Faculty Management of Complex, Federally Funded, Clinical Research Projects

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October 8, 2019
RAPID Meeting
Bench to bed Enhanced Lymphocyte Infusions to Engineer Viral Eradication
Goal: To enhance and improve immune responses to HIV, targeting antibodies, innate and adaptive cells as therapies; combine with other agents; and to target to sites where latent virus resides: Enhanced immunotherapy to HIV
Why should you BELIEVE?

**Questions:** Can we make an individual’s immune system work better? Could an improved immune system eradicate the virus?

**Progress:** Our first clinical safety trial started enrolling in Spring 2019. We will expand an individual’s white blood cells that attack parts of HIV that do not mutate.

**Meaning:** This personalized medicine uses an individual’s own immune cells to fight HIV. Generalized approaches are also underway.
Bench to Bed Enhanced Lymphocyte Infusions to Engineer Viral Eradication

NIAID UM1 Martin Delaney Collaboratory (AI126617; 7/14/2016-6/30/2021)

NIAID Program & Medical Officers: Eric Refsland, (Lillian Kuo), Tony Conley & Larry Fox

PI: Douglas Nixon (and soon R. Brad Jones as co-PI)
Program Manager: Robert Furler
Investigators: Edward Berger, Catherine Bollard, Alberto Bosque, Mark Brockman, Zabrina Brumme, Amanda Castel, Elizabeth Connick, C. Russell Cruz, Harris Goldstein, Alan Greenberg, David Hardy, Brad Jones, Esper Kallas, Princy Kumar, Rebecca Lynch, Manya Magnus, Sergei Nekhai, Ulrik Nielsen, Douglas Nixon, Una O’Doherty, Mario Ostrowski, Deborah Persaud, Gustavo Reyes-Teran, Gary Simon, Pam Skinner, Thomas Smithgall, James Whitney, Jeffrey Safrit & Peter Rhodes
Industry Partners
Community Engagement & CAB

BELIEVE MARTIN DELANEY COLLABORATORY
International Collaborators

BELIEVE MARTIN DELANEY COLLABORATORY
Who We Are
Scientific Strategy

The UM1 is designed to be **dynamic** - constantly evolving to address the **highest priority science**.
Enhanced Targeted Immunotherapy

- IRF 1: Enhancing T Cell Effectors
- IRF 2: Enhancing ADCC and NK Cell Effectors
- IRF 3: Targeting the Follicle
- IRF 4: Clinical Trial 1

Best Strategy Enhanced with LRA & Targeting with Backpacks

NHP Study

IRF 4 Clinical Trial 2
Enhanced Targeted Immunotherapy

IRF 1
Enhancing T Cell Effectors

IRF 2
Enhancing ADCC and NK Cell Effectors

IRF 3
Targeting the Follicle

IRF 4
Clinical Trial 1

JONES   NIXON
Enhanced Targeted Immunotherapy

- IRF 1: Enhancing T Cell Effectors
- IRF 2: Enhancing ADCC and NK Cell Effectors
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NHP Study

IRF 4: Clinical Trial 2
Enhanced Targeted Immunotherapy

IRF 1
Enhancing T Cell Effectors

IRF 2
Enhancing ADCC and NK Cell Effectors

IRF 3
Targeting the Follicle

IRF 4
Clinical Trial 1

GOLDSTEIN

Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY
Enhancing ADCC and NK Cell Effectors

**N-803**

IL-15N72D

IL-15Rα

IgG1 Fc

**V1V2 Glycan**

(PG9, CAP256, VRC25, PGDM1400)

**CD4 Supersite**

(VRC01, VRC07-523, N6, 3BNC117)

**Glycan-V3 Supersite**

(PGT121, 2G12, 10-1074)

**Glycans**

**gp120-gp41 Interface**

**Viral membrane**
Enhanced Targeted Immunotherapy

IRF 1
Enhancing T Cell Effectors

IRF 2
Enhancing ADCC and NK Cell Effectors

IRF 3
Targeting the Follicle

IRF 4
Clinical Trial 1

Best Strategy Enhanced with LRA & Targeting with Backpacks

NHP Study

IRF 4
Clinical Trial 2
Enhanced Targeted Immunotherapy

IRF 1
Enhancing T Cell Effectors

IRF 2
Enhancing ADCC and NK Cell Effectors

IRF 3
Targeting the Follicle

IRF 4
Clinical Trial 1

SKINNER

University of Minnesota
**Enhanced Targeted Cell Therapy**

- **IRF 1**: Enhancing T Cell Effectors
- **IRF 2**: Enhancing ADCC and NK Cell Effectors
- **IRF 3**: Targeting the Follicle
- **IRF 4**: Clinical Trial 1

Flowchart:
- **IRF 1** → **IRF 2** → **IRF 3** → **IRF 4** → **Best Strategy Enhanced with LRA & Targeting with Backpacks** → **NHP Study**
- **IRF 4 Clinical Trial 2**
Enhanced Targeted Immunotherapy

IRF 1
Enhancing T Cell Effectors

IRF 2
Enhancing ADCC and NK Cell Effectors

IRF 3
Targeting the Follicle

IRF 4
Clinical Trial 1
Selection & expansion of white blood cells with conserved HIV peptides
A Phase I Study to Evaluate the Safety, Immunologic, and Virologic Responses of HIV-Specific T-cells with non-escaped epitope targeting (HST-NEETs) as a Therapeutic Strategy in HIV-Infected Individuals on Antiretroviral Therapy During Acute and Chronic Infection
Enhanced Targeted Cell Therapy

IRF 1
Enhancing T Cell Effectors

IRF 2
Enhancing ADCC and NK Cell Effectors

IRF 3
Targeting the Follicle

IRF 4
Clinical Trial 1

Best Strategy Enhanced with LRA & Targeting with Backpacks

NHP Study

IRF 4
Clinical Trial 2
Website

http://believe.weill.cornell.edu
Planning for complex submissions
*How far out do you start thinking about the submission? *(Recompetition)*

*How far out do you begin preparing the submission?*

*How do you engage collaborators within the college, and at other institutions?*

*How can research administration work with you to make your application as successful as possible.*

*Scientific Editing*
*What resources do you look to for support?

*How do you use them?

*Cores?
*CTSC services?

*Data Management Services (ITS)?

*Do you use any services provided by our Ithaca Campus?

*Do you use any Qatar resources?
Staffing
*Do you have a non-academic staffing model?

*How do you know how many administrative staff, coordinators, etc. you will need to hire for a complex project?

*Administrative space & clarification for administrative duties between grant admin & institutional admin

*Institutional large grant committee (PIs + Program Managers)
What are some best practices for the administrative and strategic management of complex projects?
*How often do you meet with collaborators?

*Do you meet via conference calls or in person?

*What do you discuss in the meetings?
Communication

MEETINGS

- Monthly Executive Committee Meetings
- Monthly Scientific Working Group Meetings
  - IRF 1 Enhancing T Cells
  - IRF 2 Enhancing NK Cells
  - IRF 3 Localization
  - IIRF 4 Clinical Trials
  - CAR T Optimization Working Group
  - Nef Inhibitor Working Group
- Monthly Community Advisory Board Meetings
- Monthly NIH Individual Management Team
- Quarterly Steering Committee Meetings
- Quarterly Collaboratory Meetings
- Annual Meeting
- Individual Site Visits

BELIEVE MARTIN DELANEY COLLABORATORY
*How do you decide if a collaborator is meeting expectations?

*What do you do if they aren’t meeting expectations?

*How to mitigate conflict?
*How do you develop meaningful relationships with collaborators?

*How do you leverage collaborators to build a successful scientific and administrative proposal?
Using Grant Mechanism to Promote Career Growth for Members
How have departmental and central research administration personnel contributed to your success?
Financial Management and Compliance Oversight

- Mariela Flambury, Assistant Director of Research Business Management
- Omarys Herasme, Grant Portfolio Manager, Research Business Management
- Stephen Hunt, Associate Director, Research Operations
Scientific Impact
Publications from Years 1 & 2
Year 3 Publications
*What is the impact of your science?

*How has it progressed over time?

*How has your program management developed over time?

*Key factors that have contributed to your success?
Key lessons learned throughout your careers about successfully applying for and managing Complex, Federally Funded, Clinical Research Programs?