Proposed Collaborative Studies with the Center for Human Immunology (CHI)

The Center for Human Immunology is seeking collaborations for clinical trials/studies in the field of human immunology. Examples of such trials/studies include but are not limited to: interventions to treat immune mediated diseases, interventions to study to physiology of immune mediated diseases, cataloguing normal immune responses in healthy individuals.

For questions or collaborative proposals please contact Katie Stagliano, Manager of Operations. Email: staglianoke@mail.nih.gov, Phone: 301-451-5138

Please visit our website at: http://www.nhlbi.nih.gov/resources/chi/index.htm

What is desired from our collaborators?

1. A clearly formulated and incisive scientific question with referenced background
2. A clinical study plan/protocol
3. Well defined primary and secondary endpoints
4. A rationale for the value-added that would come from application of multi-omic technology and systems analytic approach to the scientific issue under study
5. An understanding that the CHI does not provide ‘service’ to simply augment a study’s data set

CHI contributions to collaborative projects

Clinical and scientific staff with the capacity to:

1. Help in developing the clinical protocol, moving it through the regulatory process, and implementing it
2. Aid in patient recruitment and collection of clinical data
3. Undertake sophisticated systems-level data processing and analysis
4. Utilize CHI experimental procedures and platforms:
   a. Isolation and cryopreservation of PBMCs and serum
   b. mRNA/microRNA expression by microarray (Affymetrix), RNA-Seq (Illumina) or qPCR (Fluidigm)
   c. Genome-wide genotyping (GWAS) analysis (Affymetrix or Illumina)
   d. Deep flow-cytometry phenotyping of PBMCs
e. Plasma/sera protein profiling by Luminex
f. Proteomic analysis by SomaLogic

How will proposals be selected for implementation?

Proposals will be evaluated by the CHI leadership together with our internal (NIH) advisory committee based on:

1. Scientific merit
2. Feasibility
3. Ability to recruit subjects
4. Fit with the integrative, systems-level of the CHI
5. Priority will be given to proposals that have the greatest potential impact

What is the proposal review process?

1) Pre-proposal phase. Informal discussions with CHI staff are held to support investigators in developing their proposals.
2) Proposal submission. The proposal application is submitted to the CHI Manager of Operations: staglianoke@mail.nih.gov
3) Initial Review. CHI Directors review electronic copy of proposal. They can reject the proposal at this stage or allow it to progress to a presentation.
4) Formal Review. Investigator presents their proposal in a 5-10 minute power point to the Directors. This meeting occurs early on Thursday mornings. The Directors can reject the proposal at this stage or allow it to progress to ISAC review.
5) ISAC Review. Our external review committee reviews proposals for final approval or rejection.
6) On-going Review. CHI Staff communicate with investigators regularly. Projects can be cut or placed on hold if they are not progressing.
Proposal for a Collaborative Pilot Clinical Trial/Study with the Center for Human Immunology, Autoimmunity and Inflammation (CHI)

Date of Submission to CHI Manager:

Principal Investigator/ Institute:

Associate Investigators/ Institute:

Title:

Abstract:

Keywords:

Objectives

Background and rational:

Study design:

Primary endpoints:

Secondary endpoints:

Relevance to other diseases:

Recruitment capability; Please estimate how many subjects/month can be recruited

Lab assay required:

1. To be performed by CHI
2. To be performed by investigator

Additional lab resources needed:

Clinical resources:

By CHI

By investigator (not mandatory)