



BRIGHAM AND  
WOMEN'S HOSPITAL

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

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# Center for Clinical Investigation

## All-User Meeting

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September 29, 2011

**Welcome!**



# Agenda

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- Introductions
- Announcements & Updates
- Infrastructure & Support
- Scientific Highlights from Community



# Introductions

## Center for Clinical Investigation

- **Dr. Gordon Williams**

Program Director

- **JoAnna Sullivan**

Operations Director

- **Yemi Talabi-Oates**

Outpatient/Off-Unit Manager

- **Bharti Thakkar**

Laboratory Manager

- **Sandra Jarrett**

Administrative Assistant

- **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)



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# Announcements

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# Lab Updates

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## Ancillary Policy Change

- Starting 9/1 – applies to new applications:
  - Senior Investigators (Professors & Associate Professors) allotted \$30/subject/day
  - Junior Investigators (Assistant Professor and below) allotted \$60/subject/day
- Note: All protocols submitted prior to 9/1 continue at previous support (\$60/subject/day)



# Lab Updates (cont.)

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## Coming Soon! Freezerworks

- New Laboratory Management System will replace GIGPAD, more information to follow

## LabCorp Reminder!

- Results only stay in 'eResults' for 6 months. Be sure to print out and archive your study results on a timely basis
- For paper requisition forms – the protocol # MUST go in the patient ID field (example)



# LabCorp Paper Requisitions:



Brigham & Womens Sleep  
 Room 446  
 221 Longwood Ave  
 BOSTON MA 02115  
 617-732-7342 NHP  
 20313760-3

To find the nearest patient service center, visit www.labcorp.com or call 888-LABCORP (888-522-2677).

Send additional copy of report to:

Fax  
 Call  
 Mail

Client Number/Physician's Name \_\_\_\_\_ Phone/Fax Number \_\_\_\_\_  
 Physician's Address \_\_\_\_\_ City, State, Zip \_\_\_\_\_

0800.09

AXS20313760 AXS20313760 AXS20313760  
 AXS20313760 AXS20313760 AXS20313760

AXS20313760

CHECK ONE  
 03 [ ] ACCOUNT BILL

| Patient's Legal Name (Last, First, MI)                                                                                                                                                                                                                                                                                                                                                                                                        |                         | <div style="background-color: #FFDAB9; padding: 5px; text-align: center;">           Include IRB protocol number here:         </div> |                         | In Time                                                                                                             | Fasting                                                     | Collection Date | Urine hrs/vol |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
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| NPI                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                                                                                                                       |                         | AM                                                                                                                  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No | MO DAY YR       | hrs vol       |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
| Physician's Name (Last, First)                                                                                                                                                                                                                                                                                                                                                                                                                |                         | Physician's Signature                                                                                                                 |                         | Patient's SS#                                                                                                       |                                                             | Patient's ID#   |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
| Diagnosis/Signs/Symptom in ICD-9-CM Format (Highest Specificity)                                                                                                                                                                                                                                                                                                                                                                              |                         | Hospital Patient Status:                                                                                                              |                         | <input type="checkbox"/> In-Patient<br><input type="checkbox"/> Out-Patient<br><input type="checkbox"/> Non-Patient |                                                             |                 |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
| R E Q U I R E D                                                                                                                                                                                                                                                                                                                                                                                                                               |                         | Patient's Address                                                                                                                     |                         | City                                                                                                                |                                                             | Phone State ZIP |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                               |                         | Name of Policy Holder (if different from patient)                                                                                     |                         | Address of Policy Holder                                                                                            |                                                             | APT # State ZIP |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
| <table border="1"> <thead> <tr> <th>PRIMARY BILLING PARTY</th> <th>SECONDARY BILLING PARTY</th> </tr> </thead> <tbody> <tr> <td>Insurance Carrier *</td> <td>Insurance Carrier *</td> </tr> <tr> <td>ID #</td> <td>ID #</td> </tr> <tr> <td>Group #</td> <td>Group #</td> </tr> <tr> <td>Insurance Address</td> <td>Insurance Address</td> </tr> <tr> <td>Name of Insured Person</td> <td>Name of Insured Person</td> </tr> </tbody> </table> |                         | PRIMARY BILLING PARTY                                                                                                                 | SECONDARY BILLING PARTY | Insurance Carrier *                                                                                                 | Insurance Carrier *                                         | ID #            | ID #          | Group # | Group # | Insurance Address | Insurance Address | Name of Insured Person | Name of Insured Person | <table border="1"> <thead> <tr> <th>PATIENT</th> <th>RESP. PARTY</th> </tr> </thead> <tbody> <tr> <td colspan="2">I hereby authorize the release of medical information related to the service described herein and authorize payment directly to LabCorp. I agree to assume responsibility for payment of charges for laboratory services that are not covered by my healthcare insurer.</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td></td> </tr> <tr> <td>Patient's Signature</td> <td>Date</td> </tr> </tbody> </table> |  | PATIENT | RESP. PARTY | I hereby authorize the release of medical information related to the service described herein and authorize payment directly to LabCorp. I agree to assume responsibility for payment of charges for laboratory services that are not covered by my healthcare insurer. |  | <input checked="" type="checkbox"/> |  | Patient's Signature | Date | <p style="text-align: center; color: red; font-weight: bold;">MEDICARE ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)</p> |  |
| PRIMARY BILLING PARTY                                                                                                                                                                                                                                                                                                                                                                                                                         | SECONDARY BILLING PARTY |                                                                                                                                       |                         |                                                                                                                     |                                                             |                 |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
| Insurance Carrier *                                                                                                                                                                                                                                                                                                                                                                                                                           | Insurance Carrier *     |                                                                                                                                       |                         |                                                                                                                     |                                                             |                 |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
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| Name of Insured Person                                                                                                                                                                                                                                                                                                                                                                                                                        | Name of Insured Person  |                                                                                                                                       |                         |                                                                                                                     |                                                             |                 |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
| PATIENT                                                                                                                                                                                                                                                                                                                                                                                                                                       | RESP. PARTY             |                                                                                                                                       |                         |                                                                                                                     |                                                             |                 |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |
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| Patient's Signature                                                                                                                                                                                                                                                                                                                                                                                                                           | Date                    |                                                                                                                                       |                         |                                                                                                                     |                                                             |                 |               |         |         |                   |                   |                        |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |         |             |                                                                                                                                                                                                                                                                         |  |                                     |  |                     |      |                                                                                                                            |  |



# Junior Investigator RFA

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*To be announced by October 1, 2011*

## **Eligibility:**

Assistant Professor or lower academic rank

\*Fellows are NOT eligible

## **Services:**

- 1) Batch assays through HCCL or LabCorp
- 2) SNPs through PPCGM

## **Awards:**

Up to \$5,000 per investigator



# Education Program

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## **WHO: Clinical Research Community:**

- Investigators
- Research Nurses
- Study Coordinators
- Research Assistants

## **WHAT: Programs include:**

- Courses
- Workshops
- Lecture Series
- Networking Events

**WHEN:** Throughout the year; find specific course details on the website:  
<http://www.brighamandwomens.org/research/CCI/education.aspx>

Subscribe to receive an email,  
**Research Connection: CCI Update:**  
<http://researchlistweb.partners.org/list/w/bwh/subscribebwh.html>

\* Sent out every other Wednesday

**HOW: Register online on the BWH Events Calendar:**  
[www.brighamandwomens.org/calendar](http://www.brighamandwomens.org/calendar)



# Upcoming Courses

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## October

- BWH Clinical Trials Billing Fundamentals - 10/12
- Topics in Biostatistics: Choosing the Correct Analysis Method \* - 10/13
- Introductory Statistics for Medical Researchers - 10/18, 10/25 & 11/1, 11/8, 11/15 and 11/22
- IRB/QI Lecture Series: New Submission - 10/19
- IRB/QI Lecture Series: Study start-up - 10/26
- Responsible Conduct of Research (RCR) Rounds: The Peer Review Process for Manuscripts - 10/20

## November

- IRB/QI Lecture Series: Continuing Review and Amendments - 11/2
- Topics in Biostatistics: Categorical Analysis and Logistic Regression Analysis \* - 11/3
- IRB/QI Lecture Series: Source documentation - 11/9
- BWH Research Nurse Gathering: Ethics in Research Nursing - 11/30

**Save the date!** Introduction to Epidemiology - 12/7

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

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

# Study Coordinator Orientation

**WHO:** Study Staff

- Study Coordinators
- Research Nurses
- Research Assistants

**WHAT:** Activities and case studies provide information regarding:

- regulations
- roles and responsibilities
- best practice and study management advice
- Clinical Skills Training with BWH Department of Nursing Center for Nursing Excellence

**WHEN:** twice yearly

- Fall 2011
- Spring 2012

# Orientation to the CCI Research Units

**WHO:** For clinical researchers and study staff new to using the BWH CCI Resources.

**WHAT:** This training includes:

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

**WHEN:** twice yearly

- Winter 2012
- Summer 2012

# Center for Clinical Investigation

Senior VP  
Barbara Bierer

Program Director  
Gordon Williams

Administrative  
Director

CTC

Stats

RCNet

Education

Genetics

IRB  
Assist.

Study  
Coord.

Coord.

Invest.

Fellows

Nursing

# Clinical and Translational Science Center

Harvard Catalyst  
Central

Program Director  
Gordon Williams

Administrative  
Director

Patient Care Sites

Patient Services

Non-Patient Services

Inpatient

9A

9B

Outpatient

221

CTC

Off-Unit Activity

Outpt Clinics

Inpt Units

HCCL

Community

Ultrasound Core

BioNutrition Core

Processing Core

9A/B

221

CTC

DFCI

Biostatistics Core

Administration

Informatics

Regulatory

Genetics Consult

Imaging Consult

Ethics

Diversity

Education

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



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**How is it paid for?**

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# Funding Sources

## 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

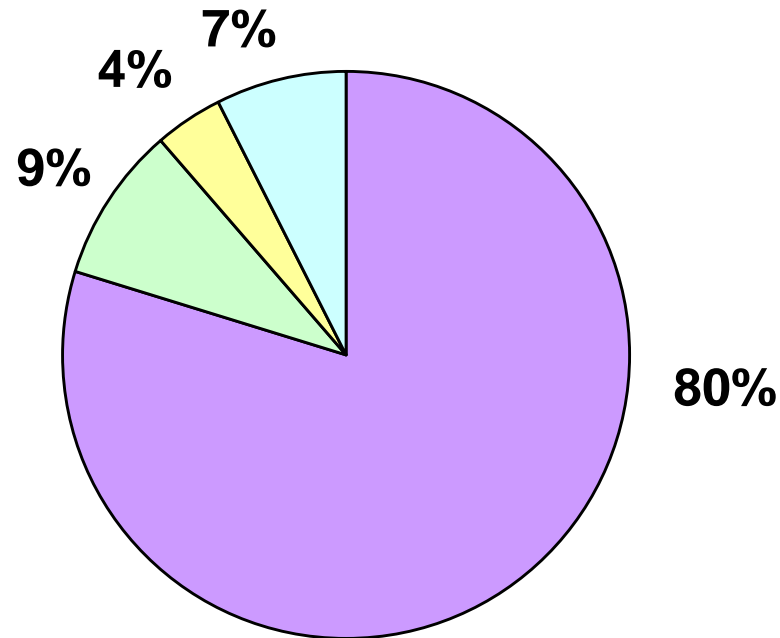
Harvard Catalyst  
Central Lab  
HC-Subsidized

### Hospital Funds

Administration  
&  
Operations



# Funding Sources



■ Harvard Catalyst  
■ HCCL

■ CROSS Core  
■ Hospital Funds



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### **HCCL Core**

Harvard Catalyst  
Central Lab  
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### **Hospital Funds**

Administration  
&  
Operations



# CCI CROSS Core

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## **CCI CROSS Core – Consolidated Offering:**

- Biostatistics
- RCNet: Research Coordinator Network
- Nursing & Nutrition Services
- Lab & Specimen Processing
- Outpatient Services
- \*\*New Service: Ultrasound

- 
- Follow the PHS Research Management Policies on Research Cores
  - Invoice PIs Monthly w/ 5 business day review period
  - Internal: Journal Transfer / External: Check (subject to indirects)
  - Policy and Rate information available:

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



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**Questions?**

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Administration  
&  
Operations



# HC - Ancillary Support

## Harvard Catalyst Ancillary Subsidy

*Updated 9/1/2011*

Allowance to support assays sent to:

- LabCorp
- BWH Clinical Labs

Senior Investigators

*Full Professor, Associate Professor*

\$30/subject/visit/day

Junior Investigators

*Assistant Professor and below*

\$60/subject/visit/day

HC Approved Assays  
@ LabCorp &  
STAT

Supported:  
Up to Cap  
\$30/\$60 per Visit

\$ Fee for Service:  
Over Cap Assays



# Funding Sources

## Center for Clinical Investigation

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

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### **CCI CROSS Core**

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### **HCCL Core**

Harvard Catalyst  
Central Lab  
HC-Subsidized

### **Hospital Funds**

Administration  
&  
Operations

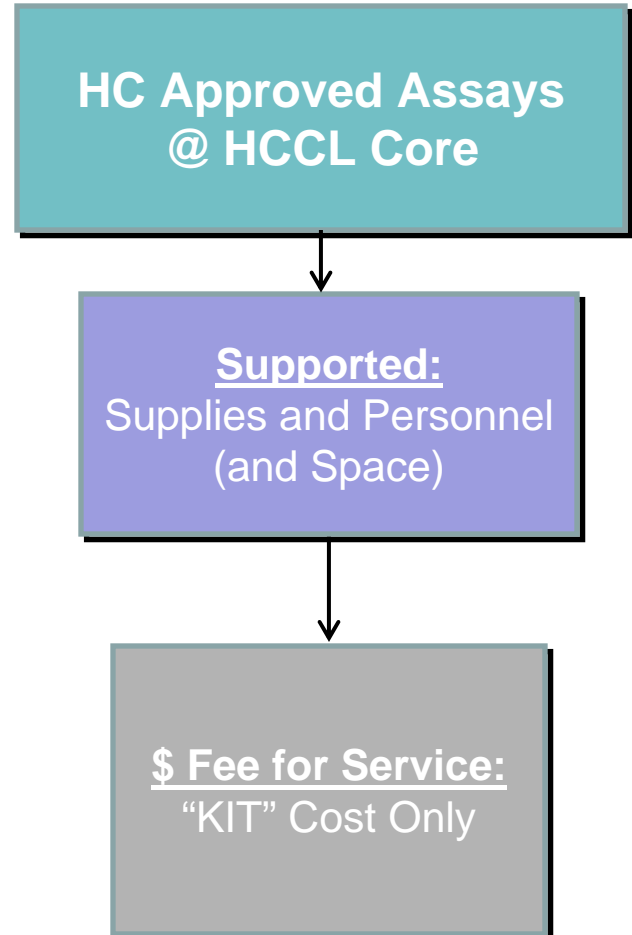


# HCCL

## Harvard Catalyst Central Laboratory (HCCL) Core *At BWH*

- Onsite
- HC subsidized
- Investigators only pay “Kit” costs

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





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**Questions?**

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# Who uses the Clinical Research Centers:

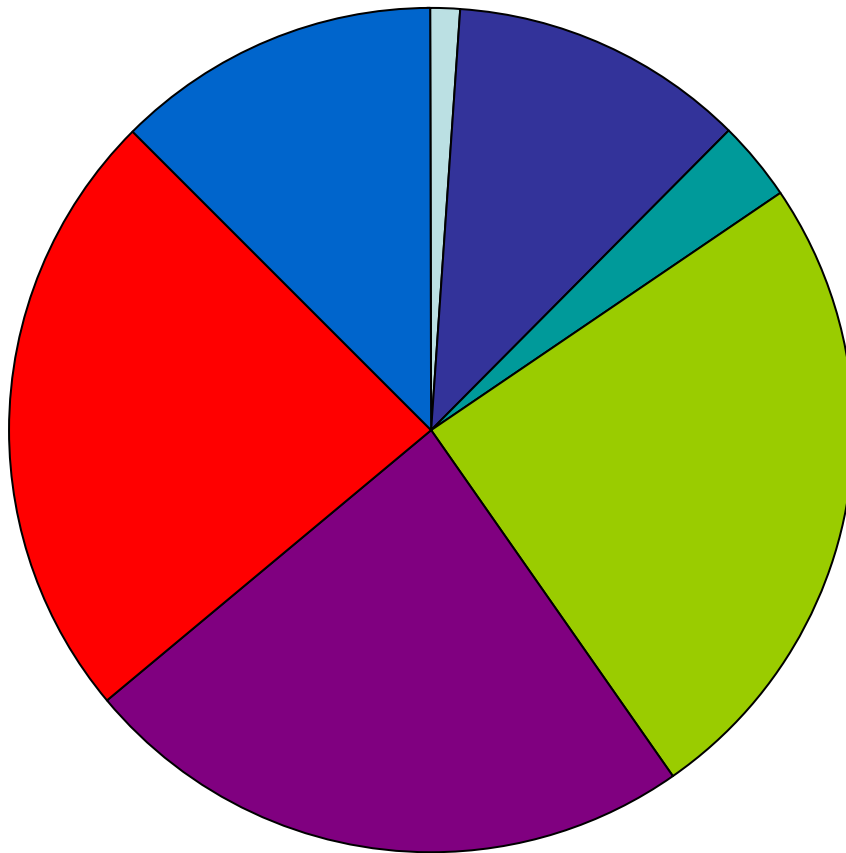
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## Research Units:

- 1154 Investigators
- 197 Unique Protocols
- 11,523 Outpatient Visits
- 1789 Inpatient Visits

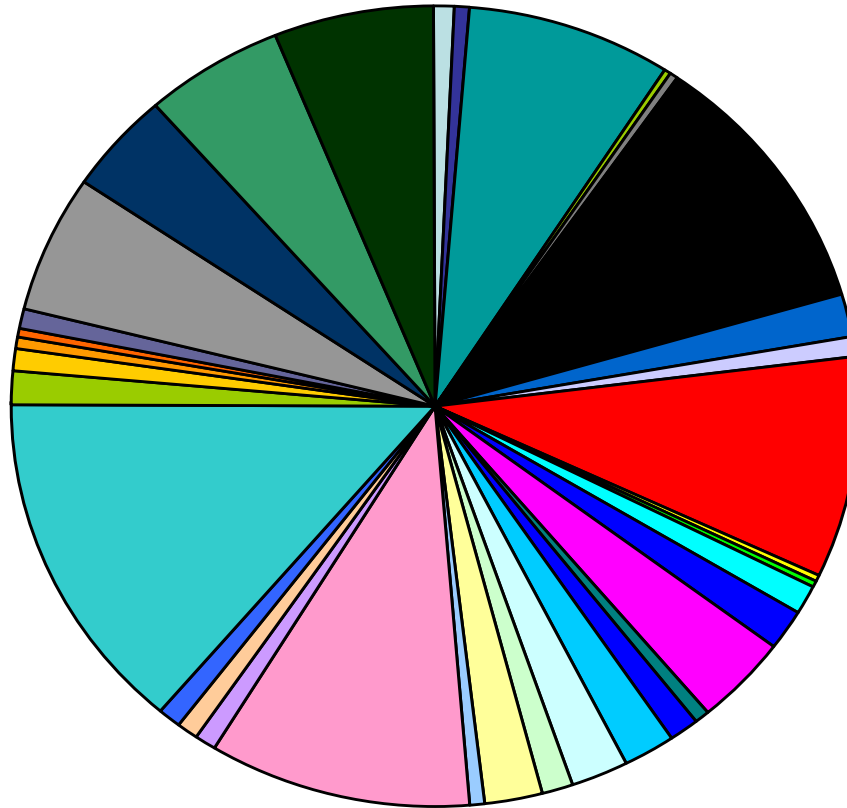
## Who uses the Clinical Research Centers (cont)

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- Research Associate - 3
- Fellow - 31
- Lecturer - 8
- Instructor - 67
- Associate Professor - 64
- Assistant Professor - 64
- Professor - 35

# Investigators by Department/Division



- Anaesthesia
- Channing
- Gastroenterology
- Internal Medicine
- Oncology
- Preventive Medicine
- Reproductive Endocrinology
- Sleep Medicine
- Women's Health
- Ophthalmology
- Pathology
- Radiology

- Dermatology
- Emergency Medicine
- Global Health
- Molecular Genetics
- Other
- Pulmonary
- Rheumatology
- Transplant
- Neurology - 37
- Orthopedic Surgery
- Pediatrics
- Surgery

- Cardiology
- Endocrinology
- Infectious Disease
- Nephrology
- Pharmacoepidemiology
- Renal
- Skeletal Health
- Viral Pathogenesis
- Obstetrics Gynecology & Repro. Bio
- Otolaryngology
- Psychiatry

Harvard Catalyst Central

BWH - Senior VP

Program Director

Admin Director

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Coordinators

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



# Next CCI-All User Meeting

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December 1, 2011 9:00-10:00 am  
Bornstein Ampitheatre

1. Clinical Investigation Committee Update
2. CROSS Core Clinical Research Resources
  - a. Nursing and Nutrition Services
  - b. Biostatistics Consultation Services
3. Scientific Highlights from the Community

**Other ideas/requests?**



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**Questions?**

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# Contact Us!

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

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



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# Scientific Highlights

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# Scientific Highlights

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## **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

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## **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.