



BRIGHAM AND  
WOMEN'S HOSPITAL

---

**CCI** Center for Clinical Investigation  
*in partnership with Harvard Catalyst*

---

# Center for Clinical Investigation

## All-User Meeting

---

December 1, 2011

**Welcome!**



# Agenda

---

- Announcements & Updates
- CCI Core Descriptions
  - Nursing, Nutrition, Processing
  - Biostatistics
- Clinical Investigation Committee
- Scientific Highlights from Community



# Introductions

## Center for Clinical Investigation

- **Dr. Gordon Williams**

Program Director

- **JoAnna Waterfall**

Operations Director

[jwaterfall@partners.org](mailto:jwaterfall@partners.org)

- **Yemi Talabi-Oates**

Outpatient/Off-Unit Manager

- **Bharti Thakkar**

Laboratory Manager

- **Sandra Jarrett**

- **Kristine Jordan**

Administrative Director

- **Mary Schneider**

Finance Director

- **Marianne Moore**

Education Manager

- **Lisa Horton**

Education Coordinator

- **Lauren Shaughnessy**

Program Coordinator

[cci@partners.org](mailto:cci@partners.org)



BRIGHAM AND  
WOMEN'S HOSPITAL

---

**CCI** Center for Clinical Investigation  
*in partnership with Harvard Catalyst*

---

# Announcements

---



# Junior Investigator RFA

---

Applications due October 28, requesting:

- Genotyping
- LabCorp Assays
- HCCL Assays

49 Applications received

BIDMC	5
BWH	19
CHB	6
MGH	19
McLean	2

Applications currently being reviewed by Program Directors

**Awards will be announced December 9, 2011**

- up to \$5,000 worth of services to awardees



# CCI Education: Upcoming Courses

## December

- IRB/QI Lecture Series: Protocol Adherence and Reporting Requirements - 12/6
- Introduction to Epidemiology - 12/7
- Topics in Biostatistics: Statistical considerations: Design, power, sample size issues \* -12/8
- **6th Annual Research Nurse/Study Coordinator Networking Breakfast - 12/13**
- Topics in Biostatistics: Survival Analysis \* - 12/15
- RCR Rounds: ClinicalTrials.gov Registration - 12/15
- REDCap (Research Electronic Data Capture) Programming Training \* - 12/19

## January

- IDS Roundtable: Drug Trials at BWH - Pharmacy Services - 1/5
- Clinical Skills Training - 1/6
- Phlebotomy Training - 1/10
- BWH Clinical Trials Billing Fundamentals - 1/11
- RCR Rounds: Collaborations with Industry - 1/31 \* *co-sponsored by the CFDD Office for Research Careers*

## February

- **Orientation to the CCI Research Units - 2/9**
- Welcome to the Genetic Code: An Overview of Basic Genetics \* - 2/16

\* *These programs are co-sponsored by BWH Center for Clinical Investigation and Harvard Catalyst.*

---

**MORE INFO & REGISTRATION:** [www.brighamandwomens.org/calendar](http://www.brighamandwomens.org/calendar)



# Center for Clinical Investigation

presents the 6<sup>th</sup> Annual

## Research Nurse/Study Coordinator Networking Breakfast

---



**WHEN:** Tuesday, December 13 from 9:00 - 10:30a.m.

**WHERE:** Carrie Hall, 15 Francis Street, BWH



This informal gathering provides the study staff community with an opportunity to meet and network with their peers as well as representatives from research-related departments.

---

**RSVP:** [www.brighamandwomens.org/calendar](http://www.brighamandwomens.org/calendar)

**CONTACT:** Lisa Horton | lhorton1@partners.org | 617-525-7654



# Orientation to the CCI Research Units

---

**WHO:** For clinical researchers and study staff new to using the BWH CCI Research Resources. This includes the research units on 9A, 9B, the ACC, CTC and the HCCL.

**WHAT:** This training covers:

- Applying to use the resources
- Scheduling/rescheduling troubleshooting
- Labs/processing
- Tour of the research units
- FAQs

**WHEN:** Thursday, February 9, 2012 from 12:30 – 2:00p.m.

**WHERE:** Duncan Reid Conference Room, BWH

---

**REGISTER:** [www.brighamandwomens.org/calendar](http://www.brighamandwomens.org/calendar)

---

*Sponsored by the Center for Clinical Investigation*

Harvard Catalyst Central

BWH - Senior VP

Program Director

Admin Director

**Career Development,  
Education, and  
Mentoring Services**

Structured Educational Programs

CCI & Harvard Catalyst Courses

Mentor Matching

K or equivalent Programs

BWH Courses

**Administrative  
Resources**

Resource Facilitation

Protocol Development

IRB Application

CCI Application Assistance

Orders Development

**Consultation  
Services**

Biostatistics

Imaging

Community Research

Genetics

**Clinical Research  
Resources**

Inpatient Research:  
Standard Bed Unit  
Intensive Physiologic Monitoring Unit

Outpatient Research:  
221 Longwood Ave  
PBB A4

Off-Unit Studies:  
Hospital inpatient and outpatient  
units & clinics

Personnel:  
PA, RN, MA, Technicians  
Nutrition, Ultrasound Technicians,  
Coordinators

Specimen Processing &  
Laboratory Services  
Harvard Catalyst Central Laboratory



# Funding Structure

## Center for Clinical Investigation

### Harvard Catalyst CTSC Grant (*Previously GCRC*)

Multi-Institutional Infrastructure Grant  
+ Ancillary Support (STAT/LabCorp)

#### CCI CROSS Core

Consolidated  
Research Service  
Offering

#### HCCL Core

Harvard Catalyst  
Central Lab  
HC-Subsidized

#### Hospital Funds

Administration  
&  
Operations



# CCI CROSS Core

---

## CCI CROSS Core – Consolidated Offering:

- **Biostatistics**
- **Nursing & Nutrition Services (includes Processing)**
- RCNet: Research Coordinator Network
- Clinical Trials Center
- \*\*New Service: Ultrasound

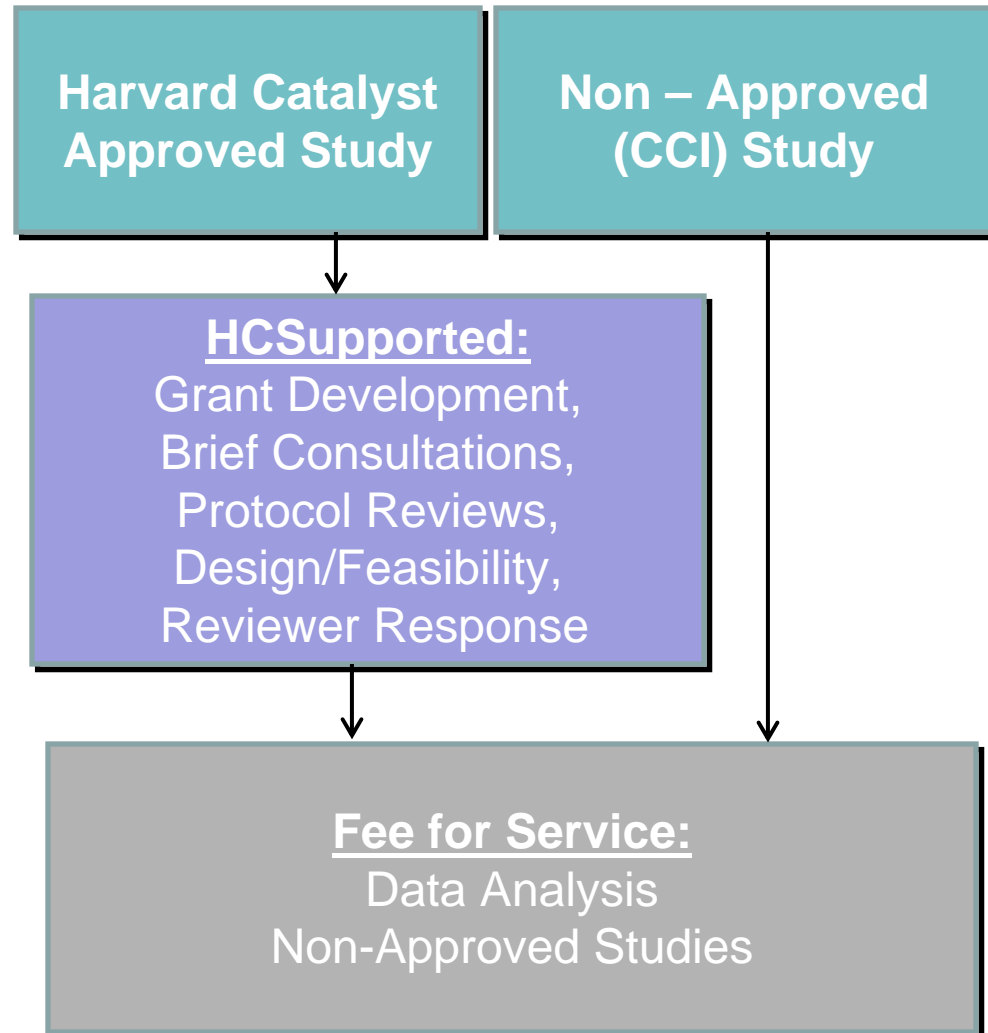
- 
- PHS Research Management Policies on Research Cores
  - Invoice PIs Monthly w/ 5 business day review period
  - Internal Payments: Journal Transfer
  - External Payments: Check (Subject to Indirects)
  - Rate and contact information available:

[http://www.partners.org/researchcores/home\\_bwh.html](http://www.partners.org/researchcores/home_bwh.html)



# Biostatistics

- **Harvard Catalyst CRC Approved**
  - Supported
    - Grant Development, Brief Consultations, Protocol Reviews, Design/Feasibility, Reviewer Response
  - Fee for Service
    - Data Analysis
- **Non - Harvard Catalyst**
  - All services billable as a fee for service



Biostatistics Director: Shelley Hurwitz, Ph.D.  
Phone: (617) 732-6467  
Fax: (617) 525-8550  
Email: [hurwitz@hms.harvard.edu](mailto:hurwitz@hms.harvard.edu)  
<http://biostatistics.bwh.harvard.edu>



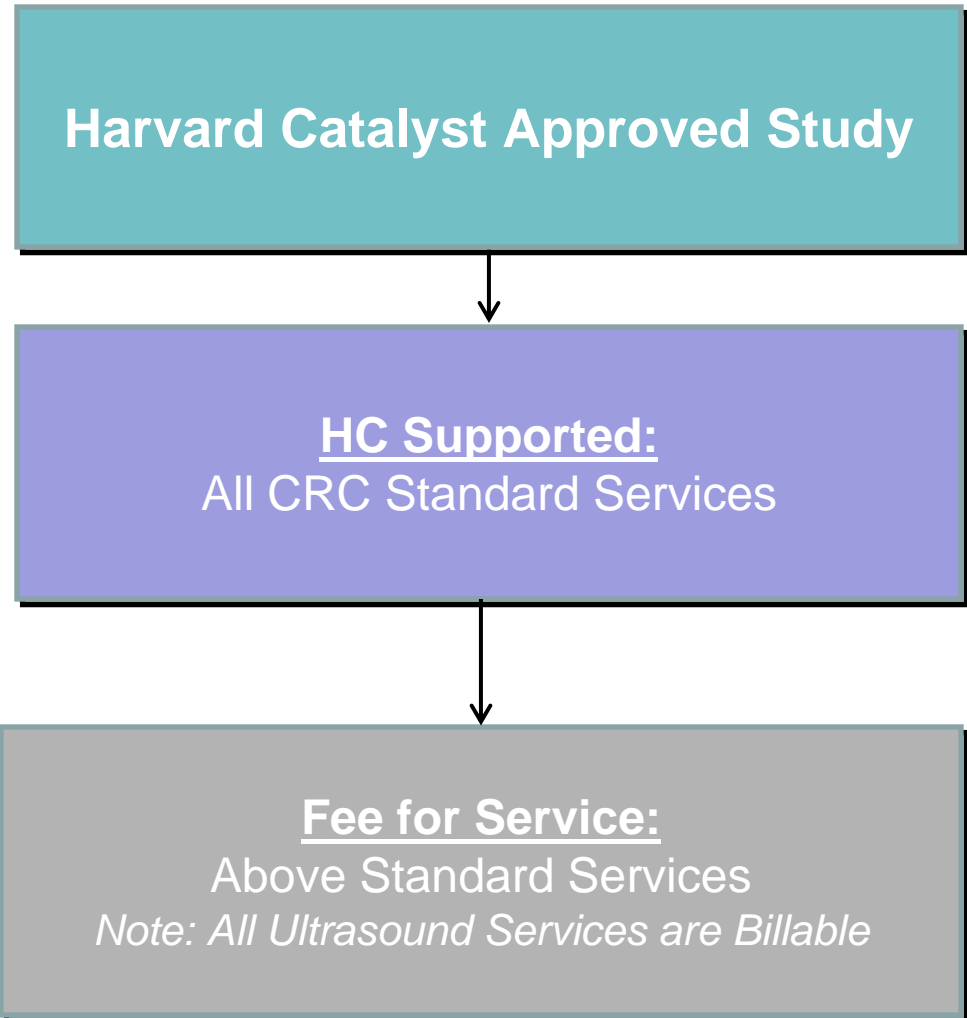
# Nursing & Nutrition (9AB & ACC)

- **Harvard Catalyst CRC  
Approved**

- Supported for all CRC  
“Standard Services”  
All supported studies must be  
HC Approved
- Fee for Service for “Above  
Standard Services”

NSS Manager: Sheila Driscoll  
Phone: (617) 732-7764  
Fax: (617) 975-0977  
Email: [sdriscoll1@partners.org](mailto:sdriscoll1@partners.org)

Nutrition Manager: Janis Swain  
Phone: (617) 732-7783  
Fax: (617) 732-7900  
Email: [jfswain@partners.org](mailto:jfswain@partners.org)





# Nursing Standard Services

---

- Standard clinical patient care
- Standard services:
  - Nurse monitoring
  - BP pressure devices with print out
  - IV infusion supplies with IV pump
  - Phlebotomy collection items
  - Bandages, tapes and dressings
- Application, study order development and consultation



# Nursing/Processing Above Standard Services

---

## Nursing Above Standard Services = \$ Fee for Service

1:1 Nursing	EEG Placement
Ultrasound/Imaging	Temperature Collection Frequent
Electrode Scalp Replacement	Frequent Blood Sampling
Frequent Special Meals Delivery	Special Processing



# Nutrition

## Above Standard Services

---

- Nutrition core provides standard meals to subjects on CCI units (standard clinical care)

### **Above Standard Services = \$ Fee for Service**

Constant Routine Meals: “Mini” meals, eaten at regularly scheduled intervals, controlled for calories, nutrients, and fluid content

Weighed Meals: Calculated/calibrated meals designed to meet specific nutrient targets

Harvard Catalyst Central

BWH - Senior VP

Program Director

Admin Director

**Career Development,  
Education, and  
Mentoring Services**

Structured Educational Programs

**CCI & Harvard Catalyst Courses**

Mentor Matching

K or equivalent Programs

BWH Courses

**Administrative  
Resources**

Resource Facilitation

Protocol Development

IRB Application

CCI Application Assistance

Orders Development

**Consultation  
Services**

Biostatistics

Imaging

Community Research

Genetics

**Clinical Research  
Resources**

**Inpatient Research:**  
Standard Bed Unit  
Intensive Physiologic Monitoring Unit

**Outpatient Research:**  
221 Longwood Ave  
PBB A4

**Off-Unit Studies:**  
Hospital inpatient and outpatient  
units & clinics

**Personnel:**  
PA, RN, MA, Technicians  
Nutrition, Ultrasound Technicians,  
Coordinators

**Specimen Processing &  
Laboratory Services**  
Harvard Catalyst Central Laboratory



BRIGHAM AND  
WOMEN'S HOSPITAL



# Clinical Investigation Committee

*Danny Pallin, MD, MPH, Chair*

Thursday, December 1, 2011



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*

# Clinical Investigators' Leadership Forum

- Learn about resources
- Network
- Advocate for clinical research
- Discuss concerns



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Format

- Monthly meeting
- 2<sup>nd</sup> Tuesday every month



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Membership

- By invitation
  - Let us know if you are interested!
- Clinical researchers
  - Professors
  - Associate Professors
  - Assistant Professors
- Divisional representation



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Leadership

- Chairman, 2-year term
- Gordon Williams, long-term oversight



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# CIC Docks With...

- BWH Biomedical Research Institute's Clinical Research Program
  - Chaired by Drs. Williams and Pallin
- BWH Center for Clinical Investigation (CCI)
  - BWH's Catalyst site (formerly GCRC)



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Types of Topic

- Regulatory updates
- Organizational structures
- Opportunities for improvement
- Innovations and resources



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Recent Topics

- Chief of the ClinicalTrials.gov program at the National Library of Medicine
- Integration of genetic components into clinical trials
- Regulatory innovations at the IRB



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Recent Topics, ctd.

- Advent of the ICD-10 system
- Partners Clinical Research Office  
(manages industry-sponsored clinical research)



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Recent Topics, ctd.

- Information technology
- Statistics



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Recent Topics, ctd.

- Catalyst Laboratory for Innovative Translational Technologies (LITT)
- Partners Technology Transfer



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Between Meetings...

- Focus groups
- Policy discussions
- Learning and advocacy



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL

# Your interest is welcome!

- CIC Chairman Danny Pallin,  
[dpallin@partners.org](mailto:dpallin@partners.org)



HARVARD  
MEDICAL SCHOOL  
*TEACHING AFFILIATE*



BRIGHAM AND  
WOMEN'S HOSPITAL



# Next CCI-All User Meeting

---

February 16, 2012 – Shapiro Breakout Room  
9:00-10:00am

1. CCI Core Clinical Research Resources
  - a. Research Coordinator Network
  - b. Clinical Trials Center
2. Scientific Highlights from the Community

**Other ideas/requests?**



BRIGHAM AND  
WOMEN'S HOSPITAL

---

**CCI** Center for Clinical Investigation  
*in partnership with Harvard Catalyst*

---

**Questions?**

---



BRIGHAM AND  
WOMEN'S HOSPITAL

---

**CCI** Center for Clinical Investigation  
*in partnership with Harvard Catalyst*

---

# Contact Us!

[www.brighamandwomens.org/cci](http://www.brighamandwomens.org/cci)

[cci@partners.org](mailto:cci@partners.org)



BRIGHAM AND  
WOMEN'S HOSPITAL

---

**CCI** Center for Clinical Investigation  
*in partnership with Harvard Catalyst*

---

# Scientific Highlights

---



# Scientific Highlights

---

## **Caveolin-1 and vascular dysfunction**

- **Luminita Pojoga, MD**

Human phenotype studies were conducted after subjects consumed a high salt (200mmol/day) for 7 days each. Participants were admitted overnight to a Clinical Research Center after the diet and measurements for plasma glucose, insulin, and lipids were obtained in the morning after an 8 hour fast.

Study results demonstrated that Cav-1 gene polymorphisms and depletion of the Cav-1 gene are associated with the co-aggregation of insulin resistance and hypertension. These results were recently published in *Journal of Clinical Endocrinology and Metabolism* (2011). Dr. Pojoga has received a R01 and Dr. Underwood has received a F32 to investigate the CAV1 gene further.



# Scientific Highlights

---

## **Postprandial Apolipoprotein B Metabolism**

- **Frank Sacks, MD**

This study addressed the metabolic basis of hypertriglyceridemia and its associated lipid abnormality, dense LDL, a condition that strongly predicts high risk of cardiovascular disease. These lipid abnormalities are growing in prevalence since they are associated with type 2 diabetes and obesity.

They found that this protein is integrally involved in the abnormal metabolism of this condition. This is leading toward a new paradigm of lipid related risk of cardiovascular disease, and suggests a new target for diet and drug treatment.