FUNDING SOURCE DEVELOPMENT GRANT

GOAL
The overall aim of this grant mechanism is to facilitate clinical research proposals to achieve a funding source.

PURPOSE
The Funding Source Development Grant (FSDG) is designed to support projects in clinical research areas important to the advancement of interventional radiology and patient care that align with SIR Foundation clinical research goals. The Funding Source Development Grant will provide support for costs related to developing any of the following:

- A complete protocol for a clinical study
- A federal application designed to seek support for a clinical study from the NIH, AHRQ, or other federal entity
- A complete clinical proposal designed for subsequent industry funding
- An operations/training manual and supporting materials as needed for a clinical study

This grant mechanism is designed to provide support for the development of projects that are identified and highly prioritized by a SIR Foundation Research Consensus Panel (RCP). However, proposals that did not go through the RCP process are also eligible for consideration. The FSDG is a planning grant and is not designed to support the collection of data or the conduct of the study.

EXAMPLES OF RESEARCH TOPICS
Projects may include but are not limited to topics such as:

- Optimal anti-thrombotic/anticoagulation strategies after venous interventions
- Nanotechnology and nanomedicine
- Women’s Health Research Agenda
- Role of Image Guided Treatment for non-GI Oligometastatic disease
- Integrating locoregional therapy with systemic therapy for HCC

AWARD
Grant funding up to $25,000 for 12 months (1 year)

ELIGIBILITY

RCP APPLICANTS:
- Grant applications are open to IR physicians who were lead PI on a Research Consensus Panel (RCP).
- The applicant must be a SIR member (in Good Standing of the Society of Interventional Radiology (SIR).
- **If an RCP applicant is the designated author of the RCP proceedings paper, s/he must have submitted a copy of the paper to SIR Foundation for publication in the JVIR prior to submitting a grant application.** Applicants who have already received major funding for their proposed clinical study will not be eligible for the FSDG. Major funding criteria is considered greater than or equal to $250,000 collectively for their specific proposal.
- Applicant must have an MD, DO, PhD or equivalent degree from an accredited educational institution within the United States and Canada.
- Applications will be accepted from citizens of the United States or Canada or those who have permanent resident status therein. Permanent residents must submit documentation of their status. If an applicant is at an institution in the US or Canada and is on a visa, a letter will be required from the department chair guaranteeing completion of the FSDG project, as well as permission for the applicant to complete the
proposed clinical study in the event that the project is funded.

- Lead Investigators may apply for funding on behalf of RCP panelists who wish to assist in the clinical project development phase. A Letter of Intent (LOI) is not required for lead investigators.
- If an applicant participated in an SIR Foundation RCP as an RCP panelist and wishes to apply, s/he must follow the non-RCP application procedures therefore, s/he must first submit a letter of intent (LOI).
- The RCP meeting must be completed before applications can be submitted for the Funding Source Development Grant.

NON-RCP APPLICANTS:

- The applicant must be an SIR member in good standing.
- Applicant must have an MD, DO, PhD or equivalent degree from an accredited educational institution within the United States and Canada.
- A Letter of Intent (LOI) must be submitted to SIR Foundation for review and consideration before a full grant application can be submitted. SIR Foundation will notify the applicant of decision within four weeks of LOI submission.
- Applications will be accepted from citizens of the United States or Canada or those who have permanent resident status therein. Permanent residents must submit documentation of their status. If an applicant is at an institution in the US or Canada and is on a visa, a letter will be required from the department chair guaranteeing completion of the FSDG project, as well as permission for the applicant to complete the proposed clinical study in the event that it receives funding.
- Applicants who have already received major funding for their proposed clinical study will not be eligible for the FSDG. Major funding criteria is considered greater than or equal to $250,000 collectively for their specific proposal.
- If an applicant participated in an SIR Foundation RCP as an RCP panelist and wishes to apply separately must follow the non-RCP application procedures therefore, s/he must first submit a letter of intent (LOI).

The Foundation leadership may modify the above if the Foundation considers the proposed project an immediate research need.

APPLICATION PROCEDURES

Applicants should propose a clinical research project that advances the field of interventional radiology. Grant applications must be submitted electronically through the online platform found at apply.sirfoundation.org by December 14, 2020. Applications must be submitted in PDF format. Incomplete applications and those submitted after the deadline of December 14, 2020 will not be reviewed.

Grant recipients will not be eligible for concurrent support through other SIR Foundation Research Grants. SIR Foundation will not accept applications that are essentially the same as one already reviewed and funded through another organization. There can be no scientific overlap.

Scientific overlap occurs when (1) the same research proposal is submitted to more than one application or submitted to two or more funding sources for funding consideration (2) specific research objective and research design are the same or are closely related in two or more applications.

Non-RCP applicants: Must first submit a letter of intent for review and consideration before submitting a full grant application. Projects should address areas of clinical research that align with SIR Foundation research
goals.

A **Letter of Intent (LOI)** providing an overview of the project and explaining how the proposed project would benefit the advancement of interventional radiology must be submitted by the LOI deadline. The LOI should not exceed a few pages excluding the publications list and the CV.

The suggested format is:

I. Project Title
II. Name of PI
III. Executive Summary Paragraph
IV. Background
V. Specific Aims
VI. Methodology
VII. Impact
VIII. Estimated Budget
IX. Timeline
X. PI’s positions and honors
XI. Selected Peer Reviewed Publications and CV

The LOI will be reviewed by SIR Foundation’s grant review committee to determine if the proposed project aligns with SIR Foundation clinical research goals as determined by the Foundation Board of Directors. The applicant will be notified within four weeks whether or not a full application should be submitted by the deadline.

The LOI should be submitted electronically in PDF format to SIR Foundation Manager of Research and Grants. **The deadline to submit the LOI for Non-RCP Applicants is May 28, 2020.**

If invited to submit a full application, the full grant application will be due by the Funding Source Development Grant application deadline (December 14, 2020). Once the LOI has been approved, the applicant should refer to the GRANT APPLICATION FORMAT when preparing the full application.

**RCP Applicants:** For RCP applicants, Research Consensus Panel Principal Investigators may apply for funding on behalf of RCP panelists who wish to assist in the clinical project development phase. **An RCP panelist who wishes to apply separately must submit a letter of intent (LOI) by November 14, 2020** and follow the non-RCP application procedures above. The RCP meeting must be completed before applications can be submitted for the Funding Source Development Grant. (If an RCP applicant is the designated author of the RCP proceedings paper, s/he must have submitted the paper to the Foundation for publication in the *JVIR* prior to submitting a grant application. The RCP proceedings paper due date is 30 days from the RCP date). **A letter of intent is not required for RCP Lead Investigators.**

**AWARD GUIDELINES**

Allowable costs in the final budget may include funds used for meetings, conference calls, travel, hotel facilities, meals, and audio and visual equipment usage/rental. Additional allowable costs may include consultant fees for biostatistician(s) and/or grant writer for review of developed project materials. If needed, SIR Foundation can provide consultant contact information. Unallowable costs include the following: faculty salaries, institutional indirect/overhead costs, and secretarial or office expenses.

**GRANT APPLICATION FORMAT**

When uploading your grant application to our online form, you must save your grant application using the naming convention below:
2021_APP_Funding Source_Mary Johnson

If you have a resubmission, you must save your grant application using the naming convention below:
2021_APP_Resubmission1_Funding Source_Mary Johnson

All the items detailed below must be included in the application before it will be considered. The format should follow the guidelines used for NIH applications. (LIMIT – FIVE (5) PAGES FOR SECTIONS A-D)

I. Title Page:
   A. Title of Research Project;
   B. Name, faculty position, and department of principal investigator, as well as other professional personnel collaborating in the research project;
   C. Brief abstract (ten [10] to twenty [20] lines), with keywords underlined;
   D. Beginning and termination dates of proposed expenditures for the Funding Source Development Grant project (the grant project refers to writing the protocol and accompanying documents to submit as part of the application to a larger funding source);
   E. Total funding requested for the Funding Source Development Grant project with specific breakdown:
      i. The schedule of meetings, e.g. weekly/biweekly to develop the protocol and operations/training manual and how they will be conducted, e.g. conference calls, in-person meetings, required travel, etc.
      ii. If intending to use a grant writer to review the Funding Source Development Grant project (e.g. the application to a larger funding source), include the consultant fees in the budget proposal.
      iii. As stated in the Award Guidelines section above, funds for the Funding Source Development Grant can be used for items including: meetings, conference calls, travel, hotel facilities, meals, audio and visual equipment usage/rental, and consultant fees for a grant writer and/or biostatistician to review the project materials once developed, etc.
      iv. Unallowable costs include: faculty salaries, institutional indirect/overhead costs, and secretarial or office expenses, and will not be funded.
   F. Signature of principal investigator
   G. Contact information of the principal investigator’s institution

II. Description of Research Plan for which the applicant is writing a protocol for the proposed study. The applicant must present his/her research logically and clearly and show that the proposed research is meaningful. (5-page limit for items A-F)
   A. Specific Aims: State in a concise and explicit manner what is/are the specific aims and hypothesis that will be tested by the implementation of the clinical research study.
   B. Background and Significance: State why the proposed work is important. Briefly identify what others have done and what gaps in existing knowledge will be filled by the results of the clinical research study.
   C. Preliminary Studies: Applicants should provide any data they have generated relevant to the application in a concise format (including references to published works by the applicant and co-investigators) to support the specific aims. (approximately one page)
   D. Research Design: Discuss the procedures to be used to test the hypothesis or accomplish the specific aims of the clinical study. Provide specific details of techniques/devices that will be employed as well as the rationale for using them. If new procedures and protocols are proposed, describe advantages over existing methodologies. Indicate how the data will be captured and analyzed. Describe the site selection plans, and if intending to request SIR Foundation involvement. Provide a discussion of the potential difficulties, limitations, and alternative approaches.
   E. Discuss any potential funding sources for the implementation of the clinical research study (providing letters of support, if possible). Indicate the desired launch timeline of the clinical study.
   F. Budget Proposal: This is the proposed budget that you will include in your application to a larger
funding source, not the budget for the Funding Source Development Grant. The Funding Source Development Grant budget should be included with Section I, Part E above.

G. Literature Cited

H. CVs of the Principal Investigator and interdisciplinary research team

I. Letters of Support from any potential Collaborative Principal Investigators or others that may participate in the execution of the study.

REVIEW PROCESS

All complete and eligible applications will be reviewed based on the scientific merit, the innovative quality of the research proposal, whether the proposal is an area of research prioritized by SIR Foundation and relevant to interventional radiology, the likelihood that the proposal can achieve subsequent funding and is feasible, and the qualifications of the applicant.

Letter of Intent (if applicable)

The LOI will be reviewed for non-RCP applicants and will receive notice of the decision within four (4) weeks of submitting the LOI.

If a LOI is submitted by an RCP applicant, they will receive notice of the decision in two (2) weeks of submitting the LOI.

If the LOI is approved and the proposal is submitted by the December 14th deadline, the application will follow the below levels of review.

First Level of Review

Completed applications will be initially reviewed by members of the SIR Foundation Grant Review Study Section, who will submit preliminary scores for each of the assigned applications. Members of the study section are assigned grant applications based on their expertise in the particular area of the proposed investigation and will review each application for scientific merit.

Second Level of Review

After the first level of review when scores are submitted for each application, reviewers will convene during Study Section held at the SIR Annual Scientific Meeting, where applications will be discussed for a second level of review and funding recommendations will be made to the SIR Foundation Board.

Post Review

The SIR Foundation Board will review funding recommendations made by the Grant Review Study Section and will make the final funding decisions. Grant applicants will be notified of final funding decisions after the SIR Annual Scientific Meeting.

AWARD PAYMENT SCHEDULE

Funding for the grant is based on the scope of the development. The funds are to be utilized to develop a clinical protocol to a standard likely to receive outside funding. Grant funds will be distributed in three installments: 40% will be paid at the start of the project, then 40% after review and approval of the Interim Progress Report (IPR) due six months after the project start date, and the final 20% will be distributed after completion of the grant project (12 months) and subsequent to the approval of the submitted Final Progress Report (FPR) (outline of progress report can be found under the Reports section of these guidelines).

There will be a grant contract between SIR Foundation and the PI’s institution. Funding will be disbursed to the PI’s institution.

The following information is needed to disburse funds:
1) Grant Official or Grant Administrator’s name, phone number, and email address
2) To whom the check should be made payable to
3) Mailing address (where payment should be mailed)

MODIFICATION OR TERMINATION OF SUPPORT
SIR Foundation reserves the right to modify or terminate the amount of any funds granted under the terms of the Funding Source Development Grant. Generally, such action would be based on the awardee’s receipt of support from sources other than SIR Foundation which might (1) limit the ability of the recipient to successfully complete the terms of the award or (2) obviate the recipient’s need for funding from SIR Foundation.

Transfer of Institution or Change of PI
In the event that the grantee relocates to a different institution, a request in writing to relocate the grant to the new institution may be made to the Director of Research and Grants. SIR Foundation will continue project funding provided a letter from the department chair is submitted to SIR Foundation indicating the PI is guaranteed support, protected research time, and adequate equipment/facilities from the new institution. The grantee must also submit any IRB or IACUC approvals to SIR Foundation, if applicable. If the new institution cannot provide the necessary support, IRB approval, or IACUC approval for the project, the original institution may appoint a new principal investigator, with SIR Foundation’s approval, to complete the project. If the project cannot be completed at the new or original institution, then all unexpended funds must be returned to SIR Foundation.

In the event that there must be a transfer of PI on a grant, the grantee must request SIR Foundation approval to appoint a permanent replacement or an interim PI.

The request of either a transfer of institution or change of PI must include the following:
• Reason for change
• CV of new PI
• Budget changes resulting from the transfer of institution or change of PI
• If transfer of institution, include expended and unexpended funds.
• Authorized business official (grant administrator) of new institution, including name, address, phone number.
• Signatures of PI, grant administrator, and department chair

REPORTS
An Interim Progress Report (IPR) is required after the first six (6) months of the project. The IPR must be submitted electronically through the online forms found at apply.sirfoundation.org. This report should be a one-page synopsis of the progress, unforeseen problems, and results to date.

Included with the report should be a cover letter that:
1. States the specific aims/goals of the research project(s) and summarizes the results to-date relating to each specific aim/goal (all supporting data should be included, if applicable);
2. Indicates the significance/possible clinical impact of the results;
3. States whether the results will be submitted for possible publication, and if so, to what journal;
4. Indicates whether results will be used to apply for additional funding from other sources, and if so, the funding agency and date of application (should be included).
5. When uploading your Interim Progress Report (IPR) to our online forms, please use the naming convention below. The year should be the year that you were awarded.
   a. 2021_IPR_Pilot_Mary Johnson

A final written report must be submitted within sixty (60) days of the project’s completion.
A Final Progress Report (FPR) must be submitted electronically through the online forms found at apply.sirfoundation.org

An FPR should include the following, as applicable:
1. A Statement of the accomplishments/outcomes of this grant
2. The current and future impact (e.g. success stories, statistics, benefits to patients, staff, and/or community)
3. The use of this award to leverage other funding
4. An account of any unexpended funds and/or major modifications of the budget
5. Include signature of Principal Investigator/Program Director’s name, Signature of Authorized Institutional Official, and date
6. When uploading your Final Progress Report (FPR) to our online forms, you must save your Final Progress Report using the naming convention below. The year should be the year that you were awarded.
   a. 2021_FPR_Funding Source_Mary Johnson

**NO-COST EXTENSION**
An extension of the term of the grant may be requested for up to twelve (12) months beyond the original ending date of the grant. The approval of an extension does not include the award of additional funds. A maximum of two 1-year extensions may be requested.

The request for a no-cost extension must be made in writing to the Grant Review Committee at least one (1) month before the original project end date and submitted electronically through the online forms found at apply.sirfoundation.org. The request must include the reason for the extension, the length of the extension (not to exceed twelve (12) months), and a brief project progress report, including to-date findings, problems encountered, presentations/publications resulting from the work, and budget expenditures. The request must be co-signed by the department chair, fellowship program director or other authorized institutional official.

Other requests for changes to the terms of an award should also be addressed to the Grant Review Committee with similar documentation and institutional approvals.

**PRESENTATIONS/PUBLICATIONS**
It is strongly suggested that recipients submit their work primarily to JVIR or to the SIR Annual Scientific Meeting. Requests to submit to other meetings or journals will be considered. Such requested should be made in writing to the Director of Research and Grants and include the reason why submission to the alternate meeting or journal is more appropriate. All posters, oral presentations, and publications must contain appropriate acknowledgement of SIR Foundation’s support.

For any additional questions, please contact SIR Foundation Manager of Research and Grants.