book).

   c. Background (section 3.3): Summarize important results to date obtained by others on the problem, citing publications. Clinical relevance must be explicitly, specifically, and clearly noted. In general suggesting that the work will "increase our understanding", will not be considered an adequate explanation. Rather, the relevance must be in terms of how the work will change the way we think about clinical problems and how we may treat patients.

   d. Specific Aims and Hypotheses (section 3.4): Provide testable, null hypothesis(es) with a concise statement of the aims of the proposed research (should not exceed one page).

   e. Pilot and/or previous data (section 3.5): Describe briefly any work you have done that is particularly pertinent. On projects where human subjects are placed at some risk, where animals are used for experimentation, or where there is a laboratory methodology with which the applying institution has not

had well documented experience, the investigator is encouraged to submit data from a pilot study.

f. Research Design and Methods (section 3.6-3.8): Give details of your research plan, including how the results will be analyzed. For each specific aim mentioned in "d", show how your plan is expected to fulfill the aim. Please include an estimated timetable. Also, include the method of statistical analysis, if relevant (section 3.8). Power calculations with clearly delineated assumptions to justify the study sample size, and therefore the cost of the Grant, are expected (section 3.7).

g. Clinical Relevance (section 3.9): Provide one paragraph that explicitly and clearly describes how your research project will impact the clinical practice of trauma/orthopedics. Describe how your project will change the way we think about clinical problems or how we treat them.

h. Relevant publications of the research group (section 3.10): List a maximum of 10 recent publications of the research group that are relevant for the research topic.

i. Literature Cited (section 3.11): List the references used in the application, including author list and full titles. This section is restricted to 20 references.

D. Sections 4:

1. Human Subjects (section 4.1) - Attach a Human IRB statement, Ethics Committee approval or equivalent according to your national regulations, if applicable. Ethics approval is required for any study involving patients or patient materials.

2. Vertebrate Animals (section 4.2) - Attach a Vertebrate Animal IACUC approval or equivalent according to your national regulations, if applicable.

E. Sections 5 and 6:

1. Enter budgets for research period in section 5.

2. Personnel (section 5.1): State what each person will be doing. No salary can be requested for the principal investigator or co-principal investigator.

3. Permanent equipment (section 5.2): Any major piece of equipment or apparatus costing more than $500 should be itemized, and justifications made. Permanent office equipment cannot be charged against the grant, unless justified reasonably.

4. Consumable supplies (section 5.3): Glassware, chemicals, supplies and all expendable materials may be grouped in this category under appropriate subheading.

5. Animal charges, core facility fees, and fees for special procedures must be itemized (section 5.4).

6. No travel funds can be charged against the Grant.

7. All other expenses (section 5.5):
   - Publication costs, including up to 200 reprints, without covers, of any paper carrying the credit line "Aided by a Grant from the Osteosynthesis and Trauma Care (OTC) Foundation" may be charged against the Grant if the principal investigator so desires.
   - No overhead or indirect costs can be charged against the Grant.

8. Other financial support (section 6.1):
   Provide information on other support in the format shown. List any research funding relevant to this topic and/or project, the Principal Investigator, Co-Principal Investigator, and other investigators have received or have applied for.

G. Correspondence:

Completed application and required copies should be directed to:

OTC Research Committee
OTC Foundation
Emmenholzweg 1
CH-4528 Zuchwil
Switzerland
research.grants@otcfoundation.org

III. 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 OTC, 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.

   (*) The OTC Foundation finds that permanent office equipment such as computers, scanners, printers, etc., in principally cannot be charged against a grant. Exceptions can be made, but only if justified reasonably.

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

3. Ownership of the Equipment - Equipment purchased under OTC Grants becomes the property of the institution, unless otherwise specified by the OTC before termination of the Grant or its extensions.

B. Budget Policies and Reports

1. Grant Term: Upon notification of Grant award, grantees must send in the signed grant letter and a fully singed 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 OTC 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 OTC 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 OTC. 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 $100 or more less any uncancellable obligations which have been subject to OTC prior approval and do not exceed the budget, must be refunded to the OTC 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 OTC prior to making any changes to approved budget.

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

C. Policy on Delinquent Financial/Research Reports

The OTC 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 OTC. 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 OTC 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 OTC 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. OTC 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. OTC 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 OTC 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 OTC, requesting permission to change the procedure and state the reasons for the change. The OTC 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 OTC 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 OTC 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 OTC 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 OTC undertake mutually that they shall neither give nor make available Confidential Information to any third-party. OTC 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 OTC. 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 OTC, the OTC reserves the right to negotiate a proportionate interest in the royalties.

M. Publication

1. The OTC 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 OSTEOSYNTHESIS AND TRAUMA CARE (OTC) FOUNDATION"

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 OTC 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. The OTC imposes no restrictions on copyrighting publication by Grantees.

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 OTC 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.