CCTS Radiology Pilot Research Initiative

Overview Information

Funding Opportunity Title	**CCTS Radiology Pilot Research Initiative**
Companion Funding Opportunities	CCTS Mini-Sabbaticals (https://www.uab.edu/ccts/training-academy/trainings/mini-sabbaticals) CCTS Research Vouchers (https://www.uab.edu/ccts/voucher-program) CCTS Pilot Program (https://www.uab.edu/ccts/research-commons/funding-opportunities/pilot-program)
Funding Opportunity Purpose	The intent of this Pilot Initiative is to support preclinical and clinical research projects in acquiring data that can be used in publications and extramural grant applications.

Key Dates*

Posted Date	August 18, 2020
Open Date (Earliest Submission Date)	August 18, 2020
Full Application Due Date	October 25, 2020, 5PM CT
Scientific Merit Review	October – November 2020
Earliest Start Date	January 1, 2021
Expiration Date	December 31, 2021

*some dates may vary as a result of unanticipated delays

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Section I. Funding Opportunity Description

Purpose

The Center for Clinical and Translational Science (CCTS) is committed to advancing patient care and public health through the use of cutting-edge imaging resources in support of innovative thinking, multi-disciplinary collaboration, expertise in molecular, functional, and anatomic imaging and basic imaging sciences research.

In collaboration with the UAB Department of Radiology and the UAB School of Medicine, the CCTS is requesting pilot study proposals for research projects requiring pre-clinical and / or human imaging on the Highlands 3T, 9.4T, PET/MR, and PET/CT. The intent of the Pilot Initiative is to support clinical research projects involving human subjects to acquire data that can be used in publications and extramural grant applications. The Radiology Pilot Research Initiative will provide direct research support to offset expense(s) for pre-clinical and research scan time and / or for the purchase radionuclides and radiopharmaceuticals from the Cyclotron Facility.

Section II. Award Information

Funding Instrument	Pilot Grant
Application Types Allowed	New
Funds Available and Anticipated Number of Awards	$75,000 has been committed to this program. The number of awards is contingent upon a sufficient number of meritorious applications and partner matching funds.
Award Budget	Applicants may request up to $15,000 Direct Costs.
Award Project Period	The maximum project period is 12 months.

Section III. Eligibility Information

Eligible Individuals (Program Director/Principal Investigator)

This program is primarily intended to support full-time faculty from across the CCTS Partner Network. Early investigators are encouraged to apply (see NIH definition, https://grants.nih.gov/policy/early-investigators/index.htm#earlystage). Faculty with previous / active K-awards are eligible and are encouraged to apply. Staff are not eligible to apply.

This program seeks to support investigators with a full-time faculty appointment. Postdocs, Residents a/o Fellows may be eligible if a faculty appointment is on the horizon, with a start date on or before the listed pilot award date – as part of the application, the investigator should include a letter from the Department Chair reflecting such. Established investigators are discouraged to serve as the PI for proposals on behalf of Postdoctoral Fellows. All projects should directly represent the ideas of the listed Principal Investigator. Postdocs may be part of the scientific team, but it is presently not advisable that they be positioned as Co-PI of the project.

Section IV. Application and Submission Information

Instructions for Application Submission

Applications should be submitted electronically as a single PDF using RED-ASSIST (https://redcap.dom.uab.edu/surveys/?s=XKRYLHKE34).

NIH Biosketch (Limit: 5 pages)

The NIH Biosketch of the PI(s) must conform to NIH requirements.

Other Support (Limit: none)

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative

agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included. Please include a complete list of current and pending other support.

Radiology Pilot Research Plan (Limit: 4 pages)

Please include up to four (4) pages (excluding references) of an expanded description of the experimental plan. Figures, if applicable, should not exceed more than one page in length when combined.

- **Font size**: must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%)
- **Type density**: must be no more than 15 characters per linear inch (including characters and spaces)
- **Line spacing**: must be no more than six lines per vertical inch
- **Text color**: must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable)
- **Rigor, Reproducibility & Transparency (R2T)**. Applicants are required to address R2T concepts in their application. Please see the CCTS R2T Resource page (https://www.uab.edu/ccts/research-commons/ grant-help/rigor-and-reproducibility-in-research) for guidance.

This section should be organized as follows:

1. **TITLE**

2. **INVESTIGATOR DETAILS**
   NAME:
   EMAIL ADDRESS:
   ACADEMIC TITLE:
   SCHOOL:
   DEPARTMENT:
   DIVISION

3. **SIGNIFICANCE**

   - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
   - Include a detailed description of the scan hours requested and/or purchase of radionuclides and radiopharmaceuticals from the Cyclotron Facility (see Core Consultation Summary, below).
   - Rigor, Reproducibility & Transparency: Describe the general strengths and weaknesses of the prior research being cited as crucial to support the application. Consider discussing the rigor of previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.
   - Please provide a clear and concise description of the central theme and goals of the program.
   - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
   - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
   - Please comment on how the proposed work fits the definition of Translational Research. Translational research refers to the multidirectional and multidisciplinary integration of fundamental, patient-oriented, and population-based research, with the goal of improving health and health care delivery.

4. **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.

5. **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 as well as any resource sharing plans as appropriate.
   - Describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Please comment on how this work will set the stage for future, extramural support.
   - Rigor, Reproducibility & Transparency: Emphasize how the experimental design and methods proposed will achieve robust and unbiased results.
   - Rigor, Reproducibility & Transparency: Explain how relevant biological variables are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex.

6. **REFERENCES CITED** (outside of 4-page limit)

   - Provide a bibliography of all references cited. Each reference must include the names of all authors, the article and journal title, book title, volume number, page numbers, and year of publication.

Rigor, Reproducibility & Transparency: Authentication of Reagents (Limit: 1 page)

The authentication plan should state in one (1) page or less how you will authenticate key resources, as needed for your research. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. Note: Do not include authentication data in your plan. For reference, see https://www.uab.edu/ccts/research-commons/grant-help/rigor-and-reproducibility-in-research

Consultation Summary (Limit: 1 page each)

Consultation. Applicants are expected to engage expert consultation from core facilities specific to the proposed aims and related to project design, regulatory considerations and other discipline-specific issues that have bearing on the study design. Budgeting of any core service or shared expertise requires sign-off by that facility. Please see Appendix 1 for the Consultation Summary document to include in your application.

Advanced Imaging (REQUIRED)
Advanced imaging capacities at UAB provide the radiology expertise and state-of-the-art technology for standardized protocol review, image acquisition, data metrics and assessment, as well as the development and implementation of new analytic tools and techniques for clinical and translational research. Through the Division of Advanced Medical Imaging Research, investigators can access seamless integration of preclinical and clinical imaging efforts. Applications involving the Highlands 3T, PET/MR, PET/CT, CT, and all Small Animal Imaging (9.4T, MRI, Micro PET/CT, etc.) require pre-approval from Dr. Andrew Smith (andrewdennissmith@uabmc.edu).

Cyclotron Facility (As applicable)
The UAB Cyclotron Facility enables a broad scope of research and cutting-edge patient care through initiatives ranging from nuclear science for novel isotope production to developing and supplying state-of the art molecular imaging agents for clinical trials and routine patient care. The TR24 cyclotron supports the production of numerous agents that are not commercially available to researchers because they must be produced and used locally. In depth, detailed research can be conducted in a variety of interdisciplinary ways to retrieve information that would not be available from other sources. Applications involving the purchase of radionuclides and/or radiopharmaceuticals from the Cyclotron Facility require pre-approval from Director-Cyclotron Facility, Dr. Suzanne Lapi (lapi@uab.edu).

CCTS Biostatistics, Epidemiology and Research Design (BERD; REQUIRED)
The CCTS Biostatistics, Epidemiology and Research Design (BERD) unit supports a multidisciplinary team of biostatisticians, epidemiologists, and methodologists who collaborate with researchers to serve fundamental, clinical and translational research. Services may include, but are not limited to, study design, sample size and power calculations, database design, data preparation for analysis, data analysis, graphical presentation of analysis results, interpretation of analysis results, training in statistical software, etc. Investigators are encouraged to work with BERD to access in-person,

directed consultation via walk-in clinics and / or scheduled expert consultation. Please contact the CCTS Research Commons (ccts@uab.edu; 205.934.7442) to schedule an appointment.

CCTS Clinical Services (As applicable)
CCTS Clinical Services is committed to providing investigators and their teams a research environment and broad range of services guided by good clinical practice. The unit equips investigators with essential tools and critical resources, while providing a highly efficient and flexible infrastructure. In addition, our Clinical Research Support Program (CRSP) provides a pool of trained, certified research nurses and coordinators to assist you with study implementation. This team is available to advise investigators on recruitment feasibility and approach as well as regulatory requirements. Please contact the CCTS Research Commons (ccts@uab.edu; 205.934.7442) to schedule an appointment.

CCTS Informatics (As applicable)
CCTS Informatics is committed to connecting investigators to analytic expertise across the spectrum of informatics research in support of the collection and the analysis of structured clinical and / or imaging data for clinical, translational and outcomes research from bench to bedside and back. Services may include, but are not limited to, study design, cohort estimation, information management solutions, data analysis, display of data and results, interpretation of results, custom applications, etc. Please contact the CCTS Research Commons (ccts@uab.edu; 205.934.7442) to schedule an appointment.

Other Shared Resources (As applicable)
Applicants are encouraged to use shared scientific facilities and research cores, which provide access to cutting-edge instrumentation, expert technical support, and scientific best practices.

Radiology Pilot Budget and Justification

Applicants may request up to $15,000 Direct Costs. Awards are limited to 12 months in duration. Applicants should follow the format of the PHS398 Form Page 4: Detailed Budget for Initial Budget Period.

Budgets are very specific to any given project and represent the financial implementation of the scientific aims.

- Investigator(s) salary/fringe may not be budgeted. Personnel expenses (e.g., research associates a/o coordinators) are permitted to enable the performance of outlined investigation, as justified.
- Allowable expenses may include inpatient / outpatient care costs and other expenses (pre-clinical a/o human imaging on the Highlands 3T, PET/MR, PET/CT, CT, and all Small Animal Imaging (9.4T, MRI, Micro PET/CT, etc.); radionuclides and radiopharmaceuticals from the Cyclotron Facility).
- The Program does not support general lab supplies or reagents for experiments to be conducted solely within an individual's laboratory.
- Consultant Costs, Alterations, Renovations, Equipment, publication charges and travel expenses are not permitted under this mechanism.
- Pilot projects are not required to budget indirect costs; IDC is not provided as part of the award.

Core Services. Budgeting of any core service or shared expertise requires sign-off by that facility.

Justification. All budget expenses should be well justified relative to experimental need. Please see the NIH Guidelines for more information on what should be included in a detailed budget justification. Pilot projects are not required to budget indirect costs. The Budget Justification should be organized as follows; If funding is not requested in any particular category, please indicate "Not Applicable."

PERSONNEL

INPATIENT CARE

OUTPATIENT CARE

OTHER EXPENSES

Letters of Support (optional)

Letters of support are encouraged to demonstrate scientific and / or financial support of collaborating units, when applicable.

Section V. Application Review Information

Review Criteria

Applications will be scored (1-9) on aspects of mission & RFA alignment, research team, scientific approach, mentoring plan (if applicable), significance, appropriateness of the budget and justification as well as overall impact. The review committee will be made up of the current research fund development committee members. Ad-hoc reviewers will be added by the committee based on the need for particular expertise. Funding recommendations will be referred to an executive committee lead by the Department Chair of Radiology, which will be responsible for final award decisions.

- **Assessment of Investigator and the Research Team.** Are the PI, collaborator(s), and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Are they significantly changing research directions to be eligible for this pilot award?
- **Assessment of Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Given the experience of the research team, is this feasible for the proposed time frame?
- **Assessment of Relevance and Significance.** The intent of the Pilot Initiative is to support research projects that rely on advanced imaging to acquire data that can be used in publications and extramural grant applications. How well does this proposal address the purpose of the program? Will achieving study aims lead to future publications and/or extramural support?
- **Overall Impact.** Upon completion of the sections above, applications receive a score (1-9) to indicate the rating of the overall scientific merit of this pilot proposal taking into account all review criteria. The score should represent a global view; an application does not need to be strong in all categories to be judged likely to have major scientific impact, and the score does not need to be a mathematical reflection of the sections above.
- **Scientific Competitiveness.** Is it likely that successful completion of this project will provide preliminary data that will lead to a subsequent NIH (or equivalent) grant?

Additional Review Considerations

Human Subject or Animal Protection. Are there any potential human subjects and/or animal protection concerns?

Budget. Is the budget appropriate for the proposed work?

Section VI. Award Administration Information

Anticipated Announcement and Award Dates

Please refer to Part 1. Overview for dates for peer review, advisory council review, and earliest start date. Section II. Award information summarizes funds available and anticipated number of awards.

Award Notices

Meritorious applications will receive formal notice in the form of a Notice of Grant Award (NOGA) provided to the applicant. Any costs incurred before receipt of the NOGA are at the recipient's risk. Any application awarded in response to this RFA will be subject to terms and conditions listed in the NOGA.

Regulatory Approvals

All lines of investigation supported by the Radiology Pilot Program require appropriate regulatory approvals (IRB, IACUC, OH&S, as applicable). These approvals must be in place in advance of human subjects and/or animal work and must remain in good standing throughout study implementation.

Reporting

Progress Reports. Awardees will be asked to submit scientific progress reports and a year-end report detailing the results, products and next-steps of your research – a template will be provided as will the deadline(s) for such reports.

Evaluation. To support the continuous improvement of this initiative, applicants and awardees will be periodically asked to provide feedback related to programmatic implementation and award outcomes.

Compliance with the NIH Public Access Policy: Award recipients are required to comply with the NIH Public Access Policy (https://www.uab.edu/ccts/clinical-translation/clinical-services/crsp/implementation/tools). This includes submission to PubMed Central, upon acceptance for publication, of an electronic version of a final peer-reviewed manuscript resulting from research supported in whole or in part by the NIH. The staff of Lister Hill Library (LHL) can help investigators navigate the Public Access Policy processes. For assistance, please contact Kay Hogan Smith (khogan@uab.edu; 205.934.2208).

Section VII. Contacts

Application Submission Contacts

CCTS Research Commons
Center for Clinical and Translational Science
O: 205.934.7442 | ccts@uab.edu

Scientific/Research Contact

Morgan Amos | Program Director III
Department of Radiology
O: 205.996.9417 | jamos@uabmc.edu

Radionuclides & Radiopharmaceutical Pricing

Suzanne Lapi, PhD | Cyclotron Facility
Director, Cyclotron Facility;
Director, Radiochemistry Laboratory
Associate Professor, Advanced Imaging Facility, Division of Advanced Medical Imaging
Research O: 205.975.8689 | lapi@uab.edu

Financial/Grants Management Contact

Richard Hines, MBA | Financial Officer
Center for Clinical and Translational Science
O: 205.934.5953 | hinesr@uab.edu

(RFA style guide borrowed from NIH for educational purposes)

CCTS Radiology Consultation Summary

Instructions: Applicants are expected to engage expert consultation from core facilities specific to the proposed aims and related to project design, regulatory considerations and other discipline-specific issues that have bearing on the study design. Budgeting of any core service or shared expertise requires sign-off by that facility.

Advanced Imaging (REQUIRED)

1. Date of Consultation: _____
2. Faculty Representative Name: _____
3. If services appear in budget, Faculty Representative Signature: _____

Cyclotron Facility (As applicable)

1. Date of Consultation: _____
2. Faculty Representative Name: _____
3. If services appear in budget, Faculty Representative Signature: _____

CCTS Biostatistics, Epidemiology and Research Design (BERD; REQUIRED)

1. Date of Consultation: _____
2. Name of Statistician: _____

CCTS Clinical Services (As applicable)

1. Date of Consultation: _____
2. Faculty Representative Name: _____
3. If services appear in budget, Faculty Representative Signature: _____

CCTS Informatics (As applicable)

1. Date of Consultation: _____
2. Faculty Representative Name: _____
3. If services appear in budget, Faculty Representative Signature: _____

Other Shared Resources (As applicable)

1. Name of Core Facility / Research Support Group: _____
2. Date of Consultation: _____
3. Faculty Representative Name: _____
4. If services appear in budget, Faculty Representative Signature: _____

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2. Date of Consultation: _____
3. Faculty Representative Name: _____
4. If services appear in budget, Faculty Representative Signature: _____