College of Nursing
Research Report
Ron Acierno
NIH vs Other Research Funding in Millions (DoD, NIJ, etc.)

<table>
<thead>
<tr>
<th>Year</th>
<th>NIH</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013-2014</td>
<td>$2.73</td>
<td>$2.00</td>
</tr>
<tr>
<td>2014-2015</td>
<td>$2.97</td>
<td>$3.00</td>
</tr>
<tr>
<td>2015-2016</td>
<td>$2.96</td>
<td>$4.00</td>
</tr>
<tr>
<td>2016-2017</td>
<td>$3.16</td>
<td>$5.00</td>
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CON Research Accomplishments

- Ranked 13th in NIH funding among Colleges of Nursing across the country (off top 10 by about 100k)

- Achieved with 16 “full time” research faculty (Most have at least 50% teaching commitment).

- P20 Center grant integrating technology enhanced, biomedically focused, and community evaluated interventions funded, four $50-$75k pilots fully approved and running

- 17 new grant awards this year
CON Research Accomplishments continued

- 41 active funded grants in the CON with 23 different faculty as principal investigators.

- 35 different CON faculty are currently serving as PI or CoI on 131 funded inter-professional grants/projects.

- 55% of funded research grants with CON PI’s have inter-professional collaborators; 56% of submissions have inter-professional collaborators.

- Good representation on SCTR Cores: Jenkins & Nichols (CE), Kelechi (Recruit), Ruggiero & Treiber (Tech)
Academic ClinicalTrials.gov Compliance

An independent analysis was done of all academic institutions and their compliance with results reporting on ClinicalTrials.gov.

MUSC ranked #15 as the most non-compliant academic institution world-wide.

MUSC ClinicalTrials.gov Stats

- Greater than **400** studies of concern
- **193** studies need immediate action
  - 4 Suspended
  - 127 Completed (No Results)
  - 16 Terminated (No Results)
  - 46 Unknown – past Primary Completion date, but has not been updated in over 2 years
- Daily fine per study = **$11,383**
- Total potential fines for MUSC = ~$2M per day
ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Find a study (all fields optional)

Recruitment status  
- Recruiting and not yet recruiting
- All studies

Condition or disease  (For example: breast cancer)  

Other terms  (For example: NCT number, drug name, investigator name)  

Submit Studies
- Why Should I Register and Submit Results?
- FDAAA 801 Requirements
- How to Apply for an Account
- How to Register Your Study
- How to Edit Your Study Record
- How to Submit Your Results
- Frequently Asked Questions
- Support Materials
- Training Materials

Explore 263,745 research studies in all 50 states and in 202 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

Before participating in a study, talk to your health care provider and learn about the risks and potential benefits.

https://clinicaltrials.gov/
Revised Common Rule (Human Subject Regulations)
Revised Common Rule

- Publication Date: January 19, 2017
- Effective Date: January 19, 2018
- Compliance Date for most provisions January 19, 2018
- Compliance Date for single IRB: January 20, 2020

UPDATE: On 1/17/18, a delay in the effective and compliance date to 7/19/18 was announced
“The limited implementation delay accomplished by this interim final rule both provides additional time to regulated entities for the preparations necessary to implement the 2018 Requirements, and additional time for the departments and agencies listed in this document to seek input from interested stakeholders through a notice and comment rulemaking process that allows for public engagement on the proposal for a further implementation delay.”
Major Changes

- Definition of Human Subject
- Informed Consent
- New Expanded Exemptions
- Continuing Reviews
- Single IRBs for Multisite Research

Note: NIH single IRB effective 1/25/18
Informed Consent forms must be clearer and more focused:

- Concise summary of “key information”
- “Reasonable person” standard
- Present in “sufficient detail”
- Organize in a way that “facilitates comprehension”
Informed Consent

• One New Basic Element
  o New basic element if the research involves the collection of identifiable private information or identifiable biospecimens;

• Three new additional elements when appropriate:
  o Commercial project
  o Return of clinically relevant research results and whole
  o Genome sequencing
More Information

- Consent Template (Posted on Forms Page of IRB Website)
- Concise Summary Samples (Posted on Forms Page of IRB Website)
- Lunch and Learn: http://academicdepartments.musc.edu/sctr/education_training/lunch_n_learns
- IRB Website Front Page - Updates
- Listserv Updates
IRB Website

http://academicdepartments.musc.edu/research/ori/irb/
IRB-I
Katherine Bright, IRB Administrator - 792-4843
Kristin Zaks, IRB Coordinator - 792-9254

IRB-II
Amy Haynes, IRB Administrator - 792-4144
Kaye Roberts, IRB Coordinator - 792-6710

IRB-III
Jackie Shedrow, IRB Administrator - 792-3071
Paul Kelly, IRB Administrator - 792-6534
Cheryl Green, IRB Coordinator - 792-3093
Jessica Orak, IRB Coordinator - 792-9128

All Expedited Studies
Amy Haynes, IRB Administrator - 792-2525

IRB Reliance and sIRB
Summer Young, IRB Reliance Manager – 792-4144
Ultra Low (-80) Freezer Repair and Opt-In Preventive Maintenance

Joe Gough, MA
Department of Medicine
Goal & Scope

- Protect the freezer and its assets

- "Reliable, professional service"

- Ultra low (-80) mainly plus misc frig (repair and PM)
Part 1 - Repair Services

- Written estimates/findings
- 90-day warranty
- Hourly rate (no travel)
- Parts (<25% markup) & receipts
- Estimates <2 days
- Repairs <5 days
- EPA license/3 references
Part 2 - “Opt-In” Preventive Maintenance

› 6 mo. or annual PM
› 1-1 contract (PI w/ vendor)
› Vendor maintain database (not MUSC) – dates, POC, model
› PM checklist
Next Steps

› MUSC Research website w/ program and vendor contact info

› Begin to use vendors/share feedback re service
ClinCard by Greenphire

Ryan Mulligan, MRA, MS, CCRP, CRA
ClinCard Program Manager, Office of Clinical Research
What Is the ClinCard?

• The ClinCard system is a web based portal that automates subject reimbursements in a study by combining real-time payments to subjects using a reloadable debit card.

• The goal of the system is to reduce administration, increase patient retention, promote protocol compliance, and overall improve the site and patient experience while centralizing reporting and reducing costs.
ClinCard Package Example
Benefits to our research participants

• Payments applied to card are available almost instantly
• Online participant portal to check balance, etc.
• Can be used anywhere Mastercard is accepted, including online.
Benefits to the study team

• Reduced administrative burden
  • Reduced check requests
  • Reduced maintenance of petty cash or gift card inventories

• Increased study team safety
  • Eliminates need to keep cash or gift cards on-hand for payments

• Real time study level reporting

• Online portal allows coordinators to initiate payments from any computer

• Appointment reminder functionality to increase protocol compliance
Benefits to the department

- **Reduced administrative burden**
  - Reduced check requisition processing
  - Reduced maintenance of petty cash or gift card inventories

- **Increased controls**
  - Real-time reporting
  - Auditable
Benefits to the institution

- **Reduced administrative burden**
  - Reduced check requisition processing
  - Reduced maintenance of petty cash or gift card inventories

- **Increased controls**
  - Real-time reporting
  - Auditable

- **Automated 1099 reporting**
For Questions or More Information:
Office of Clinical Research
(843) 792-7900
ClinCard@musc.edu
Science Communication Forum
Mark Your Calendar – March 9, 2018

The Office of the Vice President for Research and the Office of Communications and Marketing have joined forces to host an enterprise-wide Science Communication Forum on the March 9, 2018. This full-day Forum will empower researchers and physician-scientists to advocate for their science with a variety of audiences - sponsors, policymakers, journalists, the public and other scientists.

- March 9, 2018
- 8:30 a.m. to 2:45 p.m.
- Bioengineering Auditorium Room 110 & 112

Keynote Speaker
Sonya F. Duhé, Ph.D., serves as director and professor in the School of Mass Communication at Loyola University New Orleans. Her research emphasis is applied broadcast research and science journalism, including risk and crisis communications.
Afternoon Concurrent Sessions

Science Communication Using Social Media
Learn practical tips on how you can contribute to the scientific dialogue on social media and how to practice safe social media.

Pitching Your Research Concept
Discover strategies from MUSC communication experts to condense your key message into a "pitch" that can be given in the duration of a typical elevator ride.

Engaging Policymakers
Uncover how meeting with policymakers can be a valuable opportunity to educate them on the impact of your scientific research in a compelling manner.

Working Effectively with Journalists
Learn from a panel of journalists - what they look for in a story, how to develop your message, what to do when a reporter calls, and what to expect during an interview.

Sponsored by: Office of Research Development and Public Affairs & Media Relations
WHAT IS THE BIG “IDEA” BUZZ AT MUSC?

Integrated Departmental Education for Administrators Program
MUSC-IDEA LEADERSHIP TRANSITION

From: Wanda Hutto and Beth Hansell  
To: Mac Houck and Isaac Chery
MUSC-IDEA PROGRAM DATES

• **Application Enrollment:** June 15, 2018 with selections announced in August 2018

• **Next program Offering:** Anticipated for Fall 2018 (Projected start date 9/11/2018 – November 15, 2018)

• **Program Availability:** Open to all University Employees

• **Who should apply?** Designed for staff involved in the administration of all aspects of research and sponsored projects funded by both extramural and internal sources
MUSC-IDEA PROGRAM APPRECIATION

• Thank You to Wanda Hutto and Beth Hansell for their leadership and services to MUSC-IDEA Program
• A very Special Thank You to all past and present MUSC-IDEA Program Instructors and Board of Advisors
• ORSP, GCA, IRB, OCR, SCTR, and the VA
Additional Information to Come!

Administrative Contacts:

• Mac Houck: houckrm@musc.edu or 792-2507
• Isaac Chery: chery@musc.edu or 792-5872
• Ford Simmons: simmonwi@musc.edu or 792-2994