Clinical Research Resources Office
ReSPECT Registry & StudyFinder at BU/BMC

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Clinical Research Resources Office (CRRO)

November 14, 2012
Many, MANY thanks to........

- BUMC Information Technology Application Services
  - Adam Kozaryn
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# Clinical Research Resources Office

Supported by the BU CTSI, OCR, and DOM
Serving all BUMC Clinical Researchers

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See our website: [www.bumc.bu.edu/crro](http://www.bumc.bu.edu/crro)
Recruitment Services Program

ReSPECT Registry

The Recruitment Services Program of the Clinical and Translational Science Institute maintains a registry that serves as a way to connect potential research participants with clinical research investigators who are conducting studies in and around Boston University, Boston Medical Center, and affiliated community health centers.
Recruitment Services Program

How can people join the Registry?
Recruitment Services Program

- **Print Advertising**
  - Distributing card brochures throughout the city
  - Ad in the Boston Metro
  - Ad in The Bay State Banner

- **Online**
  - Online survey
  - Craigslist
  - The Word Boston
  - Boston Metro Website
Recruitment Services Program
Recruitment Services Program

- Recruitment at Information Tables
  - BU/BMC Sites
  - Community Health Centers
  - Community events (health fairs, community breakfasts, etc.)
Recruitment Services Program

Boston Medical Center
Patient Profile

- WHITE: 66,078 (34.4%)
- BLACK/AFRICAN-AMERICAN: 13,348 (6.9%)
- HISPANIC/LATINO: 7,267 (3.8%)
- OTHER: 4,455 (2.3%)
- ASIAN: 1,288 (0.7%)
- DECLINED/NOT AVAILABLE: 1,155 (0.6%)
- MIDDLE EASTERN: 804 (0.4%)
- BLANK: 726 (0.4%)
- AMERICAN INDIAN/NATIVE AMERICAN: 1,288 (0.7%)
- NATIVE HAWAIIAN/PACIFIC ISLANDER: 445 (0.2%)

Source: Provided to Kimberly Russell by Clinical Data Warehouse Manager, Linda Rosen, Boston Medical Center, May 2010
Recruitment Services Program of the Clinical And Translational Science Institute: ReSPECT
Roughly 70% of Registry members have information linked to the CDW
How Can Investigators Connect?

Using the Registry

- Investigators contact the Registry with basic information, their inclusion/exclusion criteria, and their IRB Protocol # (if study is already approved).

- Registry staff review inclusion/exclusion criteria to search the database for potential volunteers (Example: Black females, age 55 and up, who have diabetes).
  
  - Health information can be searched via the Clinical Data Warehouse

- To move forward, investigators can then create a contact message and submit either with the IRB application or with an amendment to use the Registry

- Registry staff contact Registry members via email, postal mail, or phone to inform them about the study. Registry members can contact the investigator themselves or Registry staff can have the research team contact them individually.

Consultations

- By appointment
How Can Investigators Connect?

<<Sample Letter Sent to ReSPECT Registry Members>>

Dear ReSPECT Registry Member,

Thank you for joining the ReSPECT Registry at Boston University/Boston Medical Center. As a member of the Registry, you will be informed of studies seeking study volunteers on an ongoing basis that may be of interest to you. Your information is kept confidential.

The Registry team has found the following study you may be interested in hearing more about:

“Knee Replacement Study”

Boston University is conducting a research study on how or why people might have difficulties performing home and community activities after their knee replacement.

Do you live in the greater Boston area?

Have you had a knee replacement between 1 and 5 years ago?

Are you having any difficulty with activities such as personal care, taking care of your home, or going out to public places once your knee replacement?

Are you at least 50 years old and speak English?

We will ask you to attend one interview or focus group and fill out a survey and will receive $50 for your time.

If you are interested in this study, and want to contact the research team yourself, please contact the study staff at the number or email given below.

If you are interested in this study and would like the research team to contact you directly about how to participate, call the ReSPECT Registry at 617-414-1971 or email respec@bu.edu to have the Registry staff release your personal information to the study team. Your contact information WILL NOT be released to the research team by the ReSPECT Registry once we receive your approval.

If you are NOT interested in this study, please disregard this letter or call the ReSPECT team at 617-414-1971.

If you inform us that “You will contact them” or “No, thanks” or do not respond to this letter, your contact information WILL NOT be released to the research team by the ReSPECT Registry team.

If you have received this letter in error, please disregard.

Sincerely,
The ReSPECT Registry

Boston University
72 East Concord, Evans Building, Room E710
Boston, MA 02118
Phone: 617-414-1971 Email: respec@bu.edu
How Can Investigators Connect?

Guide to Using the ReSPECT Registry for Recruitment

Thank you for your interest in the ReSPECT Registry. The ReSPECT Registry is a tool to help BU/BNMC investigators find subjects to participate in their research studies. Registry members are recruited from Boston Medical Center and surrounding communities.

To gain access to the ReSPECT Registry, please follow the below steps:

1. Contact the Registry at respect@bmc.edu to notify us that you intend to use the Registry.
   - We can send you an electronic version of this guideline, as well as an estimate of how many Registry members may potentially be eligible for your study.

2. Create a "ReSPECT Contact Message" that will be sent to Registry members by our staff to inform them about your study. Click here for a [sample ReSPECT Contact Message PDF]. We ask that you send us your contact message for review and then submit it to the IRB. It will need to be approved by the IRB.

3. Submit a request to the IRB to add the Registry as a recruitment method.
   - Attach your ReSPECT Contact Message to the IRB application.
   - In the "RECRUITMENT" section of your IRB application, list that you will be utilizing the ReSPECT Registry (Protocol Number H-28505) as a recruitment method.
   - If you already have IRB-approved brochures, flyers, or other recruitment material that you would like to be distributed along with your ReSPECT Contact Message, please indicate in your amendment that these materials will be sent to Registry members.
   - Sample language for the "Recruitment" section of your IRB application:
     The ReSPECT Registry will be used as a recruitment method. The ReSPECT Registry staff will contact potential study participants per the IRB approved procedures described in H-28505. The ReSPECT Contact Message and additional recruitment materials will be reviewed and sent to Registry members if applicable.

4. E-mail us your IRB approval letter.

5. With IRB approval confirmed, the Registry team will generate a list from the Registry database to target and recruit for your study. You will need to send a list of inclusion/exclusion criteria to the Registry Staff.

http://www.tinyurl.com/respectregistry
How Can Investigators Connect?

- 4083: Total # in Registry as of 10/31/12
- 2114: Total # participants recruited into the Registry in 2012 (as of 10/31/12)

Separately

- # people recruited via internet: 416
- # phone: 115
- # in person: 1583

- 7: # investigators recruiting from Registry in 2012

- 47+: Number of Registry members enrolled into studies
How Can Investigators Connect?

Results of using the Registry

ReSPECT Registry Referral Outcome Tracking

Instructions:
1. Fill out the below table to keep track of study participants referred to you by the ReSPECT Registry.
2. Some Registry members may contact your study team directly. In order to record those calls referred from the Registry, ask callers if they are members of the ReSPECT Registry.
3. For each month that you are approved to use the Registry, send the Registry Staff a password-protected, updated ‘ReSPECT Registry Referrals Status Log’

<table>
<thead>
<tr>
<th>ReSPECT Registry Referrals Status Log</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DOB</strong></td>
</tr>
<tr>
<td><strong>For ReSPECT Registry Office Use</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

| Total Number Per Column               | xx      | xx           | xx          | xx          | xx           | xx          | xx                | xx                | xx                    |              |                |


How Can Investigators Connect?

Case Study: Dr. Jack & the Preconception Care Study

Preconception Care Study
E-Mailing Results
November 5, 2012

- Bounced Back (12)
- Registry Member Replied to Express Interest (8)
- No Reply from Registry Member (70)

Preconception Care Study
Cold Calling Results
November 5, 2012

- Number Not in Service (28)
- Registry Member Not Interested (8)
- Unreachable - Staff Left Voice Message or Mailbox Unavailable (47)
- Registry Member Agreed to be Contacted by Study (22)
How Can Investigators Connect?

Case Study: Dr. Wang & the “Tools to Collect Family Health History” Study

Return Rate of Letters Sent in June 2012 for Family Health Study

- Total Letters Delivered: 86%
- Total Letters Returned as Undeliverable: 14%

Return Rate of E-mails Sent in September 2012 for Family Health Study

- Total E-mails Delivered: 82%
- Total E-mails bounced back: 18%
How Can Investigators Connect?
Consultation Services

- Common Barriers to Recruitment
  - Concerns about personal safety and loss of confidentiality
  - Consents are getting longer and more complex
  - Goals of research are not well understood
  - Subjects often do not get results from the study
  - Cultural competence and sensitivity
  - Unprepared study staff
Community Outreach & Education

- To provide a better understanding of what the community needs in healthcare
- To relay some of the community’s current concerns regarding health and safety about a study.
- Diverse participation in research studies can improve the community’s understanding of certain diseases or conditions that exist in the community
- Study results and/or examples shared with a community may help individuals to take personal action and change behavior to improve their health.
Community Outreach & Education
Community Outreach & Education

Massachusetts Clinical Research Education Day & Health Fair
October 21, 2011
12-4PM
Registration begins at 11:30AM
lunch at noon
Join us at the State House
Speaker Series
Health Screenings
Community resources
Free food and giveaways

Questions? Call (617)414-1971 or E-mail respect@bu.edu

Hosted by:
State Representative
Jeffrey Sanchez,
in collaboration with
the Research Subject Advocacy
Programs of the Massachusetts
Clinical Translational Science Centers
and the ReSPECT Registry at Boston
University/Boston Medical Center
Community Outreach & Education

**Attendance**
- BU/BMC Sites
- Annual Health Fairs
- Community meetings
- Massachusetts Research Subject Advocacy Group

**Presentations**
- Community sites and academic forums
Thank You
What is StudyFinder?

• Medical Campus website
• Lists BUMC research studies for public view, for purposes of:
  • general publicity/collaboration
    and/or
  • recruitment
What is StudyFinder?

- The StudyFinder website is about to “go live.”
- Currently, accessible for searching via the CRRO-Community website: http://www.bumc.bu.edu/crro-community/recruitment/
  - Will be posted on various BU/BMC websites

- Current StudyFinder listings:
  - 427 General Publicity
  - 21 Recruitment
What is StudyFinder?

- Listings are approved administratively by the CRRO.
- Per **OHRP guidance**, the listing itself will not require IRB approval.
- However, your protocol must be approved by the IRB for the listing to “go live” on the StudyFinder website.
### General Publicity Listings

- **Study title, the Study Summary (from the Summary in INSPIR Section 8), PI name and e-mail.**

<table>
<thead>
<tr>
<th>Title</th>
<th>Summary</th>
<th>Study Principal Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 dimensional evaluation of bone dimensions in maxilla</td>
<td>Click here for more detailed information about this study</td>
<td>Ahmad Alshadwi</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Email: <a href="mailto:alshadwi@bu.edu">alshadwi@bu.edu</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A 16-WEEK PILOT STUDY OF GENOMIC PROFILES IN PULMONARY HYPERTENSION - SCLERODERMA PATIENTS TREATED WITH TADALAFIL</td>
<td>Click here for more detailed information about this study</td>
<td>Harrison Farber</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Email: <a href="mailto:hfarber@bu.edu">hfarber@bu.edu</a></td>
</tr>
</tbody>
</table>
### General Publicity Listings

- **Expanded view (with Summary)**

<table>
<thead>
<tr>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 dimensional evaluation of bone dimensions in maxilla</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hide</strong></td>
</tr>
<tr>
<td>Bone thickness in the anterior maxilla will largely impact the decision of immediate dental implant placement, deferent relationships between the basilar bone and the tooth roots have been prescribed but with no scientific impact on the treatment planning. The aim of this study is to quantify the amount of bone available between the roots of the anterior maxillary teeth and the buccal bone plate on three deferent vertical levels to aid in decision of anterior maxillary implants placement using con beam CT scan.</td>
</tr>
</tbody>
</table>

**Study Principal Investigator:**

Ahmad Alshadwi  
Email: alshadwi@bu.edu
## Recruitment Listings

- **List view: title, purpose**

<table>
<thead>
<tr>
<th>Title</th>
<th>Purpose</th>
<th>Click here for more details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect of Oxytocin on Pro-Social Behavior in Social Anxiety Disorder</td>
<td>This is a study testing the effects of a hormone on social interactions in males with Social Anxiety Disorder, compared to healthy males.</td>
<td></td>
</tr>
<tr>
<td>MDACC #2009-0288: Comparative Study of Oncologist Recommended, Home-Based Exercise Program and Relaxation Training for Physical Functioning and Symptom Control in Colon Cancer Patient</td>
<td>Participants with colon cancer will be randomly assigned to an exercise program or a relaxation intervention to compare the effects on fatigue, sleep, pain, nausea and psychological distress.</td>
<td></td>
</tr>
<tr>
<td>MEMORY DISORDERS RESEARCH CENTER MULTIPROJECT RECRUITMENT 2003-386B</td>
<td>This is a study that compares cognition in patients who have memory problems due to brain injury with cognition in healthy controls.</td>
<td></td>
</tr>
</tbody>
</table>
Recruitment Listings

- Expanded view: title, purpose, eligibility, payment, contact, PI name and e-mail

Study Details

Go back to search results

Title:
MEMORY DISORDERS RESEARCH CENTER MULTIPROJECT RECRUITMENT 2003-386B

Purpose:
This is a study that compares cognition in patients who have memory problems due to brain injury with cognition in healthy controls.

Click here for more detailed information about this study

Who may be eligible?
Potential participants are males or females aged 35 and above without history of neurological illness who can serve as healthy controls.

There are more study criteria to be assessed in addition to the main ones noted above. The study researcher can discuss all of the eligibility criteria with you.

Payment/compensation:

Additional information:

For more information:

Matt Cruz
Research Associate
Phone: 857-938-
E-mail: mattcruz@bu.edu
Website: Not Available

The Memory Disorders Research Center provides the clinical and administrative core for a number of research programs aimed at understanding the cognitive and neural basis of the memory deficits seen in subjects with a variety of neurological disorders such as stroke, aneurysm, head injury, encephalitis, anoxia and Korsakoff syndrome. The primary objective of this project is to put in place a uniform method of recruitment of participants into the MDRC and to provide a full characterization of participants' neuropsychological functioning. This in turn, provides the information necessary to allow assignment of participants to the various ongoing research projects. In addition to subjects with memory disorders, the MDRC also recruits as control participants normal individuals without a history of neurological illness and individuals with a history of alcohol abuse. The neuropsychological evaluation of subjects with memory disorders is comprehensive, and consists of standardized tests of general intelligence, language, memory, perception and problem solving. The evaluation of control participants is restricted to the areas of general intelligence and memory. Results of these tests provide the necessary information to determine for which research projects a participant is eligible.
**Looks great! How do I get one?**

- If you have a new protocol, then in INSPIR.....

Check whether or not you want the general publicity listing in Navigation Section 10.3.

<table>
<thead>
<tr>
<th>10.12 StudyFinder Listing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you agree to have the study title, summary, and PI name and e-mail address listed on StudyFinder, a publicly viewable medical campus website for general publicity and collaboration purposes? (If you also want to use StudyFinder to recruit subjects, there is another question to answer in the Recruitment section.)</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

Check whether or not you want the recruitment listing in Recruitment section of INSPIR.

<table>
<thead>
<tr>
<th>19.3 Recruitment using the StudyFinder website</th>
</tr>
</thead>
<tbody>
<tr>
<td>The BUMC Study Finder is a medical campus website that lists research studies for public view. If you are using Study Finder to recruit subjects, you should complete the Study Finder Form in the Submission Forms section of INSPIR.</td>
</tr>
<tr>
<td>Will you be listing your study in Study Finder to recruit subjects? If &quot;yes,&quot; select &quot;yes&quot; below and complete the Study Finder Form (located in the Submissions Forms section of the Study Management view of INSPIR II - click on the (?) icon for instructions).</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

- If you only want general publicity listing, that is all you have to do!
- If you want a recruitment listing, you must complete a simple form within the Submissions Forms in INSPIR.
Looks great! How do I get one?

- If you have an already submitted, or already approved protocol...... or if you want a recruitment listing, complete the StudyFinder Form in Submissions Forms in INSPIR.
  - Full tutorial on completing the SF form available on the CRRO website (and as a link in INSPIR).

- What follows are a few of the slides from the tutorial.
Under Submission Forms, click on StudyFinder Form.
Click Add New Form.
For a General Publicity listing only: Complete Section 1 (1.2 should be “yes” and 1.3 should be “no”); click “Save and Continue to the Next Section.”

For a Recruitment listing plus General Publicity: Complete Section 1 (1.2 should be “yes” and 1.3 should be “yes”); click “Save and Continue to the Next Section.”
Complete Section 2 (items 2.1 – 2.8). Then click “Save and Continue to the Next Section.”
This is the sign-off screen. Click “Notify PI to Sign off,” or if you are the PI click “Sign off and Submit” (as in this example).

The form will be routed to the CRRO for review, and once “approved” will appear in the StudyFinder website (as long as there is initial IRB approval for the protocol). These listings do NOT require an amendment to the IRB.

You can also click here to go to the CRRO website for information about StudyFinder.
Helpful Hint in Creating your Listing

- If you decide to include your INSPIR Study Summary in your Recruitment listing, read it to make sure it is in SIMPLE LAY LANGUAGE.
Accessing StudyFinder

- From CRRO-Community Website:

**Recruitment Services Program of the Clinical Translational Science Institute (ReSPECT)**

Thank you for your interest in clinical research at Boston University (BU) and Boston Medical Center (BMC)!

Our goal is to support the community in learning about clinical research and finding opportunities to participate in research studies.

Please click the links below to learn more about clinical research, the ReSPECT Registry, and to search for studies taking place at BU and BMC.

- Clinical Research - Why Volunteer?
- We invite you to join the ReSPECT Registry
- Find a Research Study
- Calendar of Events
- Contact Us
- Helpful Links
Accessing StudyFinder

- From CRRO-Investigator website:
  [http://www.bumc.bu.edu/crro/](http://www.bumc.bu.edu/crro/)
  (Click Recruitment and then StudyFinder)

*Use the StudyFinder to Search for Studies*

To use StudyFinder to search for BU/BMC research studies for participation or for general publicity/collaboration purposes, [click here.](http://www.bumc.bu.edu/crro/)

- Coming soon….. Link to StudyFinder from other BMC/BU patient-related web-pages…….
Thank you!!

Any questions?