

FUND FOR COLLABORATIVE RESEARCH IN IMAGING (FCRI) GRANT

2024 Request for Applications (RFA)

PURPOSE

The FCRI Grant is designed for unique one-time investments in the most compelling, innovative research ideas that ultimately lead to the advancement of the practice of radiology.

AWARD

Funding of \$42,420 per PI (20% FTE off NIH salary cap as of January 1, 2023, includes fringe + benefits) will be awarded; the ACR will develop the rest of the project budget, with funding needed to be sufficient to support ACR staff and infrastructure. Each project will be awarded for 12 months, with the option for a no cost extension to be requested. Funding is limited for up to two (2) PIs per project. Current NIH salary cap will be utilized at time of award, with a 15% indirect rate.

NATURE OF PROJECTS

Projects are typically pilot or seed grant-type projects that test a new idea or help support a new area or direction of *clinical* research in radiology. These grants generally address a specific hypothesis, and generate preliminary data that could be used to justify or strengthen subsequent comprehensive applications to national peer-reviewed funding agencies. This mechanism is not appropriate for AI development projects, but certainly supports projects related to developing infrastructure to support AI and real-world data (RWD) analysis. Successful applications will require overall project sustainability and collaboration with the ACR. The project must outline a plan for future growth in science and funding. *ACR is welcoming projects related to the domains of our Research Committees: Molecular Imaging, Pediatric Imaging, Cardiothoracic radiology, Neuroradiology, Head Injury, and Interventional Radiology*. Projects that do not fall within the Research Committees may not be considered.

ELIGIBILITY

Applicants must be current, in good standing members of the American College of Radiology. Individuals or dual PIs may submit proposals. Grants are available to full-time faculty and trainees with an MD, DO, PhD, or equivalent degree in educational institutions and private practices within the United States. Applicants must submit a Letter of Intent (LOI) and subsequently be invited to submit a full application.

LETTER OF INTENT AND APPLICATION SUBMISSION AND DEADLINE

To be invited to apply, applicants must first submit a Letter of Intent (LOI) by 5pm ET on January 31, 2024 via email to Research@acr.org. Each LOI must be completed using the template attached to this

HEADQUARTERS 1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St, N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215–574–3150 ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020 Silver Spring, MD 20910 703-648-8900



RFA and should be no more than three (3) pages in length. Incomplete LOIs or those submitted after the deadline will not be considered.

Once the appropriate Research Committee provides project approval via review of the LOI, applicants will receive a letter inviting them to submit a full application via email to <u>Research@acr.org by 5pm ET on</u> <u>May 20, 2024</u>. Applications not submitted by this time or that are incomplete will not be considered.

REVIEW PROCESS

Following an ACR staff administrative review, project concepts in the form of a Letter of Intent (LOI) are then submitted to and vetted by Research Committee Chairs. All LOI applicants are notified of a decision and Chair-approved projects are invited to submit a complete clinical project application to the ACR. ACR staff conducts a preliminary review of submitted applications, and confirms they are complete and meet eligibility criteria. Feasible, eligible applications advance to the members of the FCRI Research Selection Committee (RSC), which includes ACR's Chief Research Officer, ACR Research Commission Chair, and a board member. The RSC reviews eligible applications and makes recommendations on projects to fund. Applicants will be notified of the results of the RSC review process. Awarded applicants may be required to participate in a collaborative design process to further refine the design of the study and resources required.

Funding recommendations may be based on impact, feasibility, funding growth potential or other factors the RSC deems significant. The review process and scoring guidelines are modeled on the NIH scoring system.

- 1. **Significance:** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? Does the project align with the ACR strategic priorities?
- 2. **Investigators:** Are the investigators capable of performing the research described? Do they have the needed skills and expertise?
- 3. **Innovation:** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- 4. **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Is the research approach rigorous?
- 5. **ACR Collaboration*:** Is there suitable collaborative nature with the ACR; specifically, use and description of use of the ACR clinical trial services and infrastructure?

*ACR capabilities attached to this RFA to be used as a reference. Contact ACR Staff at Research@acr.org with any questions about ACR expertise and infrastructure available to proposed projects.

6. **Likelihood of future funding:** Assess description of the likelihood that the pilot data generated from this project could be used in application of federal or non-ACR foundation funding. Assess the likelihood of translation of this project into a larger funded project or trial.

In addition, the RSC will take the following factors into consideration:

HEADQUARTERS 1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150 ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020 Silver Spring, MD 20910 703-648-8900



- **Project Period.** Reviewers will consider whether the requested period of support are fully justified and reasonable in relation to the proposed research.
- Letters of Support. Letters of support with collaborators will be taken into consideration; at least one is required.

PAYMENT SCHEDULE

Upon execution of a fully executed grant agreement, awarded funds are transmitted to the institution(s) for support of the PI(s). Each project will be awarded for 12 months, with the option for a no cost extension to be requested.

APPLICATION PROCEDURES

The application must contain a detailed research plan for the planned research.

A complete application will include a **Research Narrative** limited to ten (10) pages, not including a one (1) page **Executive Summary**, **Reference List**, **Letter(s) of Support** and NIH **Biosketches or CVs** for Key Personnel.

The **Research Narrative** must include the following elements:

- 1. Title of the Activity/Project
- 2. Abstract
- 3. Background and Significance
- 4. Research Strategy
 - Specific Aims
 - o Methods
 - Analysis Plan
- 5. PI Capabilities
- 6. Institutional Capabilities, if applicable
- 7. Project Timeline, including brief descriptions of major milestones
- 8. Financial Sustainability Plan: Describe plans for funding future project phases or expansion at conclusion of FCRI project period.
- 9. ACR Collaboration: Describe how this project will leverage ACR resources

Letter(s) of Support:

At minimum, include one (1) letter of support from the applicant's Department Chair. Additional letters may be submitted at the applicant's discretion.

Biosketches: NIH Biosketch for all Key Personnel or CV if Biosketch is not available.

Reference List

Format: 8.5x11 page size, at least 1.5 spacing, 1" margins, Times Roman font, 10 point size.

HEADQUARTERS 1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150 ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020 Silver Spring, MD 20910 703-648-8900



The application must be submitted electronically via email to <u>Research@acr.org</u> by 5 pm ET on May 20, 2024. Incomplete applications or those submitted after the deadline will not be reviewed.

<u>NOTE:</u> Applicants with questions are encouraged to reach out to ACR staff using <u>Research@acr.org</u> during the application period.

GRANT APPLICATION FORMAT

- 1. Research Narrative limited to ten (10) pages, not including the Reference List
- 2. A one (1) page Executive Summary,
- 3. Letter(s) of Support
- 4. NIH Biosketches or CVs for Key Personnel

When uploading your application elements to <u>Research@acr.org</u>, you must save your files using the naming convention below.

2024_FCRI_<Element Name>_<PI First Initial Last Name>

- 2024_FCRI_Research Narrative_J Doe
- 2024_FCRI_Exec Summ_J Doe
- 2024_FCRI_LoS_J Doe
- 2024_FCRI_CV_J Doe

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W.

Washington, DC 20004 202-223-1670

CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215–574–3150 ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020 Silver Spring, MD 20910

703-648-8900



ACR Center for Research and Innovation (CRI)

Staff and Systems Overview for FCRI grant applicants





ACR CRI Program Overview



Physical facility and virtual program

OVER 50 YEARS' EXPERIENCE

Over **500 projects** conducted, more than **350** research sites worldwide, greater than **170,000 study participants**, **2 million+** images processed annually



Distributed staff and technology



Both remote and central (on-site) inerpretation analysis





\$30-\$40 Million annual budget – both federal grants + industry projects



Core Competencies

Research Programs



Clinical Research Staff

160 Research Staff spread across different areas of expertise

| Finance and Accounting | Information Technology | Imaging Core Lab | Clinical Research Administration: Diagnostic Imaging, Informatics, | Clinical Data Management | Biostatistics | Legal |
|--|---|---|---|---|------------------|----------------------------------|
| Grants and Contracts Specialists | Data Scientists, Imaging Informatics Specialists, Software Engineers, Application Developers, Quality Assurance Specialists | Imaging Technologists, Dosimetrists | Radiation Oncology Clinical Project Managers, Project Associates, Business Developers, Protocol Development, Regulatory Specialists | Data Programmers, Data Managers, Data Analysts | Biostatisticians | Attorneys, Contracts Officers |



ACR Research Operations Infrastructure





ACR CRI Services

Services of a full clinical CRO

| Funding | Project Development | Study Document Creation | | | |
|--------------------------------|--|--|--|--|--|
| Grants and Commercial Sponsors | Study Design and Contracting | Protocol, Charter, Imaging Manual, Data Management Plan, Blinded Read Manual | | | |
| | | | | | |
| Site Services | Study Execution & Operational Management | Analysis | | | |



Research Project Types

Clinical trial services to support all project types



Therapeutic/Response Trials

🗸 Radiation Therapy

Novel Imaging Methods

- Biomarker Development/Validation
- Central Reader Studies





Software/Hardware Validation



Registries



AI Algorithm Development / Validation



Socio-Economic Research



ACR Research Clinical Systems



ACR TRIAD & ACR DART

- TRIAD- <u>Transfer of Images and Data</u>
- Developed to support image-sharing and workflow needs
- Standards-friendly (DICOM, IHE) and FDA Compliant (CFR 21 Part 11)
- Over 10 Years Serving Diagnostic and Radiation Therapy Clinical Trials
- Unique anonymization profiles configured by Administrator
 - Flexibility to assign at the trial, site, submission parameters or DICOM tag level
 - Applied automatically locally prior to ingestion and/or outbound
- ACRConnect, as the next generation, provides a vendorneutral infrastructure, making it easier for collaborations and expansion
- https://acr-1.wistia.com/medias/yark5c83be

- **DART-** <u>D</u>ata <u>A</u>rchive and <u>R</u>esearch <u>T</u>oolkit
- Cloud-based, integrated platform
- Federated access to data across domains for analytics, tool development, and closed-loop storage
- Easier for researchers to analyze images and other clinical data – can run within platform or download locally
- Data commons that houses not just imaging data, but all clinical + imaging data
- https://acr-1.wistia.com/projects/1uile69d9a

Third Party Software Solutions

• Medidata RAVE

- Industry's leading solution for capturing, managing, and reporting patient data
- Scalable, configurable, flexible

| medidata' | D | ev | Hessages 🖾 Ny i | Profile 🖳 Help 🤗 | Home 🕯 | 요 Logout 문 | 1 |
|---|--|-----------------------------------|-----------------|--|-------------------|------------------|------------------------------------|
| | 🕰 🕕 Mediflex 🖉 Uxbridge Medic | al Centre 🔒 123 ABC 🗂 Screening [| Demographics | | | | |
| Screening Vist Date Include / Exclude Criteria Demographics Medical History Physical Examination Vital Signs YRA Condition Assessment | Subject: 123 ABC Page: Demographics - Screening | | | | 6, | 8 | |
| | Date of Birth: | | | 01 JAN 1980 | ۵ و | 8 🗆 | |
| | Age: | | | years | 9 x | 80 | |
| | Sex | | | Male | 3 P | 8 🗆 | |
| | Ethnicity.® | | | White | ۵ و | 8 🗆 | |
| CRF History 123 ABC - Denographice 123 ABC - Vet Date | Country: Printable Vers CRF Version 230 | Attanta | Dev | | | Messages D | ⊠My Profile № Help 🦿 Hame 🏦 Logout |
| | 123 ABC Screening Vist 01 | C Enrollment | | | | | Subject Administration |
| | Visit 02 | Visit | Date | V Task | Summa | ry: Subject | Pages |
| | Visit 03 | Screening | 21 E-L 2222 | A NonConformant Data S Requiring Translation | | | 0 🗇 |
| | Vist 04 | 10 Visc 21 Peo 2000 | 21 Pep 2009 | | | | 0 🗗 |
| | Yearui | | | D 3 0 | pen Que | nes | 0.00 |
| | Concomitant | | | | Q Answered Quenes | | 019 |
| | Adverse Events | Add Event - | Add | | verdue D | ata Data Lash | 0.09 |
| | Image Library | | | | Created Oracia | | 319 |
| | CRF History 123 ABC - Vak Date 122 ABC - Nakobritation 123 ABC - Vak Date 123 ABC - Denographics | Icen Key | | 9 9 6 | | | 0.2 |

Core Lab Imaging Applications

- Various qualified and FDA cleared applications to support all modalities and review types
 - Volumetric Measurements/Segmentation
 - DICOM Viewer/QC
 - **RECIST Evaluation**
 - Angiography/CTA
 - SUV Measurements
 - Fusion
 - Dynamic Contrast MRI
 - MR Spectroscopy



Focused. Forward. Together.™