VCU CCTR
Overview and the Clinical Research Services

Betsy Ripley, MD, MS
Professor of Medicine Division of Nephrology
Executive Director Clinical Research Services
Senior Chair VCU IRB
Associate Chair for IM Faculty Development
New Award Number

UL1TR000058 from the National Center for Advancing Translational Sciences (NCATS).
Clinical Research Services

VCU CCTR

Informatics
Research Incubator
Regulatory Knowledge and Support
Community Engaged Research
Education
Evaluation
Research resources
Clinical Research Services

- Biomedical informatics
- Biostatistics
- Study design
- Dissemination of innovation
- Research Incubator
- Clinical research ethics review
- Research liaison
- Community liaison
- Community engagement
- Grant writing and review
- Epidemiology
- Education

Local, regional and national research communities

Center for Clinical and Translational Research
Virginia Commonwealth University

Award number UL1TR000058
Clinical Research Services

Research Incubator

Design, biostatistics and clinical research ethics

- Investigator and project
- Research liaison (Incubator staff member)
- Primary mentor
- Team building
  - Academy of mentors
  - Collaborators
- Advisory committee
- Improved design
- Project objectives met
- Services
  - Biostatistics
  - Data management
  - Ethics consultations
  - Study design
  - Networking help
Regulatory Knowledge and Support
Clinical Research Services

Community Engaged Research

Co-Directors:
Maghboeba Mosavel PhD; VCU
Mike Royster MD, MPH; VDH
Clinical Research Services

Education

• KL2 (K12) program: 75% salary and protected time

• MS/PhD in Clinical and Translational Science
Evaluation
Clinical Research Services

Research Resources

Core Laboratories

Clinical Research Services
Our mission is to augment, cultivate, facilitate and refine high quality, subject-oriented clinical research. Our primary customers include investigators, research and administrative staff and funding organizations. We also partner with VCUHS, sponsored programs, the IRB and other university and hospital service providers to standardize, streamline and support clinical research. The safety and support of research participants is paramount. We provide clinical trial training, expertise, and opportunities; enhance administrative; operational and resource efficiencies to support clinical trials; and support the discovery of safe, effective and timely treatment options for the communities we serve.

While our mission is to provide mechanisms for quality clinical research the overarching goal is to improve the overall health and wellness of our community.
# Clinical Research Services

## CRS Office
- CDA/ Feasibility
- Budget Negotiation and Contracting
- IRB Packet completion and submission
- Media and Recruitment
- Coordinators

## CRS Unit
- Facility
- Nursing
- Lab
- Bionutrition

- Ethics Review and Consultation
- Audit and Compliance
- Education
- Best Practice and Efficiency
Clinical Research Services

• Initiatives
  – Recruitment task force
  – Standardizing, capturing and analyzing start-up timeline metrics including contract negotiation
  – Integrated cancer center pre-award processes and program management with the crs
  – Coordinator Best Practices and certification training
  – Investigator Education
  – Standardization of cost
  – Billing process and procedures both internal and external
  – Increasing industry sponsored studies
  – Evaluate programs to encourage new and continued faculty participation in research
Clinical Research Services

Full Time Executive Director of CRS
Clinical Research Services
Research Subject Advocate
Clinical Research Services

Where is the CRS?
What about cost?

- NIH/Foundation
- Investigator Initiated
- Industry

- Can you budget anything in your grant?
Clinical Research Services

General Rules as of January 2012

- CRS Lab - Industry full cost, others kit and supply costs
- Facility - Industry full cost, other no cost
- Nursing - Industry full cost, other no cost
- Coordinators - Full cost
- Bionutrition: Industry Full cost, other no cost
- Budget building and negotiation: Cost
- WIRB preparation, submission, and regulatory: Cost
Dear Dr. Know it All,

At its January 17, 2012 meeting, the CRS (Clinical Research Services) Protocol Review Committee reviewed and approved the following protocol pending acceptance of the CRS resource allocation and PI responsibilities and receipt of the IRB approval letter and stamped consent form. The CRS will utilize the VCU IRB tracking number as the CRS protocol number. Please refer to this number in all communications regarding this particular study.

IRB#: HM 99999

Protocol Title: Stress in research coordinators

Sponsor: National Coordinator Foundation

Total Subject # at VCU: 60 Study Duration: 3 yr

We are pleased to make our staff and facilities available to you for this protocol. Please review the following resource allocation and responsibilities for accuracy. A CRS audit template will be provided (sent separately) to you for information purposes and a CRS audit will be performed following study enrollment of the first three subjects.

CRS Resources Requested:

- Budget & Negotiations Support: not needed
- IRB & Regulatory Packets Support: not needed
- Research Coordinator Support: not needed

Facility and Nursing Resource: One visit only
- Registration, nursing, line placement, OGTT, 5 blood draws per visit
- Glucometer readings at 0 & 120 min only
- Urine collection with pregnancy test
- EKG- no interpretation
- FMD Procedure:
  - Ultrasound equipment
  - Nitroglycerin for adult subjects (please confirm provider of drug)

Bionutrition Resource:
- Waist measurements

A bagged snack will be provided following testing. Please verify bagged lunch/snack preferences with Sakita Sistrun (CRS bionutritionist; 828-9229).

CRS Resources Requested cont’d:

CRS Laboratory Resources:
- Insulin & glucose analyses: $7.20/sample
  - 5 samples per subject
- Any additional lab analyses will need clarification and agreement by both CRS laboratory and PI with supply cost provided by PI.

Investigator/Study responsibilities:
- Have reviewed the CRS resource section (see above) for any errors and agree with the resources allocated.
- An index code for reimbursements will be provided prior to study initiation. Payment will be made by journal voucher.
- Will promptly report any changes in the funding mechanism, protocol, consent, unanticipated AEs, serious AEs, and sponsor notifications impacting study conduct to the CRS and the VCU IRB.
- Will forward to the CRS the annually renewed informed consent documents upon approval by the IRB.
- Publication of data resulting in any way from this study whether clinical, computer, or lab/bench focused, must cite the Center for Clinical and Translational research grant #UL1TR000058, NCATS (National Center for Advancing Translational Sciences), NIH. THIS NUMBER IS A CHANGE!!

By reply email (shelm@mche-vcu.edu), please respond that you have reviewed and agree with the above CRS resources, pricing and PI responsibilities. Once a reply and all regulatory documents have been received, an in-service may be scheduled with the CRS Unit (Lou Usry or Yvonne Gotico, 828-9101).

We look forward to working with you on your new clinical research protocol.

Regards,

Elizabeth Ripley, M.D., M.S.
Clinical Research Services Executive Director
Center for Clinical and Translational Research
Clinical Research Services

• Initiatives
  – Recruitment task force
  – Standardizing, capturing and analyzing start-up timeline metrics including contract negotiation
  – Investigator Education
  – Standardization of cost
  – Billing process and procedures both internal and external
  – Increasing industry sponsored studies
  – Evaluate programs to encourage new and continued faculty participation in research
  – Coordinator Best Practices and certification training, Council.....
VCU “Coordinator” Survey
Virago, Bradley, DeWilde, Anderson, Rodriguez, Anderson, Markowitz, Stickler, Robb, Gotico, Ripley

Sent to 869 on “list serves”
155 Responses (120 marked complete)

A quality improvement imitative: IE not Human subjects research
<table>
<thead>
<tr>
<th>Position</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accountant</td>
<td>Business and Personnel Manager</td>
</tr>
<tr>
<td>Adjunct Prof</td>
<td>Business Manager</td>
</tr>
<tr>
<td>Administrative Assistant</td>
<td>clinical coordinator, RN</td>
</tr>
<tr>
<td>Administrative Director</td>
<td>Clinical Research Coordinator</td>
</tr>
<tr>
<td>Administrative Director for Clinical Research</td>
<td>clinical research assistant, doctor, doctoral student in nursing (formally research coordinator)</td>
</tr>
<tr>
<td>Administrator</td>
<td>Clinical Research Coordinator, doctor, doctoral student in nursing (formally research coordinator)</td>
</tr>
<tr>
<td>Advanced Clinical Research Coordinator</td>
<td>Clinical Research Nurse Coordinator</td>
</tr>
<tr>
<td>Assistant Professor</td>
<td>Clinical Research Nurse Coordinator, NP</td>
</tr>
<tr>
<td>Assoc Prof</td>
<td>Coordinator</td>
</tr>
<tr>
<td>associate administrator</td>
<td>Coordinator specialist/ Spanish Translator</td>
</tr>
<tr>
<td>Associate Director</td>
<td>CRA</td>
</tr>
<tr>
<td>Associate Professor</td>
<td>CRA (lead)</td>
</tr>
<tr>
<td>Asst Professor</td>
<td>CRA/Research Coordinator</td>
</tr>
<tr>
<td>Bone Densitometry Technologist/Research</td>
<td>CRC</td>
</tr>
<tr>
<td>Coordinator</td>
<td>Grants Specialist</td>
</tr>
<tr>
<td>Manager, Research &amp; Fiscal Administration</td>
<td>Department Administrator</td>
</tr>
<tr>
<td>MATR Administrator</td>
<td>Senior Clinical Research Coordinator</td>
</tr>
<tr>
<td>Nurse Manager I</td>
<td>Senior Contract and Grant Administrator</td>
</tr>
<tr>
<td>Nurse Manager RN</td>
<td>Senior Research Associate</td>
</tr>
<tr>
<td>Office Manager</td>
<td>senior research associate</td>
</tr>
<tr>
<td>PI</td>
<td></td>
</tr>
</tbody>
</table>
Clinical Research Services

Who Employs Coordinators

• 87.8% VCU
• 12.2% VCUHS
• VA (1 person)
What types of studies do you manage/coordinate

• Social- Behavioral 21%
• Biomedical 39%
• Both 24%
### Clinical Research Services

**What Roles Do You Play?**

<table>
<thead>
<tr>
<th>Role</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Entry</td>
<td>48%</td>
</tr>
<tr>
<td>Subject Enrollment</td>
<td>50%</td>
</tr>
<tr>
<td>Subject Visits</td>
<td>40%</td>
</tr>
<tr>
<td>Regulatory Manager</td>
<td>51%</td>
</tr>
<tr>
<td>Compliance</td>
<td>58%</td>
</tr>
<tr>
<td>Manage/Supervise Staff</td>
<td>53%</td>
</tr>
<tr>
<td>Manage Financial Support</td>
<td>37%</td>
</tr>
<tr>
<td>Budget Negotiation</td>
<td>26%</td>
</tr>
</tbody>
</table>
## Coordinator Certification

<table>
<thead>
<tr>
<th>Certification</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Socra/CCRP</td>
<td>11%</td>
</tr>
<tr>
<td>ACRP</td>
<td>7%</td>
</tr>
<tr>
<td>CRA</td>
<td>1%</td>
</tr>
<tr>
<td>OSP</td>
<td>19%</td>
</tr>
<tr>
<td>Cert. IRB Prof</td>
<td>0.60%</td>
</tr>
</tbody>
</table>

15% want information on certification
<table>
<thead>
<tr>
<th>Service</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinator Orientation</td>
<td>48%</td>
</tr>
<tr>
<td>Training</td>
<td>51%</td>
</tr>
<tr>
<td>Mentoring</td>
<td>48%</td>
</tr>
<tr>
<td>Scheduled meetings</td>
<td>30%</td>
</tr>
<tr>
<td>Social Networking</td>
<td>31%</td>
</tr>
<tr>
<td>Workshops</td>
<td>46%</td>
</tr>
<tr>
<td>Subcommittees tasked to recommend wpp's</td>
<td>27%</td>
</tr>
<tr>
<td>Disseminate Information</td>
<td>36%</td>
</tr>
</tbody>
</table>
Clinical Research Services
Coordinator Mentors

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>I have been a mentor</td>
<td>56%</td>
</tr>
<tr>
<td>I have been mentored</td>
<td>51%</td>
</tr>
</tbody>
</table>

Would you participate?

<p>| | |</p>
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<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>No</td>
<td>14%</td>
</tr>
<tr>
<td>As a mentor</td>
<td>23%</td>
</tr>
<tr>
<td>As a mentee</td>
<td>24%</td>
</tr>
<tr>
<td>No time</td>
<td>40%</td>
</tr>
</tbody>
</table>
Clinical Research Services

How Can We Help You?