

ISAKOS RESEARCH GRANTS PROGRAM: POLICIES & PROCEDURES

I. Available Grants

ISAKOS will consider applications for four types of grants:

- New Researcher Four possible grants for eligible applications with scientific merit. One grant at up to \$25,000 USD and three additional grants at up to \$10,000 each.
 - New Researcher grant qualifications: has not received external funding over \$15,000; no significant history of publication, presentations, or research/experiment participation. *
- Translational Research Four possible grants for eligible applications with scientific merit. One grant at up to \$20,000 USD and three additional grants at up to \$10,000 each.
 - Foster high quality clinical or translational research in early osteoarthritis and prevention, as well as treatment of osteoarthritis.
 - Could include total knee replacement, osteotomy, meniscal transplant, OCD transplant, etc.
- Clinical Outcomes One grant for eligible applications with scientific merit up to \$50,000.
 - Support outcomes research through well-designed clinical trials to evaluate the efficacy of interventions in orthopaedic sports medicine.
 - Example: Level I III study on biologics in Rotator Cuff repair
- Countries with Limited Resources Two possible grants for eligible applications with scientific merit. One grant at up to \$15,000 and one additional grant at up to \$10,000.

*New Researchers and Countries with Limited Resources applicants are requested to enlist the assistance of a research mentor from the Scientific Committee members to assist in the research project.

Please note the limitations for grant funding include:

- No indirect costs
- Equipment purchases using grant funds must be approved in advance by the Research Advisory Group.
- ISAKOS must be named in research title & publication.
- ISAKOS will review industry requests for access to study data.
- All other research funds received for the study must be disclosed.

II. Eligibility

The applicant must serve as the principal investigator and be an Active Member of ISAKOS in good standing.



- A. The orthopaedic surgeon/principal investigator must provide a statement on time to be allocated to the project indicating percent of average time allocated and how time will be spent. It is suggested that a timetable be provided as part of the Research Plan, to be included with the grant application.
- B. All proposals must be clinical or translational, including the study of live patients, cadaveric models or animals.
- C. Applicants are limited to one submission per individual for grant funding term.
- D. ISAKOS will fund only one research grant per institution per year.
- E. All members of the ISAKOS Grant Review Committee (IGRC) and the Executive Committee and their institutions are not eligible to apply. The ISAKOS Grant Review Committee (IGRC) consists of the Scientific Committee Chairs (Chair, Deputy Chair, and Immediate Past Chair). The Executive Committee will serve as final review of disputed winners. Elected Grants are sent to Executive Committee to confirm correct rules were followed for Review Process.
- F. All members of Research Infrastructure Task Force are not eligible to apply. The Task Force will make recommendations related to international research collaborations and registries.

III. Fiscal Policies and Procedures

- A. Facilities to be provided by Grantee Institution(s):
 - 1. Grantee Institution(s) are 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.
 - 2. In particular, it is expected that the grantee institution will provide, whether from its own funds or from grant funds other than those of ISAKOS, the following, unless otherwise specifically agreed upon:
 - a) Laboratory space
 - b) Maintenance service, including maintenance, supplies, and service contracts.
 - c) Telephone services
 - d) Library service, including subscriptions to periodicals and the purchase of books.
 - e) Laboratory furniture
 - Salary of principal investigator, co-principal investigator and of secretarial personnel
 - g) Worker's Compensation, public liability, or other hazard and special insurance
 - h) Office equipment
 - i) Employee group life, disability, medical expense, or hospitalization insurance
 - j) Lantern slides, color plates, etc.
 - k) Hospital bed expenses, nursing, or related services, even those used for research studies.
 - Indirect Costs
 - m) Tuition expenses of personnel on grant.



- B. As a matter of policy, ISAKOS funds may not be used for remodeling or building construction costs.
- C. Ownership of the Equipment: Equipment purchased under ISAKOS grants becomes the property of the Grantee Institution, unless otherwise specified by ISAKOS before termination of the grant or its extensions.
- D. Use of ISAKOS research grant funds may be used for a Contract Research Organization which will support data management and carry out statistical analysis, biological analysis and dissemination activities.

IV. Budget Policies and Reports

- A. 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 ISAKOS for approval, within thirty (30) days after notification.
- B. Reports of expenditures must be prepared every six months, be signed by the responsible financial officer, and submitted to ISAKOS for approval with accompanying documents. The approved financial report is returned to the financial officer with the grant payment. Expenses must be submitted by category (e.g., Salary and Wages, Equipment, Supplies, Animals, Other, etc.). Fifty percent (50%) of ISAKOS funds must be expensed before the next grant payment will be sent.
- C. Ten percent (10%) of grant funds will be withheld until the final report of expenses and the two final reports of the research are received by ISAKOS. Upon receipt of both reports, withheld funds will be sent to the grantee institution.
 - 1. At expiration of grant, any unexpended balance of \$100 or more must be refunded to ISAKOS within sixty (60) days together with the report of expenditures and accompanying documentation, properly submitted.
 - 2. Separate accounts must be maintained for each grant. These accounts, with substantiating invoices and payrolls, must be available at all times to representatives of ISAKOS.
 - Grantee must request permission and receive written approval from ISAKOS prior to making any changes to approved budget and moving funds between budget categories.
 - 4. Grantee may terminate a grant prior to its normal expiration date by notifying ISAKOS in writing and stating the reasons for termination. Unexpended funds must be returned to ISAKOS within sixty (60) days, together with a final report of expenditures. ISAKOS reserves the right to terminate grants at any time upon three months written notice.
 - 5. If grantee has not completed the project prior to expiration, and for just reason, grantee may submit to the Grants Board thirty (30) days prior to expiration, a request for a no-cost extension, stating reason and requested period of extension.



6. If a grant recipient receives NIH or other funding for this project before or during the term of their grant, they are required to notify ISAKOS of such funding. They are also required to submit a financial report of expenses for monies already expended and return the remaining funds to ISAKOS. ISAKOS then cancels the grant and returns the monies to the grants pool for the funding of future grants.

V. Research Reports

- A. Progress Report
 - 1. **Grantees must submit quarterly progress reports on January 1, April 1, July 1, and October 1.** This allows time to set up the project and report on the progress to date. It is extremely important that the investigator report these accomplishments, because the criteria established in the proposal will be used by the reviewers to determine if funding should be continued.
 - **2.** The report must be sent to ISAKOS; an electronic version is acceptable. Upon receipt of an acceptable report the investigator will be notified of continued funding.

B. Final Reports

- 1. Grantees are required to submit two versions of the final report to ISAKOS. The investigator is given six months 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 for general understanding of the project and would be similar to a press release stating what was accomplished during the period of the grant.
 - c) An electronic version of both reports is required and will be periodically reviewed by the Scientific Committee.
- C. ISAKOS reserves the right to deny additional grants to any institution where the final reports have not been submitted within six months, or if they are deemed inadequate or insufficient.

VI. Policy on Delinquent Financial/Research Reports

ISAKOS reserves the right to deny additional grants to any institution where after proper notification, an investigator has not submitted their final reports, and/or the financial officer has not submitted the final report of expenses, as required. This policy will be enforced when reports are one year past the final due date (18 months after the project ends). Upon receipt of these reports, the institution shall again become eligible for ISAKOS grants.

VII. Policy on Animals in Research



- A. The institution must justify the number of animals requested for project and, if applicable, provide IACUC approval, regarding the use of and number of animals requested for project.
- B. All animals used in research supported by ISAKOS 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 kinds and sources of animals that are most appropriate for particular studies. ISAKOS 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.

VIII. Policy on Human Subjects in Research

- A. Use of human subjects and sample size must be justified. If applicable, IRB statements from your 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.
- B. ISAKOS grantees are entrusted to assure adequate protection of human subjects. NIH regulations or the country's equivalent where the patients are studied regarding human subjects should be followed.

IX. Policy on Transfer of Grant

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

X. 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 ISAKOS requesting permission to change the procedure and state the reasons for the change. The ISAKOS Scientific Committee Chair will respond to the principal investigator.

XI. Policy on Requesting Additional Grant Funding

In certain rare and unusual instances, the principal investigator and collaborators may find that the original funding approved for the grant will not be sufficient for the original aims of the grant to be accomplished and that to continue/complete the project, an extension and additional funding is needed. In such uncommon cases, the principal investigator must write to ISAKOS indicating an extension and additional funding is requested. Any requests for extensions with additional funding must be submitted in the form of an additional application, to be submitted when ISAKOS opens and accepts new applications for Research Grants (typically each term in the odd year, between June 1 and September 1). The ISAKOS Scientific Committee's Research Advisory Task Force will review such requests for additional grant funding while reviewing all new applications for grant funding. If approved, a notification of award



will be made to the principal investigator, along with a request for completion of an updated budget form (see Budget Policies and Reports). Grantees approved for such an exception of additional grant funding will be expected to continue submitting quarterly progress reports as well as a final report upon completion (see Research Reports).

XII. Publication

- A. As of January 1, 2018, the Journal of ISAKOS retains first right of refusal for publication of original scientific content produced as a result of research funding.
- B. ISAKOS encourages 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 INTERNATIONAL SOCIETY OF ARTHROSCOPY, KNEE SURGERY AND ORTHOPAEDIC SPORTS MEDICINE AND THE ORTHOPAEDIC RESEARCH AND EDUCATION FOUNDATION

- C. Additionally, when a grantee presents a paper at a professional scientific meeting, the aforementioned acknowledgment must be included.
- D. ISAKOS 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.
- E. ISAKOS imposes no restrictions on copyrighting publication by grantees.

XIII. Patents

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