SOCIETY OF INTERVENTIONAL RADIOLOGY (SIR) FOUNDATION
REQUEST FOR PROPOSALS (RFP)

Part 1. Overview Information

Participating Organization:	SIR Foundation
Funding Opportunity Title:	2022 Special Funding for Registries using Standardized/Structured Reporting – Request for Proposals
Number of Applications:	Applicant organizations may submit more than one application, provided that each application is scientifically distinct.
Award Amount:	Project Budget may not exceed $250,000.
Funding Opportunity Purpose:	This opportunity is intended to encourage Interventional Radiology (IR) developmental research using structured reporting and a registry-based approach.
Open Date (Earliest Submission Date)	May 20th, 2022, before 5:00 p.m. EST
Application Due Date:	August 1st, 2022, on or before 5:00 p.m. EST
Scientific Review:	August 2nd, 2022 – September 16th, 2022
Grant Review Study Section Review:	September 2022
Earliest Project Start Date:	January 1, 2023

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

SIR and SIR Foundation believe in promoting a culture of inclusion and strengthening the specialty of interventional radiology (IR) through different perspectives.

SIR Foundation supports research in interventional radiology and benefits researchers at all levels, from graduate students to established practitioners. The emergence of interventional radiology as a medical specialty over the past four decades has changed the face of modern medicine. Developing new devices, better medications, and improved procedures is the process of innovating and research is key to innovation. Fostering research that leads to improved patient care and quality of life is essential to perpetuating the future of this innovative specialty and is the mission of this organization. The Society of Interventional Radiology (SIR) Foundation is dedicated to fostering research in IR for the purposes of advancing scientific knowledge, increasing the number of skilled investigators and developing innovative therapies that lead to improved patient care and quality of life. SIR Foundation is a 501 (c)(3) charitable organization. Our work is not funded through SIR or SIR membership dues.

Successful applications for this opportunity must include a registry-based research design using standardized procedure reporting (structured reporting) with at least 3 separate institutions contributing data. Costs incurred by respondents for the preparation of a proposal and the negotiation of contract are not reimbursable. SIR Foundation is not bound to accept any of the proposals submitted. SIR Foundation reserves the right to accept or reject any offers of proposal without further discussion.

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Section ll. Award Information

Funding Instrument:	All grant applications must be submitted through apply.sirfoundation.org
Clinical Trial?	Allowed
Anticipated Number of Awards:	SIR Foundation will fund relevant and quality research proposals based on the merit of each proposal and total number of submissions during the RFP period.
Project Budget:	Project Budget may not exceed $250,000. Facilities and Administrative Costs (F&A) are not allowable costs for this solicitation.
Award Project Period:	The total project period may not exceed 2 years; a no-cost extension request may be requested for an additional year.
Research Criteria:	SIR Foundation encourages applicants to deliver high impact studies of a registry-based design that can be incorporated into the IR VIRTEX Registry. The successful applicant will have a project that incorporates an existing

research registry into VIRTEX or answers a clinical research question using a registry-based approach. Requirements include:

- A multi-center approach using at least 3 (5 or greater preferred) distinct institutions (at least 1 private practice site preferred)
- Use of Standardized Reports (structured reporting) for procedural data collection (use of existing SIR standardized reports or new standardized reports to be developed in conjunction with the SIR structured reporting committee)
- Plans for data submission into VIRTEX using either automated data submission or manual data entry

Projects that include the following will be viewed more favorably:

- Incorporation of 5 or more sites (total)
- Incorporation of at least one private-practice site
- Incorporation of some sites that have not begun the process of activating VIRTEX
- Incorporation of a plan to enable automated data submission
- Use of validated Patient-Reported Outcomes Surveys, standardized performance measures and/or established performance metrics
- Development and validation of IR-specific Patient-Reported Outcomes Surveys
- Focus in one of the following clinical areas:
    - Uterine artery embolization
    - Prostate artery embolization
    - Joint embolization
    - Peripheral arterial disease
    - Venous interventions
    - Vertebral/Skeletal interventions
    - Stroke interventions
    - Interventional oncology
    - Pain interventions
    - Palliative interventions
    - Pediatric interventions

Please contact Dr. Matt Johnson, matjohns@iupui.edu , or Dr. Raj Shah, RaShah@stanfordhealthcare.org , for any research related questions.


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Section lll. Eligibility Information

1. Eligible Applicants

- Must be an SIR member
- Eligible candidates must be full-time faculty members at an accredited educational institution in the United States. Candidate must hold an MD, DO, PhD, or equivalent degree.
- Applications will be accepted from citizens of the United States. If an applicant is at an institution in the US and is on a visa, a letter from the department chair guaranteeing completion of the project will be required.
- Collaborative funding sources (Federal, academic, corporate etc.) are encouraged, including proposals that augment onto ongoing Clinical Trials.

2. Cost Sharing

This RFP does not require cost sharing.

Section IV. Application and Submission Information

1. Content and Form of Application Submission

It is critical that applicants follow the instructions in this guide. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Formatting Basics

Formatting Basics
Paper Size: Standard paper size (8 1/2" x 11")
Font Size: 11 pt or larger Smaller font maybe used in figures, graphs, diagrams and charts
Recommended Fonts: Arial, Georgia, Helvetica, Palatino Linotype
No headers or footers
Page numbers
Margins: Minimum of ½ inch margin on all sides

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Proposal Component

Section of Application	Page Limits	Details/Instructions
Cover Letter	1 page maximum	Introduction
Project Summary	30 lines of text maximum	The Project Summary is meant to service as a succinct and accurate description of the proposed work.
Project Narrative	3 sentences maximum	Relevance of the proposed research to IR
Specific Aims	1 page maximum	Plan to describe each aim in a separate paragraph. Include a brief summary of the experimental approach and anticipated outcomes for each aim
Research Strategy	5-page limit a. Significance b. Innovation c. Approach	**(a) Significance** - Explain the importance of the problem or critical barrier to progress in interventional radiology. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in interventional radiology or other fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive interventional radiology will be changed if the proposed aims are achieved. **(b) Innovation** - Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. **(c) Approach** - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.

		(d) Explicit timeline with milestones including expectations of and plans for data upload to VIRTEX.
Bibliography & References Cited	None	Provide a bibliography of any references cited in the Research Plan. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations.
Biosketch	5 pages maximum per biosketch (new NIH format)	Completed for all **senior/key personnel** and other significant contributors **A.** Institution and Location in reverse chronological order **B.** Personal Statement **C.** Positions and Honors **D.** Contributions to IR
Current & Pending Awards and Submissions	No page limit Must be completed for each key personnel	**A.** Active **B.** Pending For each category Active (A) and Pending (B) include: Project Number, Source, Title of Project, Major goals of project, Period of Performance, Annual Direct Costs, and Effort

Clinical Trial

Is your project a clinical study or clinical trial?

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention
- Only one aim or sub-aim of your study meets the clinical trial definition

Studies intended solely to refine measures are not considered clinical trials.
Studies that involve secondary research with biological specimens or health information are not clinical trials.

Clinical Trial Documents	
Protection of Human Subjects – IRB Approvals	Attach plan
Multi-site study?	Yes/No
Plan / timeline for data sharing and data upload into VIRTEX	Upload timeline with project milestones
Structure of Study Team	Upload investigator organizational chart
Protocol Synopsis	Primary purpose Intervention type/description Study Phase Intervention Model Masking Is the study randomized or non-randomized?
Approved Institutional Review Board IRB Protocol	Provide if awarded

Budget Documents	
Detailed Budget	Appendix A
Budget Justification	Appendix B

Section V. Application Review Information

Evaluation Criteria and Scoring

Priority scores will range from 1.0 (highest priority) to 9.0 (lowest priority) amongst the following categories:

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- **Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, and appropriate to data submission plans and/or multiple site data integration plans?
- **Innovation:** Is the project original and innovative? For example: the exposition of the metrics being employed, such as which performance measure or patient reported outcomes, or the innovation regarding use of either.
- **Investigators:** Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?
- **Relevance to IR:** Does the application advance the research and/or clinical interests of Interventional Radiology? Does this application offer a potentially sustainable research program that could potentially lead to future NIH funding?

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Section VI. Post Award Compliance

Required Deliverables & Milestones:

Fully Executed Contract
IRB Approval
Interim Progress report
Final Progress report
Draft of publication or proposal for follow-on funding

Activities	Milestones
1st Installment	Fully Executed Contract Signed
2nd Installment	IRB Approval
3rd Installment	Approval of Standardized Reporting Data Elements and Case Report Forms
4th Installment	Successful data submission from at least 3 institutions
5th installment	Successful data submission from all participating institutions

Section VII. Appendices

APPENDIX A: Budget Template

APPENDIX B: Budget Justification