

Overview and Key Dates*

Funding Opportunity Title	Cooperative Centers on Human Immunology (CCHI) Infrastructure and Opportunity Fund (IOF)
Funding Opportunity Purpose	Through the CCHI Infrastructure and Opportunity Fund Management Core, we seek applications from CCHI centers to support mechanistic and hypothesis-testing studies to understand human immunity applicable to the biodefense effort.
Posted Date	September 2, 2022
Open Date (Earliest Submission Date)	September 9, 2022
Application Due Date	October 25, 2022
Awards Announced	January 27, 2023
Awards Issued	April 1, 2023

**See additional project period information in the budget section below.*

Table of Contents

Overview Information

Key Dates

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts

Section I. Funding Opportunity Description

Background and Purpose

The CCHI Infrastructure and Opportunity Fund Management Core is soliciting applications from CCHI centers to capitalize on emerging opportunities and encourage multi-center, multi-disciplinary collaborations. The immediate objective of the CCHI is to support mechanistic and hypothesis-testing studies to understand human immunity applicable to the biodefense effort (i.e. innate, adaptive and mucosal immune responses to infection, vaccination and adjuvants). Studies on immune-mediated diseases (e.g. airway allergy, food allergy, autoimmunity, organ transplant rejection) and basic human immunology are also of interest, as these data will provide a more comprehensive understanding of the human immune system.

- Proposals supporting research on the molecular mechanisms by which the human immune system is activated and regulation in response to infection, vaccination against infectious disease, or administration of a vaccine adjuvant(s) will be considered responsive to this RFA. Proposals that examine the molecular mechanisms controlling human immune responses to allergens, autoantigens and transplant antigens are also appropriate for this RFA. Please see **Special Considerations** for a description of studies that will not be considered responsive to the RFA. (below)
- Proposals may be focused on addressing fundamental basic immunologic questions but must include work with primary human cells/tissues; human cell lines are not sufficient.
- Proposals may include animal work, but only if used to test phenomena already discovered in experiments with human cells/tissues. Studies with the following are allowed:
 - nonhuman primate studies
 - studies with humanized mice reconstituted with human immune cells (subject to potential HHS-level ethics review of any proposed humanized mice that may utilize human fetal tissue)
 - studies with mice expressing human molecules such as HLA
- Applications may include:
 - Discovery research (i.e. high risk/high impact)

- Mechanistic project - answer important mechanistic/function questions
 - Technology development project – broad and high impact
 - Service core project - a specialized service provided to CCHI investigators. May involve training for technology transfer/collaborations
- Proposals may be scientific, core or course proposals. At least one of the two submitted per Center must be scientific.

Special considerations: Special consideration will be provided to investigators from groups shown to be under-represented in the biomedical workforce ([NIH's Interest in Diversity, NOT-OD-20-031](#)), Early Stage Investigators/New Investigators (ESI/NI, please see [NIH Next Generation Researchers Initiative policies](#)), and investigators who are relatively new to human immunology research. Proposals involving more than one CCHI Center will also be given special consideration. Collaborative projects working across two or more laboratories, bringing together complimentary disciplines, will be given special consideration.

Proposals *may not* propose clinical trials (i.e. clinical studies testing novel interventions in humans, or using licensed interventions in a manner different from the conditions described in the intervention product's label), however, the use of samples obtained from human subjects in clinical trials funded through independent mechanisms is allowed.

Proposals *may not* include 1) cancer studies, except for immune response in response to infectious diseases or pathogen-specific vaccines in cancer patients, or examining mechanisms of immune checkpoint blockade; 2) Behavioral research; 3) Work on HIV/SIV; or 4) Epidemiological studies or GWAS

Section II. Award Information

Funding Instrument	CCHI Infrastructure and Opportunities Fund Management Core
Application Types Allowed	CCHI U19 Centers
Award Budget	Applicants may request up to a maximum of \$103,000 in Direct Costs
Award Project Period	The project period will be 04/01/22 – 03/31/23; Awards will be made for one year funding period.

Section III. Eligibility Information

Eligible Individuals (Program Director/Principal Investigator)

Each CCHI U19 center may submit up to two applications. Applications may be scientific, core or course proposals, but at least one of the two proposals must be scientific.

This award mechanism encourages collaborative proposals spanning two or more research laboratories, bringing together complementary disciplines. If two centers are involved in a proposal, it will count as a submission from only one of the centers, however you must indicate which is the submitting center.

The Project Leader of the proposed project is not required to be an existing CCHI investigator, but a CCHI U19 center must 'host' and/or endorse the project application as one of their allowed submissions. Project Leader must hold a faculty appointment at their respective institution.

Section IV. Application and Submission Information

Instructions for Application Submission

Applications will be submitted through an [online REDCap submission form](#). **Chrome is the preferred browser for the REDCap submission form.** Please note that instructions for completing the form and returning to it at a later date (before submission) are contained within the form's "Instructions" section.

The submission form requests the following information:

Principal Investigator(s)

Please be prepared to provide the following information for Project Leader(s) in the submission form: first name, last name, degrees, institution, school, department, division, rank, phone number, email, gender, race, ethnicity, diversity status. For more information about diversity status, please see ["Notice of NIH's Interest in Diversity."](#)

Project Details

Enter the following information in the submission form:

- Project title
- A Yes/No answer to the following questions:

- Will the project involve human subjects research? If yes, does your study meet the [NIH's definition of a clinical trial](#)?
- Will the project involve animal models research?
- Will the project involve FDA-regulated research?
- Indication as to whether or not the project will meet any special considerations for this funding mechanism (see Section I. Funding Opportunity Description).

Proposal

Upload your proposal as a [single PDF](#).

Formatting requirements: **Font:** Arial 11 point (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%). **Line spacing:** Single-line spacing. **Margins:** Provide at least one-half inch margins (top, bottom, left, and right) for all pages. No applicant-supplied information can appear in the margins. **Text color:** Must be black (color text in figures, graphs, charts, tables, footnotes and headings is acceptable). **Pages:** Pages must be 8.5" x 11".

Proposals must include following information (in the order listed below).

Completed Face Page: Include a [PHS 398 form Face Page](#) from each site, [signed by each respective business official](#).

Subaward Letter of Intent: Include UAB Letter of Intent to Establish a Subaward for each site included within your proposal, [signed by each respective business official](#)

Research Subaward Agreement: Include a Subaward Agreement attachment 3B (http://thefdp.org/default/assets/File/Documents/Att_3B_2017.pdf), specifying subrecipient contacts and information.

Federally Negotiated Rate Agreement: Include a copy of the submitting Institution's Federally Negotiated Rate Agreement, and that of any additional sites proposed on the project.

Budget and Justification: Applicants may request up to \$103,000 in Total Direct Costs over the one year funding period

- Detailed Budget: Include [PHS398 Form Page 4: Detailed Budget for Initial Budget Period](#)
- Justification: Include direct and indirect F&A costs, proposed % effort/months effort for the Project Leader and any other personnel. Include a budget and summary for each participating institution in the submission.

PHS 398 Checklist: Include a completed [PHS 398 Checklist](#) calculating the proposal's total direct and indirect costs.

NIH Biosketch(es) (5 page maximum per individual) Include an NIH-type biosketch ([NIH Biosketch requirements](#)) for each proposed Project Leader and any other Key Personnel. In the biosketch's "Research Support" section, include % effort/months effort for active funding.

Research Plan (3 page maximum) Items that should be addressed in the research plan section include:

- Rationale (how the project will advance human immunology)
- Project Leader's prior work in human immunology, if any
- Description of the proposed work
- Preliminary data, if relevant
- Why the project is unsuitable for an R01 or other mainstream NIH grant application
- How the CCHI program as a whole will benefit from this project (what is the value added?)
- Feasibility of the work
- How the proposed work will be completed within the requested timeframe/budget
- Statement regarding the necessity of animal use (e.g. hu-mice, NHPs), if applicable
- Figures are included in the 3 page limit.

References Cited: 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. No page limit applies to References Cited. (References are not included within the 3 page limit)

Human Subjects section: [description and justification of human subjects research](#). if relevant.

Vertebrate Animals section: [description and justification of vertebrate animal research](#). if relevant.

Foreign site information (if relevant)

Reviews

Reviews will be completed by the CCHI Steering Committee.

Anticipated Announcement and Award Dates

Please refer to Overview and Dates for review and earliest start date. Section II. Award information summarizes funds available and anticipated number of awards.

Section VI. Award Administration Information

Regulatory Approvals

All lines of investigation supported by this funding mechanism require appropriate regulatory approvals (IRB, IACUC, as applicable). IRB and IACUC protocols **MUST** be submitted to your institutional research administration office at the time of submission. If chosen for funding, sites **MUST** have required approvals by **April 1, 2023**. These approvals must be in place in advance of human subjects and/or animal work and must remain in good standing throughout study implementation.

Section VII. Agency Contacts

Application Submission Contacts

CCTS Research Commons

Center for Clinical and Translational Science

O: 205.934.7442 | ccts@uab.edu

Scientific/Research Contact

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(RFA style guide borrowed from NIH for educational purposes)