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 UAB investigators to support mechanistic and hypothesis-testing studies that impact our fundamental understanding of human immunity.
Application Due Date	December 2, 2024
Awards Issued	April 1, 2025
Award Budget	Applicants may request up to a maximum of \$150,000 in Direct Costs
Award Project Period	The project period will be $04/01/25 - 03/31/26$ ; Awards will only be made for one year funding period
Eligible Investigators	The Project Lead must hold a faculty appointment at their respective institution.

## **Background and Purpose**

The UAB CCHI (U19 Al181105) is soliciting applications from UAB investigators <u>for consideration as one of two applications</u> submitted on behalf of the UAB CCHI to the national CCHI RFA. The CCHI IOF encourages mechanistic, hypothesis-testing studies to understand human immunity in both healthy and vulnerable populations (i.e., across lifespan, organ/tissue transplant recipients, pregnant women) such as innate, adaptive and mucosal immune responses to infection, vaccination, adjuvants; immune-mediated disorders (e.g. airway allergy, food allergy, autoimmunity, organ transplant rejection); and basic human immunology.

- Proposals supporting research on the molecular mechanisms by which the human immune system is activated and regulated in response to infection, vaccination against infectious disease, or administration of a vaccine adjuvant(s) will be considered responsive. Proposals that examine the molecular mechanisms controlling human immune responses to allergens, autoantigens and transplant antigens are also appropriate. Please see Special Considerations (below) for a description of studies that will not be considered responsive to the RFA.
- 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

**Special considerations:** Special consideration will be provided to **multi-center proposals** involving more than one CCHI center. Special consideration will also be given 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. Collaborative projects working across two or more laboratories, bringing together complimentary disciplines, will be given special consideration.

Proposals <u>may not</u> 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 <u>may not</u> 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

# **Instructions for Application Submission**

#### **Proposal**

Email your proposal as a single PDF to Carol Ballinger at caball@uab.edu.

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).

Cover Sheet with the following information:

- ✓ Principal Investigator(s) first name, last name, degrees, institution, school, department, division, academic 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 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).

### Completed Face Page: Include a PHS 398 form Face Page

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 Lead'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.

**Budget and Justification:** Applicants may request up to \$150,000 in Direct Costs over the <u>one year funding period</u>. You <u>must include travel expenses to the annual CCHI investigator meeting</u> (December 11-12, 2025, Rockville MD) to present the results of your project in person.

- 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 (<u>NIH Biosketch requirements</u>) for each proposed Project Lead and any other Key Personnel.

**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.

\*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, 2025. These approvals must be in place in advance of human subjects and/or animal work and must remain in good standing throughout study implementation

## **Anticipated Announcement and Award Dates**

The UAB CCHI will review applications internally to determine which two applications move forward to the national submission due by December 15, 2024. Final CCHI awards will be announced by late January 2025 for an April 1, 2025 start date.

**Questions:** Please contact:

**Carol A. Ballinger, PhD** Administrative Director, CCHI IOF O: 205.934.3046 | <u>caball@uab.edu</u>