

# DHVI PROGRAM MANAGEMENT ONBOARDING PACKAGE



9/26/2017



**Duke University**  
School of Medicine

Welcome to the Duke Human Vaccine Institute Program Management group. We are so excited for you to begin your journey at DHVI!

# DHVI Program Management Onboarding Package

## WELCOME

Welcome to the Duke Human Vaccine Institute (DHVI) and the Program Management Group. The DHVI is a vibrant research organization committed to advancing the fight against major infectious diseases. By focusing on the scientific “bottlenecks” for the development of HIV, TB, and other vaccines, DHVI investigators continue to make significant contributions to overcome global health challenges on behalf of society. The program management team is an integral part in this mission. This document will help you as your transition to your new role at DHVI. Welcome to our team—we look forward to your many successes at DHVI!

## OVERVIEW OF PROGRAMS AT DHVI

So many global health problems are not being solved because they primarily affect developing countries that have few resources. TB, HIV, malaria and lack of clean water are all serious global health problems, and the health of developing countries is vital to the overall health and stability of the global society. DHVI has received numerous grants to develop diagnostics, therapeutics and vaccines against these major infectious diseases. Working in collaboration with investigators worldwide, we are committed to performing the translational research necessary to take products from “bench to bedside.”

### **Duke Center for HIV/AIDS Vaccine Immunology and Immunogen Discovery (CHAVI-ID)**

The Duke **Center for HIV/AIDS Vaccine Immunology and Immunogen Discovery** ([CHAVI-ID](#)) is a consortium that was established by the National Institute for Allergy and Infectious Diseases (NIAID) to undertake the immunologic research that will tackle the major scientific obstacles in the development of an effective HIV-1 vaccine. The Duke CHAVI-ID builds on the progress that was made by the [CHAVI](#) consortium and applies state-of-the-art technologies and both immunologic and virologic tools to improve rational HIV-1 vaccine design. The vaccine strategy of the Duke CHAVI-ID is based on identifying and targeting novel HIV-1 vulnerabilities to B, T and NK cell immune responses and using this information to design vaccines that will induce protective immunity at the time and location of HIV-1 transmission.

The goal of the Duke CHAVI-ID is to design a practical preventive HIV-1 vaccine that incorporates protective innate, antibody and T cell-targeted immunogens. These immunogens will be designed to prevent HIV-1 transmission by inducing the following types of protective immune responses at the site of HIV-1 entry:

1. Innate immune responses
2. Antibody responses
3. CD4+ and CD8+ T cell responses

The Duke CHAVI-ID will be a component of the Global HIV-1 Vaccine Enterprise, which is comprised of outstanding investigators who employ state-of-the-art technology to address the critical gaps in scientific knowledge through carefully designed, focused, and coordinated studies that are aimed at developing a successful HIV-1 vaccine.

For more information, please visit the Duke CHAVI-ID website: <http://chavi-id-duke.org>.

### **Collaboration for AIDS Vaccine Discovery (CAVD)**

The Global HIV Vaccine Enterprise was established in 2003 as a collaborative global effort to promote the development of a safe and effective HIV vaccine. The Bill and Melinda Gates Foundation set out to advance this mission by contributing more than \$287 million in support of HIV vaccine development and discovery. The CAVD provides funding for a range of innovative strategies aimed at designing an effective HIV vaccine. The program is designed to foster collaboration among researchers to speed up the communication of results and the sharing of ideas. In addition to focusing on fundamental HIV research, the funded projects emphasize translational research, bridging the gap between basic discovery and product development.

DHVI Director Dr. Barton Haynes is the Principal Investigator of the following CAVD grants:

[B-Cell Lineage Envelope Design from RV144 Antibodies](#)

[Centralized Envelope Phase I Study](#)

[MPER-Peptide Liposome Immunogen Testing](#)

[Protein Production Facility](#)

### **Defense Advanced Research Projects Agency (DARPA) Pandemic Prevention Platform (P3) Program**

Biologic countermeasures, such as monoclonal antibodies (mAbs), are a rapid/effective means of controlling and containing outbreaks of emerging pathogens where no licensed therapeutic or vaccine is available. However, standard paradigms for their production and delivery limits their use as a first-line prophylactic or therapeutic, since the process for their identification, optimization and production can take months to years. The Defense Advanced Research Projects Agency (DARPA) has recently funded Duke as part of their [Pandemic Prevention Platform \(P3\)](#) to address these challenges.

The overall US Department of Defense DARPA program aims to develop an integrated technology platform that gives public health officials the capability to halt the spread of any viral disease outbreak within 60 days, before it can escalate to pandemic status. In contrast with state-of-the-art medical countermeasures, which typically take many months or even years to develop, produce, distribute, and administer, the envisioned P3 platform would cut response time to weeks and stay within the window of relevance for containing an outbreak.

The **Duke DARPA Pandemic Prevention Platform (P3)** team seeks to apply its experience, innovations, cutting-edge research portfolio, and in-house [cGMP manufacturing capabilities](#) to greatly expedite mAb countermeasures for future pandemics. The fully integrated platform will be a major

advancement in rapid pandemic countermeasure development and will address the significant global challenge pandemic outbreaks have on both civilian and military populations.

The **Duke DARPA P3** program (DARPA agreement number HR0011-17-2-0069), under the leadership of Dr. Gregory Sempowski, will combine world-class expertise in virology, immunology and CGMP manufacturing to create a fully integrated platform capable of responding to a viral pandemic. For this program, we are focusing on three main areas of innovation to development platform to be applied in future pandemics:

1. On-Demand Platform to Grow Virus: Develop methods to support viral propagation, so that virus can be used for downstream studies
  2. System to Identify and Evolve Antibodies: Isolate neutralizing antibodies from convalescent PBMC and plasma, improve the antibody 100-fold in function by in vitro antibody evolution and transfer antibody sequence for production and delivery optimization/testing
- Deliver Medical Countermeasures: Develop an mRNA-based medical countermeasure with optimal potency, half-life and ease of use in the field

### **External Quality Assurance Program Oversight Laboratory (EQAPOL)**

The **External Quality Assurance Program Oversight Laboratory (EQAPOL)** is a National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID)-Division of AIDS (DAIDS) funded resource located at Duke Human Vaccine Institute's (DHVI) Immunology and Virology Quality Assessment Center (IVQAC); to support the development, implementation and oversight of external quality assurance programs that monitor laboratories involved in HIV/AIDS research and vaccine trials around the world.

The EQAPOL Program consists of the following components:

- Maintain a Peripheral Blood Mononuclear Cell (PBMC) Cell Bank and Reagent Repository
- An External Quality Assurance (EQA) Program for Flow Cytometry-based Assays
- An Enzyme-linked Immunosorbent Spot (ELISpot) Assay EQA Program
- A Luminex EQA Program
- A Limiting Antigen (LAg) Avidity Incidence Assay EQA Program
- Establish and Characterize Unique Clade-Specific HIV Virus Panels
- Create a Central Web Database for the Above Activities

### **Vaccine and Treatment Evaluation Unit (VTEU)**

The National Institute of Allergy and Infectious Disease **Vaccine and Treatment Evaluation Units (NIAID VTEUs)** play a key role in the development new and improved vaccines and therapies against infectious diseases. VTEUs have run hundreds of clinical trials, many of which have contributed vaccines becoming licensed for use. A key feature of the VTEUs' success is their ability to enroll large numbers of volunteers into trials rapidly and vaccinate them in a safe, effective and quick manner.

In September 2013, the Duke Vaccine and Trials Unit was named a VTEU unit with Dr. Chip Walter Dr. Geeta Swamy, and Dr. Kenneth Schmader as the Co-Principal Investigators. The Duke VTEU joins eight other VTEU units around the country.

## Clinical Immunization Safety Assessment (CISA) Project

Duke University is a member of the Centers for Disease Control and Prevention (CDC) sponsored **Clinical Immunization Safety Assessment (CISA)** Project. As part of the national network, Duke assists safety experts from the CDC's Immunization Safety Office (ISO) in providing a comprehensive vaccine safety public health service to the nation. The mission of the CISA project is to improve understanding of adverse events following immunization (AEFI) at the individual-patient level. Project goals include: 1) serving as a vaccine safety resource for consultation on clinical vaccine safety issues; 2) developing strategies to assess individuals who may be at increased risk for AEFI; 3) conducting studies to identify risk factors and preventive strategies for AEFI, particularly in special populations. More specifically Duke assists with clinical case evaluation for US healthcare providers who have vaccine safety questions about a specific patient residing in the US and provides consultation that enhances understanding of vaccine safety issues and informs clinical and public health practices.

In September 2012, the Duke Vaccines and Trials Unit was named a CISA site with Dr. Chip Walter and Dr. Geeta Swamy as the Co-Principal Investigators. The Duke CISA Team joins six other sites around the country.

## Immunology Quality Assessment (IQA)

Immunology and Virology Quality Assurance Laboratory ([IVQAC](#)) is a NIAID DAIDS resource designed to help Domestic and International Immunologists evaluate and enhance the integrity and comparability of immunological laboratory determinations performed on patients enrolled in multi-site HIV/AIDS therapeutic, vaccine and prevention investigations. Through the IQA proficiency testing is administers for cryopreservation of PBMCs and CD4/CD8 Immunophenotyping by Flow Cytometry.

## PROGRAM MANAGEMENT MENTOR

Regardless of your background, starting a new job is always an adjustment. There is a lot to learn about the type of projects and tasks you will be working on, the different people and departments you will be interacting with, and maybe even the science itself. This onboarding package was built to help provide an overview and serve as a general guide, and much of your first couple of months will be spent shadowing others, sitting in on meetings, and asking questions. While you'll interact with and learn from your direct supervisor and others in program management of similar roles, you will also be paired with a dedicated mentor who will be available to show you around your first couple of days, introduce you to others you will be working with, and be available for any questions you have. Please never hesitate to reach out to your mentor for questions or advice on a task or project – that's their job!

## ABOUT ME FORM

You are a vital part of our team, and we want to learn more about you. Please complete the "About Me Form" available on the share drive:

DHVI\Program Management\TemplatesandTools\Onboarding Package\About Me Forms.

All staff members have completed this form so you can learn about them too!

## AROUND YOU AT DHVI

### **Durham Restaurants (within 1 mile of campus)**

#### [Pho & Poke House](#)

Erwin Terrace  
2816 Erwin Rd # 207  
(919) 309-4864

#### [Black Twig Cider House](#)

Erwin Terrace  
2812 Erwin Road Durham  
(919) 321-0203

#### [Chipotle Mexican Grill](#)

Lofts at Lakeview Plaza  
2608 Erwin Rd # 144  
(919) 309-2901

#### [Chopped Greens](#)

Lofts at Lakeview Plaza  
2608 Erwin Rd #132  
(919) 321-8001

#### [Nosh](#)

Erwin Terrace  
2812 Erwin Rd # 101  
(919) 383-4747

#### [Sushi Love](#)

Erwin Terrace  
2812 Erwin Road, Suite 204  
(888) 799-8037

#### [Firehouse Subs](#)

Lofts at Lakeview Plaza  
2608 Erwin Rd # 128  
(919) 383-2100

#### [Smash Burger](#)

Lofts at Lakeview Plaza  
2608 Erwin Rd  
(919) 237-1070

### **Other Durham Restaurants (within 5 miles of campus)**

#### [Blu Seafood and Bar](#)

Ninth Street District  
2002 Hillsborough Road  
(919) 286-9777

#### [Elmo's Diner](#)

Ninth Street District  
776 Ninth Street  
(919) 416-3823

#### [Parizáde](#)

Erwin Square  
2200 W Main Street  
(919) 286-9712

#### [Vin Rouge French Café & Wine Bar](#)

Ninth Street District  
2010 Hillsborough Road  
(919) 416-0466

#### [Watts Grocery](#)

1116 Broad Street  
(919) 416-5040

#### [Blue Corn Cafe](#)

Ninth Street District  
716 Ninth Street  
(919) 286-9600

#### [Nana's Restaurant](#)

Fine Dining  
2514 University Drive  
(919) 493-8545

#### [Piedmont Restaurant](#)

Downtown Durham  
401 Foster Street  
(919) 683-1213

#### [Torero's](#)

Brightleaf District  
800 W. Main Street  
919-682-4197

#### [Washington Duke Inn & Golf Club](#)

3001 Cameron Blvd  
(919) 493-6699

For a more comprehensive list of area restaurants, visit the [Durham Convention & Visitors Bureau website](#).

**Coffee:**

Dunkin Donuts - LakeView, Pavilion East - 2608 Erwin Road Durham, NC 27705

Saladelia Cafe - Hock Plaza - 2424 Erwin Rd, Durham, NC 27705

Starbucks - Located at the back of the Atrium Cafe (Duke Hospital)

**Duke Hospital Food Services:**

**Atrium Café** - Located on Level 1 in Duke Hospital

**Duke Clinic food court**

**Duke Medicine Pavilion café** - Located on Level 1 East in Duke Medicine Pavilion

**The Commons- Searle Center**

## DHVI AND PROGRAM MANAGEMENT CONTACTS

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Cynthia Nagle  
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MSRB II, Room 3083  
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## DUKE HOLIDAYS (2017)

Holiday	Day of the Week	Date
New Year's Holiday	Monday	January 2, 2017
Martin Luther King Jr. Holiday	Monday	January 16, 2017
Memorial Day	Monday	May 29, 2017
Independence Day	Tuesday	July 4, 2017
Labor Day	Monday	September 4, 2017
Thanksgiving Day	Thursday	November 23, 2017
Christmas Day	Monday	December 25, 2017

The days listed above will be recognized as designated holidays. In addition, university staff in academic medical and research units who are eligible for holiday benefits and on the active payroll on the first day of the calendar months listed below will earn a discretionary holiday in each of these months:

- February
- March
- April
- June
- August
- October

## IT TIPS

### Multi-Factor Authentication

Use the Duke ServiceNow tool at <https://duke.service-now.com> and search for KB 0023263

### Virtual Private Network (VPN) Access

Use the Duke ServiceNow tool at <https://duke.service-now.com> and search for KB 0020802

### Meeting Space Requests

Meeting space is requested through Microsoft Outlook and are ultimately approved by Lettie Anderson and/or Shannon Devine. Further information, including step-by-step instructions, can be found in the document titled "Outlook Meeting Space Invitations" or on the DHVI intranet. This document is saved at the following location on the N Drive: Z:\DHVI\Program Management\TemplatesandTools\Onboarding Package\Appendices

### Time off Requests

Time off is requested through Microsoft Outlook and are ultimately approved by your direct supervisor or Human Resources. Further information, including step-by-step instructions, can be found in the document titled "Outlook Time Off Calendars Demo" or on the DHVI intranet. This document is saved at the following location on the N Drive: Z:\DHVI\Program Management\TemplatesandTools\Onboarding Package\Appendices

## Instructions to Add Email to iPhone/Android

Use the Duke ServiceNow tool at <https://duke.service-now.com> and search for KB 0023335

## Citrix (Q-Pulse) Access

Access to the Q-Pulse server will need to be requested through the [QADVIP@duke.edu](mailto:QADVIP@duke.edu) email address. Once access has been granted, you will login in using your DHE username and password. Q-Pulse is a program used to access standard operating procedures (SOPs) and provides users with a mechanism to document their training on a particular SOP.

## WebEx

Use the Duke ServiceNow tool at <https://duke.service-now.com> and search for KB 0014282

## Duke Box

Use the Duke ServiceNow tool at <https://duke.service-now.com> and search for KB 0023400

## N Drive Layout

The N Drive is the primary server folder structure used at DHVI. The N Drive comes pre-populated with the following folders for all users:

- DHVI (Administrative, Financial Management, IT, Legal, and Program Management)
  - Program Management folder will include documents pertinent to the Program team including meeting agenda, meeting minutes, resources, and contact lists
- DHVI-Users
  - This is a personal folder that you may use to save files
- Investigators
  - Houses folders that are specific to particular Principal Investigators and their laboratory/team staff
  - These are only available to particular staff members
- Safety (all information related to safety including policies and SOPs)
- Shared (miscellaneous folder)

## Cisco Jabber

Jabber is a Duke approved instant messaging tool that helps streamline communication between team members without relying so heavily on email. To download, visit [oit.duke.edu](http://oit.duke.edu). You will login using your DHE username and password.

## FREQUENTLY ASKED QUESTIONS

**What is the regular workday?** Program Management team members work Monday – Friday, 8:30am – 5pm. Occasional early mornings, late evenings, or weekend work may be necessary depending on critical projects deadlines. Additionally, some team members may be asked to participate in off-site conferences; travel and accommodations for these will be arranged by DHVI. You should discuss any concerns about working overtime or temporarily rearranging a schedule with your supervisor.

**What about inclement weather?** Personal safety is of primary importance when determining whether to report to work during inclement weather. Duke University releases inclement weather policy updates and alerts via multiple outlets. All Duke University employees receive such updates in their Duke email; additionally, you can sign up for text alerts via the [Duke@Work Self-Service portal](#).

**What is our address?** Adapt the following to include your room number:

Duke University - Duke Human Vaccine Institute  
Mailbox 103020  
2 Genome Court  
Durham, NC 27710

**Where can I get lunch?** You may take your lunch break as your daily schedule allows. There are multiple restaurants within walking distance of MSRB2, as well as a cafeteria in Duke Hospital North. If you prefer to bring a lunch, there is a shared refrigerator and microwave for Program Management team members in the PM wing. Additionally, you may use any break room on the 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> floor in MSRB2. The 3<sup>rd</sup> and 4<sup>th</sup> floor break rooms have coffee machines for all DHVI staff to enjoy free of charge. If you like, there are multiple picnic tables near the Snyderman Building, some with umbrellas, for enjoying your lunch outside.

**How do I request time off?** Send an email to [DHVI.DHVIPro684@dm.duke.edu](mailto:DHVI.DHVIPro684@dm.duke.edu) with the dates you are requesting off. You will receive an email back saying that your request is pending. Your supervisor will then approve your time off and it will be added to your Outlook calendar.

**How do I get office supplies?** Simply send an email to a Program Coordinator with the Staples catalogue number of any items you need. There is a \$50 minimum per complete order. While waiting for your order to arrive, there are extra basic supplies (pens, notebooks, etc.) in the bookshelf outside of Room 3089.

**Where is the copier/fax machine/mailbox?** Program management team members share a copier in the PM wing in MSRBII, Room 3074. Here is also where the mail is delivered.

**How do I install software onto my computer?** Contact DHVI IT to help install appropriate software, update licenses, etc. You may need an approval email from your supervisor.

## RECOMMENDED TRAINING

### Professional training within Duke

Duke University offers training opportunities throughout the year for employees through **the Duke Learning Management System** and the **Learning and Organization Development** unit. L&OD provides classes and workshops, program development and consulting services, some of which may be helpful to you as a member of the DHVI Program Management team. Course offerings for Duke LMS and L&OD can be found by navigating to the following in Duke@Work: MyCareer -> MyLearning -> Catalog Search

All Program team members are strongly encouraged to take the following courses within six months of starting at DHVI:

- Pre-Award Fundamentals
- Post-Award Fundamentals

Additionally, the following courses are relevant for Program team members:

- Project Management Fundamentals (Project Management 1 and 2)
- Managing Multiple Priorities

If you are or plan to be in a supervisory position, the following classes may be helpful:

- Keys to Supervisory Success
  - Guide to Managing at Duke
  - Leading with Emotional Intelligence
-

If you are interested in additional LMS or L&OD courses that may help you improve your skill set, you are encouraged to discuss them with your supervisor. For all courses that require payment, your supervisor will ensure that you are provided a fund code to use.

### Other training resources at Duke

The DHVI works closely with the Regulatory Affairs group (directed by Amanda Parrish) housed within the Duke Translational Medicine Institute. Dr. Burnett's team offers seminars and lectures throughout the year pertaining to Investigational New Drug (IND) applications as well as Good Manufacturing Practices (GMP) for clinical trial product development. Program managers affiliated with the DHVI CGMP Manufacturing Facility or other clinical trial product manufacturing programs are encouraged to take these seminars.

The Regulatory Affairs website can be found here:

<https://www.dtmi.duke.edu/what-we-do/regulatory-affairs>

Recently, a new group has formed at Duke in support of Project/program managers—the [Duke Project Management Community of Practice](#). You will be added to their list serv, and are encouraged to join their events. Ana Sanchez is currently a member of their Steering Committee.

### Training outside of Duke

Some team members may find it helpful to explore additional training opportunities offered outside of the Duke system. Wake Tech Community College offers courses under their Workforce Continuing Education program that pertain to topics such as Good Manufacturing Practices (GMP), which is relevant to any program managers affiliated with the DHVI CGMP Manufacturing Facility or other clinical trial product manufacturing programs. Wake Tech course offerings can be found here:

<http://www.waketech.edu/programs-courses/non-credit/enhance-your-career/biotechnology>

## GROUP MEETINGS

### PROGRAM MEETINGS:

- **Bi-weekly Program Meeting:** Fridays, 3:00-4:00 PM (MSRBII, Room 3090)
- **PI Finance Meeting:** ask corresponding finance/grant administrator (times can vary)

### LAB MEETINGS:

- **DHVI Wide Lab Meeting:** (biweekly) Thursdays, 8:30 AM (Jones Building, Room 143)
- **Barton Haynes:** Wednesdays, 8:30 AM (MSRBII, Room 4022)
- **Georgia Tomaras:** Mondays, 10:00 AM (MSRBII, Room 3018)
- **Gregory Sempowski:**
  - RBL Research Leadership Group: Tuesdays, 9:00 AM (GHRB Conf. Room)
  - RBL Immunology Team: Wednesdays, 9:30 AM (GHRB Conf. Room)
  - RBL Virology Team: Fridays, 12:00 PM (GHRB Conf. Room)
  - DHVI Flow Team: Fridays, 9:00-10:00 AM (GHRB GDS Office)
- **Kevin Saunders:** Mondays, 9:00- 10:00 AM (MSRBII, Room 4022)
- **Laurent Verkoczy:** (biweekly) Mondays, 2:00-3:30 PM (MSRBII, Room 1154)
- **Mattia Bonsignori:** Fridays, 8:30 AM (MSRBII, Room 1154)

- **Munir Alam:** Mondays, 10:00 AM (MSRBII, Room 4004-Munir's Office)
- **Sallie Permar:** Tuesdays, 8:30 AM (MSRBII, Room 3090)
- **Tony Moody:** Fridays, 1:00-2:30 PM (MSRBII, Room 3090)
- **Tom Denny:** Wednesdays, 9:00 AM (GSRBII, Room 4002)

### **JOURNAL CLUB:**

- **DHVI Journal Club:** Mondays, 12:00 PM (MSRBII, Room 4022)

Please note that the above is a comprehensive list of all general DHVI meetings. Your assigned project portfolio and your grants will dictate as to what PI(s) you will be closely working with, hence what lab meetings would be applicable to attend.

## **USEFUL RESOURCES**

- DHVI Website: <http://dhvi.duke.edu/>
- Duke@Work Website: [www.work.duke.edu](http://www.work.duke.edu)
- Duke HR Website: <http://www.hr.duke.edu/>
- CHAVI-ID Website: <http://chavi-id-duke.org/>
- Duke Vaccine and Trials Unit Website: <http://dvtu.dhvi.duke.edu/>
- IVQAC, IQA Program Website: <http://iqa.center.duke.edu>
- EQAPOL Website: <http://eqapol.dhvi.duke.edu>
- Social Media Policy: <http://medschool.duke.edu/communications/resources-faculty-staff/social-media-policies>

## **APPENDICES**

Find a list of appendices on the Share Drive: DHVI\Program Management\TemplatesandTools\Onboarding Package\Appendices

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