Welcome!
Agenda

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

**Center for Clinical Investigation**

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
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<tbody>
<tr>
<td>Program Director</td>
<td>Dr. Gordon Williams</td>
</tr>
<tr>
<td>Operations Director</td>
<td>JoAnna Sullivan</td>
</tr>
<tr>
<td>Outpatient/Off-Unit Manager</td>
<td>Yemi Talabi-Oates</td>
</tr>
<tr>
<td>Laboratory Manager</td>
<td>Bharti Thakkar</td>
</tr>
<tr>
<td>Administrative Assistant</td>
<td>Sandra Jarrett</td>
</tr>
<tr>
<td>Administrative Director</td>
<td>Kristine Jordan</td>
</tr>
<tr>
<td>Finance Director</td>
<td>Mary Schneider</td>
</tr>
<tr>
<td>Education Manager</td>
<td>Marianne Moore</td>
</tr>
<tr>
<td>Education Coordinator</td>
<td>Lisa Horton</td>
</tr>
<tr>
<td>Program Coordinator</td>
<td>Lauren Shaughnessy</td>
</tr>
</tbody>
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[cci@partners.org](mailto:cci@partners.org)
Announcements
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.)

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)
Include IRB protocol number here:
Junior Investigator RFA

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

**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
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

MORE INFO & REGISTRATION: www.brighamandwomens.org/calendar

* These programs are co-sponsored by BWH Center for Clinical Investigation and Harvard Catalyst.
<table>
<thead>
<tr>
<th>Study Coordinator Orientation</th>
<th>Orientation to the CCI Research Units</th>
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<tbody>
<tr>
<td><strong>WHO:</strong> Study Staff</td>
<td><strong>WHO:</strong> For clinical researchers and study staff new to using the BWH CCI Resources.</td>
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<tr>
<td>- Study Coordinators</td>
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<tr>
<td>- Research Nurses</td>
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<tr>
<td>- Research Assistants</td>
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<tr>
<td><strong>WHAT:</strong> Activities and case studies provide information regarding:</td>
<td><strong>WHAT:</strong> This training includes:</td>
</tr>
<tr>
<td>- regulations</td>
<td>- Applying to use the resources</td>
</tr>
<tr>
<td>- roles and responsibilities</td>
<td>- Scheduling/rescheduling troubleshooting</td>
</tr>
<tr>
<td>- best practice and study management advice</td>
<td>- Labs/processing</td>
</tr>
<tr>
<td>- Clinical Skills Training with BWH Department of Nursing Center for Nursing Excellence</td>
<td>- Tour of the research units</td>
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<tr>
<td>- FAQs</td>
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<tr>
<td><strong>WHEN:</strong> twice yearly</td>
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<tr>
<td>- Fall 2011</td>
<td>- Winter 2012</td>
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<tr>
<td>- Spring 2012</td>
<td>- Summer 2012</td>
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</table>
How is it paid for?
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

## Center for Clinical Investigation

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- **CCI CROSS Core**
  - Consolidated Research Service Offering

- **HCCL Core**
  - Harvard Catalyst Central Lab
  - HC-Subsidized

- **Hospital Funds Administration & Operations**
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
Questions?
## Funding Sources

### Center for Clinical Investigation

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<td><strong>Hospital Funds</strong></td>
<td>Administration &amp; Operations</td>
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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
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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

HC Approved Assays @ HCCL Core

Supported:
Supplies and Personnel (and Space)

$ Fee for Service:
“KIT” Cost Only
Who uses the Clinical Research Centers:

Research Units:
• 1154 Investigators
• 197 Unique Protocols
• 11,523 Outpatient Visits
• 1789 Inpatient Visits
Who uses the Clinical Research Centers (cont)

- Research Associate: 3
- Fellow: 31
- Lecturer: 8
- Instructor: 67
- Associate Professor: 64
- Assistant Professor: 64
- Professor: 35
Next CCI-All User Meeting

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

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?
Questions?
Contact Us!

www.brighamandwomens.org/cci

cci@partners.org
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.
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.