

ISAKOS RESEARCH GRANTS PROGRAM: POLICIES & PROCEDURES

I. Available Grants

ISAKOS will consider applications for four types of grants: (Depending on funding and applications)

- New Researcher – New Researcher grants qualifications: has not received external funding over \$15,000; no significant history of publication, presentations, or research/experiment participation.
- Translational Research - 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 – Support outcomes research through well-designed clinical trials to evaluate the efficacy of interventions in orthopaedic sports medicine. Example: Level I - III study on Orthobiologic augmentation in Rotator Cuff repair
- Countries with Limited Resources – As defined by the world health organization's list of countries with limited resources

All four grant types require applicants to enlist the assistance of a research mentor to assist with the research project. The mentor must be an Active ISAKOS member and confirm mentorship acceptance.

Applications are evaluated and ranked within their own grant type category only. An application competes only against other applications submitted under the same grant type; it does not compete against applications submitted under a different grant type.

Please note the limitations for grant funding include:

- No indirect costs
- Equipment purchases using grant funds must be approved in advance by the ISAKOS Grant Review Committee.
- 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.

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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 or receive a grant. The ISAKOS Grant Review Committee (IGRC) consists of the Scientific Committee Chairs (Chairs, Deputy Chairs, 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. Review Process: Eligibility and compliance items are reviewed first, before any scientific scoring begins. An application that fails any eligibility or compliance requirement is denied without further review. If a reviewer identifies a conflict of interest with a specific application, that reviewer must recuse from reviewing that application; the application is reassigned to a different reviewer rather than denied.

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. 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
 - f) 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.
 - l) 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. 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. Term and Extension Limits

- A. Initial Grant Term: The maximum duration for an initial research grant term shall be two years from the time the grant agreement is signed by all parties. Grants may be awarded for shorter periods, subject to the needs of the research project and availability of funds. With the exception of Clinical Outcomes Grants. Clinical Outcomes grant term shall be four years from the time the agreement is signed by all parties.
- B. Extension Request: Grant terms may be eligible for a one-time extension upon completion of the initial 2-year term. Requested extensions, which must be submitted by the principal investigator at the end of the initial 2-year term, are subject to a review process. To be approved for a 2-year term extension, funded research projects must demonstrate substantial research progress during initial term, as well as continued relevance of the research.
- C. Maximum Total Duration: The total duration of funding for any single research project, including both initial grant term and the one-time extension, shall not exceed 4 years from the time the grant agreement is signed.

V. Budget Policies and Reports

- A. ISAKOS Research Grant funds are provided to the Grantee Institution following completion of a signed agreement; funds are not provided by ISAKOS directly to the principal investigator.
- B. If approved grant is less than the budget requested, budget forms will be sent to grantee when notification of award is made, for updating the budget in line with approved grant. 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 of award.
- C. Reports of expenditures must be prepared every six months during the 2-year grant term, be signed by the responsible financial officer, and be submitted to ISAKOS for approval with accompanying documents. Expenses must be submitted by category (e.g., Equipment, Supplies, Animals, Other, etc.). Fifty percent (50%) of ISAKOS funds must be expended before the next grant payment will be sent, up to a total of 90% of grant funds.
- D. Ten percent (10%) of grant funds will be withheld until the final report of expenses and the two final reports on the research project are received by ISAKOS (see "Final Reports" below). Upon receipt of both reports, withheld funds will be sent to the grantee institution.
 - 1. At expiration of grant term, any unexpended balance of \$100 or more must be refunded by grantee institution to ISAKOS within sixty (60) days, together with the final 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 always be available to representatives of ISAKOS.
3. 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-funded research project prior to its normal term expiration by notifying ISAKOS in writing and stating the reasons for termination. Unexpended funds must be returned by grantee institution 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 initial grant term expiration, and for just reason, grantee may submit to the ISKAOS Grant Review Committee thirty (30) days prior to expiration, a request for a one-time 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 ISAKOS funds 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.

VI. 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 principal investigator complete these quarterly progress reports and document accomplishments, because the criteria established in the proposal will be used by the reviewers to determine if funding should be continued.
2. Each quarterly 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 up to six months to complete the reports following the grant term.
 - a) One version is the scientific report of the project. This report should refer to the original proposal so the reviewer can determine whether 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 like 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 reviewed by the ISAKOS Scientific Committee.

C. 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 Delinquent Financial/Research Reports

Research Grants are considered delinquent if no Research Reports or Financial Reports are submitted a minimum of once during each calendar year of the grant term. ISAKOS will notify the Grantee and the Grantee institution of the delinquency and provide a grace period of 30 days for the submission of any overdue report(s). The notification will include a new deadline for report submission and instructions for addressing any deficiencies.

If the report remains delinquent beyond the grace period, ISAKOS reserves the right to take the following actions:

1. Suspension of Funding: Funding may be suspended until the required reports are submitted and approved.
2. Termination of the Grant: ISAKOS reserves the right to terminate the grant before its scheduled expiration if the Grantee fails to comply with the report requirements. Termination will be effective immediately upon notification to the Grantee. ISAKOS then officially cancels the grant and returns the monies to the grants pool for the funding of future grants.
3. Recovery of Funds: In the event of grant termination due to delinquent reporting, ISAKOS may seek to recover any disbursed funds that have not been properly accounted for.

Exceptions to this policy may be granted under exceptional circumstances, such as serious illness or other unforeseen situations. Grantees may appeal grant termination or suspension decisions by submitting a written request to the Grants Review Committee. Appeals must be submitted within 30 days of receiving the termination notice and should include a detailed explanation and any supporting documentation.

VIII. 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 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.

IX. 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.

X. Policy on Transfer of Grant

If the principal investigator moves to a new institution, he/she must submit a letter to ISAKOS requesting a transfer of grant. This letter must detail resources, personnel, and curriculum vitae of investigators at the new institution. In addition, the letter must be signed by both a financial officer at the original grantee institution, and by a financial officer at the new institution. The ISAKOS Grant Review Committee shall review the request to determine whether the change in institution is approved and respond to the principal investigator. This step shall be taken for any institution changes, whether occurring before signature of the funding agreement or after, and, if approved, a new funding agreement must be put in place with the institution to which future fund disbursements would be made, prior to any additional funding.

XI. 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.

XII. 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, financial reports every 6 months, as well as required final reports upon completion (see Research Reports).

XIII. Publication

- A. The Journal of ISAKOS retains first right of refusal for publication of original scientific content produced as a result of research funded by ISAKOS.
- B. ISAKOS Research Grant recipients are encouraged to use awarded funds to cover Article Processing Charges (APCs) for publications in JISAKOS or other journals.
 - 1. Research Grant recipients may request a waiver for one APC for a manuscript accepted by JISAKOS. Please note that waivers are not guaranteed. Grant status must be clearly stated in the cover letter at the time of submission. APC waivers are limited and will be considered only for manuscripts that are accepted for publication.
- C. 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
- D. Additionally, when a grantee presents a paper at a professional scientific meeting, the aforementioned acknowledgment must be included.
- E. 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.
- F. ISAKOS imposes no restrictions on copyrighting publication by grantees.

XIV. 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.