Commit to Patients & Families First

Build Healthy Communities

Advance New Knowledge and Scientific Discoveries

Foster Innovative Education and Learning

Embrace Diversity and Inclusion
Setting the stage for success: 

**Implementation Teams**

- 5 goals have 17 prioritized initiatives
- Implementation teams developing action plans
- Information on 17 initiatives can be found at:
  [http://horseshoe.musc.edu/everyone/imagine-2020/implementation-teams](http://horseshoe.musc.edu/everyone/imagine-2020/implementation-teams)
MUSC 2020 – Research Initiatives

• Under the auspices of the VP for Research, provide central strategic coordination (i.e., a strategy that accounts for diversified research funding, campus research needs, current abilities, improved research communication, research space allocation, etc.) of campus-wide research.
  – Diversification of Research Funding – Carla Frichtel/Kathleen Brady
  – Research Communications – Loretta Lynch Reichert
  – Research Infrastructure
    • Chris Davies – cores and space
    • Patrick Flume – clinical research, etc.
CTSA Trial Innovation Network (TIN)

- Collaborative initiative: CTSA Programs, Trial Innovation Centers (TICs), Recruitment Innovation Center (RIC)
- Vision: innovatively address critical roadblocks and accelerate clinical trials. Focused on operational innovation, operational excellence, and collaboration
  - single IRB system
  - master contracting agreements
  - quality by design approaches
  - evidence-based strategies for recruitment and patient engagement.
Trial Innovation Network

How to Leverage the Network

- **Level 1 Network Projects**
  - Basic Services and Consultations

- **Key Points**
  - Investigators can select from an array of services/consultations
  - Investigators can use their own coordinating centers
  - NCATS will provide service/consults up to a pre-specified threshold

<table>
<thead>
<tr>
<th>Basic Services and Consultations</th>
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<tbody>
<tr>
<td>A. Operationalize Master Agreements</td>
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<tr>
<td>B. Operationalize Single IRB</td>
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<tr>
<td>C. Study Design Consultation</td>
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<tr>
<td>D. Study Budget Consultation</td>
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<tr>
<td>E. Site Identification Consultation</td>
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<tr>
<td>F. Recruitment Planning Consultation</td>
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<tr>
<td>G. Recruitment Feasibility Assessment</td>
</tr>
<tr>
<td>H. Recruitment Materials (Standard Tools)</td>
</tr>
<tr>
<td>I. Patient Engagement Studio</td>
</tr>
<tr>
<td>J. Other Consultation/Service, specify ________</td>
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</tbody>
</table>
Trial Innovation Network
How to Leverage the Network

- **Level 2 Network Projects**
  - Comprehensive Consultation
  - Investigators work with TICs/RIC to develop a proposal into a Trial Innovation Network protocol

- **Key Points**
  - Investigators have access to operational and recruitment experts
  - Protocols vetted with potential CTSA Hubs before funding decisions
  - If TICs/RIC used as Coordinating Centers, NCATS will provide infrastructure/resources up to a pre-specified threshold

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<table>
<thead>
<tr>
<th>Level 2 Network Project (Comprehensive Consultation)</th>
<th>A. Protocol Development and Potential Trial Implementation</th>
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<tbody>
<tr>
<td></td>
<td>1. Development of Protocol</td>
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<tr>
<td></td>
<td>a. Project Planning</td>
</tr>
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<td></td>
<td>b. Development of Study and Site Budgets</td>
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<td></td>
<td>c. Site Selection/Assessment</td>
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<td></td>
<td>d. Data Safety and Monitoring Plan</td>
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<td>e. Statistical Analysis</td>
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<td>f. Risk Based Monitoring Plan</td>
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<td></td>
<td>g. Regulatory Support for FDA Submission</td>
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<tr>
<td></td>
<td>h. Development of Recruitment Plan/Feasibility Assessment/Informatics Tool Consultation/Recruitment Training</td>
</tr>
<tr>
<td></td>
<td>2. Trial Implementation</td>
</tr>
<tr>
<td></td>
<td>a. If study funded, potential implementation of clinical trial</td>
</tr>
</tbody>
</table>
Trial Innovation Network
Website

www.trialinnovationnetwork.org

Questions? E-mail us at info@trialinnovationnetwork.org
Record-Breaking Year for Research Funding

NIH, ARRA* and Other Funding
*American Recovery/Reinvestment Act of 2009

Ranked 52 in 2007, 42th in 2016
Stem Cell Research Oversight

• Why is there a need for an SCRO committee?
  – Federal requirement to review and track stem cell related research on campus
  – Service for investigators as journals are requesting certification of SCRO review prior to accepting manuscripts

• What has been done so far?
  – SCRO committee formed, completing policies
  – Thank you Aimee, McRae, Yashmin Karten, Amanda Larue, and all committee members

• What comes next? Approval of studies:
  – Prior to July 1, 2017: investigators using stem cells please register trials
  – After July 1: all trials will need SCRO review prior to receipt of approval from IBC, IACUC, and/or IRB
Changes to IRB Fee Schedule

• New fees will be charged to industry-sponsored studies (effective July 1, 2017)
  – Amendments (sponsor requested only) $500
  – Continuing review increase to $750

How we compare to other universities

<table>
<thead>
<tr>
<th></th>
<th>MUSC</th>
<th>Industry average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial review</td>
<td>$2500</td>
<td>$2716</td>
</tr>
<tr>
<td>Continuing review</td>
<td>$500</td>
<td>$1083</td>
</tr>
<tr>
<td>Amendments</td>
<td>$500 (new)</td>
<td>$593</td>
</tr>
</tbody>
</table>
GCP Compliance

• NIH policy: all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH)
  – Effective January 1, 2017

• MUSC plan:
  – Currently NIH-funded were requested to complete the training ASAP (187 still need to complete)
  – All future training (new or updates) will complete the training so all are compliant
Conflict of Interest

Mary Evelyn Armstrong MA, CRA
MUSC Conflict of Interest Officer
Conflict of Interest: New approach

- Going live Monday, February 6
- If any MUSC Investigators listed on the ePDS have an SFI reported, the PI will be required to answer two COI screening questions.
  - Answers will be used to triage awards that may have Investigator COI to the COI Office for review.
  - PI will certify answers.
  - Departments share accountability through the ePDS approval process.
Benefits

- Enhancing our culture of transparency:
  - Creating departmental awareness of Investigator interests
  - Facilitating conversations that should occur among the research team

- Promoting efficiency:
  - Research teams become aware of related interests and anticipate downstream effects if the project is awarded
  - PI’s have more control to incorporate safeguards against bias within their proposed research design and to budget for any related costs (e.g., effort for an independent monitor)

- Strengthening effectiveness:
  - Broader institutional awareness, expertise and engagement to reduce the risk of COI “falling through the cracks”
Impact of Noncompliance

- For unreported interests discovered and determined to constitute COI with the project, actions may include but are not limited to:
  - A report to the supervisor, the Research COI Committee, the Designated Institutional Official for COI, the IRB (if human subject research), ORSP and Dr. Brady
  - Stopping award expenditures until the project has been reviewed and COI managed
  - If PHS funded, conducting a retrospective review to identify any bias during the period of noncompliance
    - If bias is found, submitting a mitigation report to the PHS awarding component
Recommendations

➢ Address COI questions with the PI and study Investigators during the proposal development process; obtain any updates at time of award.

➢ Carefully read and answer the questions that are asked; it is up to MUSC to determine if there is a COI.

➢ Develop a general awareness of your Investigators’ outside activities through ongoing engagement.

➢ The COI Office will provide presentations and consultations to departments, small groups and individuals upon request.
Conflict of Interest Office
843-792-5907
www.musc.edu/coi
conflicts@musc.edu
eProtocol

• Web-based Platform for
  • Institutional Animal Care and Use Committee (IACUC)
  • Institutional Biosafety Committee (IBC)
  • Division of Laboratory Animal and Care (DLAR)

• State-of-the-art design
  • Linking IBC and IACUC protocols
  • Linking IACUC and DLAR for animal ordering

• Comprehensive strategy
  • Intelligent design designed to reduce the need to input data in separate places
  • Multiple personnel can edit protocols
eProtocol

• **Time Frame**
  • In production now – *soft opening* as we get all the pieces in place
  • Anticipated that as of May 1\textsuperscript{st} all IACUC and IBC protocols will use the eProtocol platform
  • Board Administrators will email further specifics

• **Education and Guidance**
  • Town Halls coming shortly to introduce the platform
  • Recommendation that *at a minimum* primary personnel working with the system attend one session
  • Web-Based Guidance - Researchers Users Guides forthcoming for the IACUC and IBC platforms
  • Group introductions available – faculty meetings or lab meetings
eProtocol

• Questions?
  • Site Administrator – Lynn M. Veatch, Ph.D.
    • Training on use of the eProtocol Platform for IACUC and IBC protocols
    • Procedural Issues - Navigating the platform, platform problems and accessibility
  • IACUC / IBC Administrators
    • IACUC : Cyndi Rosenblatt
    • IBC: Yashmin Karten
    • Content Issues
AAHRPP

• Association for the Accreditation of Human Research Protection Programs

• History
  • MUSC initially accredited in 2009 for an initial 3 years
  • Reaccredited in 2012 for 5 years
  • Steps to document MUSC policies and procedures initiated in September 2016 and accepted by AAHRPP in December

• Site Visit
  • Purpose is to determine if we follow the policies and procedures
  • 2 Day Visit (3 days in the past)
  • Scheduled for Thursday, June 28 through Friday June 29
AAHRPP

• Interviews with site visitors
  • AAHRPP selects IRB protocols
    • Random, special populations, drugs, devices, funding
  • Principal Investigators and study staff – in separate interviews
  • Interviews with Researchers are in groups – 4 MUSC PI/staff
  • IRB Members also interviewed in groups – scientists, lay members

• Site Visit
  • MUSC will receive the list of individuals selected for interviews
  • Request to make every effort to meet with the reviewers
  • AAHRPP makes few exceptions
AAHRPP

• Preparation?
  • Protocol in order?
  • Personnel on protocol?
  • Personnel know the protocol?

• Be honest and open!

• Questions?
  • Lynn M. Veatch, AAHRPP Liaison
  • veatchlm@musc.edu
  • 843-792-3247
Research Data Warehouse (RDW) with Natural Language Processing Capability

NLP projects examples:

- Extracting laboratory eligibility criteria from IRB protocol
- Extracting social determinates from clinical notes (health disparity research)
- Identifying HIV patients with fatigue (clinical trial)
- Critical findings from radiology reports (patient safety)
- Falls risk assessment (quality improvement)
i2b2 – Self-service Queries from RDW

- MUSC faculty and sponsored staff members will have access
- All non-faculty users must be sponsored by a MUSC faculty member; please send a completed Sponsorship Form to datarequest@musc.edu. Access is granted within 1-2 business days
**Epic-REDCap Survey Capabilities**

**REDCap-Epic Survey Queue Allows:**

- Study Teams to use of the Epic MyChart secure messaging patient portal
  - Configurable SmartText language can be created to ensure continuity across messages
  - Provides study teams access to patient populations they do not have a clinical relationship with & who have agreed to be contacted

- **Survey queue** is a reusable link so patients will always be able to see what surveys they have been invited to and/or completed (after informed consent)

- Keeps a clear defined line between the “Research Record” (in REDCap) and the “Legal Medical Record”
Office of Clinical Research
Royce Sampson, MSN, RN, CRA
Director, Office of Clinical Research
Office of Clinical Research MOU signed 10/13/2016
Authorizing Officials:

David J. Cole, MD, FACS
President
Medical University of South Carolina

Lisa K. Saladin, PT, PhD, FAPTA, FASAHP
Interim Provost
Medical University of South Carolina

Kathleen T. Brady, MD, PhD
Vice President for Research
Medical University of South Carolina

Raymond N. DuBois, MD, PhD
Dean College of Medicine
Medical University of South Carolina

Patrick J. Cawley, MD, MBA
Chief Executive Officer
Medical University Hospital Authority
Vice President of Health Affairs, MUSC

Bruce M. Elliott, MD
Chief Physician Executive
University Medical Associates of the Medical University of South Carolina
OCR Implementation Activity Timeline

Year One Activities
Coverage Analysis for studies with Standard of Care (SOC) billing
Provide Feasibility and Budget Development Support Services
Build Research Records and Billing Calendars in Epic & other research systems

Year Two and Year Three Activities
Implement and Manage Sponsor Invoicing Support Services
License and Implement an enterprise-wide Clinical Trials Management System
(as funding allows)
OCR: Activities to Date

1. Positions Filled:
   1. Associate Director, Research Learning Development & Design
   2. Associate Director, Research Opportunities & Collaborations
   3. Associate Director, Prospective Reimbursement Analysis
   4. Interviews are being scheduled for other positions

2. A Contract with Aegis Compliance & Ethics to support OCR implementation and campus-wide training has been executed and a training plan is in development

3. Presentations scheduled: ICCE Chiefs, Department Administrators, Research Administrators

4. Developing and piloting a Billing Compliance Workflow

5. OCR Advisory Board convened with first meeting held January 18th

6. OCR Research Subcommittee convened with first meeting held January 12th

7. OCR Billing Compliance & Revenue Workflow Subcommittee ongoing – last meeting Jan. 18th

8. COM Departmental Rollout Plan in development:
   1. Radiology volunteered to be the first group (research group & service provider)
   2. Other Departments to volunteer include Department of Medicine & Neurology
## OCR Institutional Fees

<table>
<thead>
<tr>
<th>Institutions</th>
<th>Fees</th>
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<tbody>
<tr>
<td>University of North Carolina</td>
<td>$2,000</td>
</tr>
<tr>
<td>Emory University</td>
<td>$3,900</td>
</tr>
<tr>
<td>Icahn School of Medicine at Mount Sinai</td>
<td>35% Indirect Costs + Coverage Analysis fee</td>
</tr>
<tr>
<td>Stanford University</td>
<td>$3,200</td>
</tr>
<tr>
<td>Medical University of South Carolina</td>
<td>$2,000</td>
</tr>
</tbody>
</table>
Greenphire – Participant Reimbursement

Lunch n Learn February 22nd, 12N, BEB 112

For questions: Contact Ryan Mulligan
SCTR SUCCESS Center
(843) 792-8300
Research Master ID (RMID)

- **Standardized protocol numbering system**
  - Unique numeric identifier that links a research study across multiple MUSC research systems

- **Harmonize research system data**
  - **Phase 1**: To support metric tracking, continuous quality improvement activities and reporting
  - **Phase 2**: To reduce duplicative data entry

- Systems include: SPARCRRequest, eIRB, ePDS (COEUS)

- Clinical research studies submitting an IRB application (exempt, expedited, and full board) will be phased in first

- Will work with the research community to define how RMID should be applied for non-clinical research
QUESTIONS AND DISCUSSION

Please contact Office of Clinical Research at 843-792-8300

Website and email address coming soon…