Expectations of K Scholars and Their Mentors

Marc I. Chimowitz, MBChB
Mentee Expectations

1. Programmatic Requirements
2. Progression through Research Project and Training Plan
3. Meeting & Reporting Deadlines
4. Percent Effort Requirements
5. Take Charge of the Mentee – Mentor Relationship
1. Programmatic Requirements

- Annual Translational Science Conference in April
  - Attend and submit abstract
- Attend Annual MUSC Mentoring Retreat
- Monthly K to R Club Meetings
- Grant Writing Course
- Mock Study Section
- Citing the CTSA Grant on Publications

Strongly Encouraged:
- SOCRATES
- Tools for Mentors & Mentees
K to R Club Attendance for Mentee Presentations

- 4th Tuesday of each month at 5pm in BEB 102 (unless otherwise noted)
- Each scholar is required to attend every meeting whether presenting or not
- Each scholar is required to present at least once a year*

*Please check with your specific program to determine your number of presentations.
Grant Writing Course and Mock Study Section Participation

- **Participation in both is required.** Prior to grant submission scholars will participate in a grant writing course and mock study section.
Citing CTSA Grant

- Publications must cite grant funding and adhere to the NIH Public Access Policy
2. Progression through Research Project/Training Plan

- Create Individual Development Plan
- Set Annual Goals with Mentor and K program directors
- Use your K specific timeline (found in your folders) as a guide
- Ongoing training in conducting clinical & translational research
- CTRC rotation
The Individual Development Plan (IDP) is Your Career Compass
Individual Development Plan

- Individual Development Plan (IDP) provides a planning process that identifies both professional development needs and career objectives.

- IDP serves as tools to help facilitate communication between mentees and their mentors.
IDP Process

- The development, implementation and revision of the IDP require a series of steps to be conducted by the mentee, and then discussed with his/her mentor.

- These steps are an interactive effort, and ideally both the mentee and his/her mentor will fully participate in the process.
IDP – 3 Steps to Success

- **Step 1  Conducting a Skills-assessment:**
  Conduct an assessment of your strengths, weaknesses, and skills; then ask your mentor/colleague to review your skills assessment with you.

- **Step 2  Completing the IDP:**
  State your career goals and write your Annual IDP.

- **Step 3  Implementing your IDP:**
  - Set an appointment with your mentor.
  - Discuss your IDP with your mentor;
  - Implement the steps in your IDP;
  - Periodically review progress with your mentor.
Individual Development Plan (IDP)

Please complete the questions below for your Individual Development Plan (IDP).

Thank you!

PURPOSE OF THE IDP:
The Individualized Development Plan is a tool you will use in association with your mentor to help you reach short and long-term goals for your career and personal development. As you prepare to complete this form, please review the goals you set forth in last year’s IDP. Assessing your success in reaching those goals and developing refining your goals for the next academic year is crucial to your career development. Please note: The contents of this document may be shared with your division director at your request or his request. However, any discussions privately held with your mentor or the Vice-Chair for Faculty Development will be held in the strictest of confidence.

Division
* must provide value

First Name
* must provide value

Last Name
* must provide value

Degree(s)
- MD
- PhD
- MD
- MS
- MSCR
- RN
- JD
- DO
- DDS

Current Rank
* must provide value
- Instructor
- Assistant Professor
- Associate Professor

Years at Current Rank

Academic Track
- Clinician Educator
- Academic Clinician (Clinician Investigator)
- Academic Investigator (Basic Investigator)

Would you like to review examples of IDPs?
- Yes
- No

How many mentors do you have?
* must provide value

Overarching Goals
In no more than 2 sentences for the foreseeable future, as well as for the long term, what do you wish to achieve in your career?
Then list your goals below, for the next five years. Be as specific as possible. Be both qualitative and quantitative.
* must provide value

CLINICAL GOALS
This should describe your view of how you would like to develop your clinical expertise, if at all. Include elements that describe your lifelong learning goals. For example, a goal may be to become an expert clinician, or perhaps the best clinician in your field in the region.

How many clinical objectives would you like to establish?
1

Clinical Objective 1
* must provide value
TEACHING GOALS
This should focus on how you envision your contributions to teaching and education of others within the institution. For example, a goal may be to become known as an excellent teacher, or become recognized as an outstanding educator of students/residents/fellows.

How many teaching objectives would you like to establish?
* must provide value

RESEARCH GOALS
This should relate to a global vision of how your research will ultimately improve medicine. For example, a research goal could be: "To understand the pathogenesis of lung cancer so as to develop novel therapies." A clinical research goal might be: "To determine the best therapy or therapies for patients with COPD, and to thus improve all patients health with this disease".

How many research objectives would you like to establish?
* must provide value

LEADERSHIP and CAREER GOALS
This should reflect a leadership or administrative title you see yourself holding in 5-10 years, such as Director of a Program or Center, or Division Director. For example, a personal career goal might be: "To lead a multidisciplinary Center for Human Genetics."

How many leadership objectives would you like to establish?
* must provide value

Leadership Objective 1
* must provide value

What type of grant proposals do you plan to submit within the next two years?
* must provide value
- NIH, VA, other federal
- Career Development (NIH, VA, other)
- Foundation
- Corporate
- None

In reviewing the goals you set in last year's IDP: How successful have you been in reaching those goals?
* must provide value
- Not at all
- Achieved < half
- Achieved half
- Achieved > half
- Achieved all

What hindered or helped you in achieving your goals?

In the past academic year, did you have a 1:1 mentoring session with Dr. Silvestri or Dr. Wong?
* must provide value
- Yes
- No

I fully understand the criteria for faculty promotion.
* must provide value

Please update metrics for previous academic year as applicable.
- Manuscripts submitted
- Manuscripts published
- Manuscripts rejected
- Manuscripts resubmitted
- Editorials, reviews, etc published
- Grants submitted
- Grants awarded
- Nominations, teaching awards, etc.

Have you made changes to this form since your last meeting with your mentor?
* must provide value
- Yes
- No

I acknowledge joint completion of this plan with my mentor.
* must provide value
- Yes
- No
3. Meeting & Reporting Deadlines

- Meet with mentor at least monthly
- Meet with K program directors quarterly/every 6 months (depending on which K program you are in)
  - Submission of written progress reports 2 weeks before meeting
- Annual Progress Reports – yearly for the next ~7 years after support ends
- By end of Year 2, scholars are expected to have submitted an extramural grant application
- Year 3 – resubmission of an extramural grant application if applicable
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2014</td>
<td>Appointment begins: Submit CITI training documents, budget, work towards IRB approvals if not yet obtained</td>
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<tr>
<td></td>
<td>SOCRATES; Tools for Mentors &amp; Mentees</td>
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<tr>
<td>May 2014</td>
<td>Mentoring Retreat 5/3</td>
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<tr>
<td></td>
<td>K to R Club – 5/27 5pm (4th Tues each month)</td>
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<td></td>
<td>Establish mentoring contract if not done</td>
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<td></td>
<td>SOCRATES; Tools for Mentors &amp; Mentees</td>
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<tr>
<td>June 2014</td>
<td>June 3rd – Progress Report Meeting</td>
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<td></td>
<td>June 6&amp;7 - Longitudinal &amp; Multilevel Modeling of Continuous &amp; Categorical Data Course</td>
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<td></td>
<td>K to R Club – 6/24 5pm</td>
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<td></td>
<td>SOCRATES; Tools for Mentors &amp; Mentees</td>
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<tr>
<td>July 2014</td>
<td>July 11th - Orientation</td>
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<td></td>
<td>K to R Club – 7/22</td>
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<tr>
<td></td>
<td>SOCRATES; Tools for Mentors &amp; Mentees</td>
</tr>
<tr>
<td>August 2014</td>
<td>K to R Club – 8/26</td>
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<tr>
<td></td>
<td>SOCRATES; Tools for Mentors &amp; Mentees</td>
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<tr>
<td>September 2014</td>
<td>K Didactic Grant-writing Training Course</td>
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<td>Progress Report Meeting</td>
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<td>K to R Club – 9/23</td>
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<tr>
<td></td>
<td>SOCRATES; Tools for Mentors &amp; Mentees</td>
</tr>
<tr>
<td>Month</td>
<td>Event Description</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| October 2014 | K to R Club – 10/28  
SOCRATES; Tools for Mentors & Mentees                                          |
| November 2014 | K to R Club – 11/25 (*may change due to holiday)  
SOCRATES; Tools for Mentors & Mentees                                           |
| December 2014 | Progress Report Meeting  
K to R Club – TBD  
Mock study section  
SOCRATES, Tools for Mentors & Mentees                                           |
| January 2015 | Individual Training Report Due for inclusion in SCTR Annual Progress Report  
KL2 Abstracts due for the Translational Science Conference in April  
K to R Club – 1/27  
SOCRATES; Tools for Mentors & Mentees                                           |
| February 2015 | K to R Club – 2/24  
SOCRATES; Tools for Mentors & Mentees                                           |
| March 2015   | Progress Report Meeting  
K to R Club – 3/24  
SOCRATES; Tools for Mentors & Mentees                                           |
|             | Additional Goals Beyond Year 1  
Targeted time frame for mock study section:  
Targeted Grant Submission: |
4. Percent Effort Requirements

- Mentee **must be able to document** that the percent effort of your award (eg. 75%, 50%) is dedicated to K activities
- Mentor must help ensure that Department is providing the mentee with the protected time that the award requires
- If not being fulfilled, PI of K Program needs to be informed
5. Take Charge of the Mentee – Mentor Relationship

- Mentoring is key to career success and satisfaction
- “The mentee is not an empty vessel receiving the mentor’s advice and wisdom but, rather, an active participant, shaping the relationship”

Zerzan et al. 2009
Mentees Should Learn to “Manage Up”

“Managing up” -- the mentee takes ownership of and directs the relationship, letting the mentor know what he or she needs . . . Managing up makes it easier for a mentor to help a mentee, which makes the relationship more satisfying and successful for both.”
Other Take Home Points for Mentees

- Mentoring is reciprocal – look for opportunities to teach your mentor (and give feedback)
- Take time to reflect on your values, skills, weaknesses, and goals – this will form the foundation for decision-making
- Use an Individual Development Plan (IDP)
Mentor Expectations

- Mentor Attributes
- Mentoring Contract
- K to R Club attendance
- Mock Study Section Participation
- Meeting & Reporting Deadlines
Attributes of Outstanding Mentors

1) **Time commitment** to mentoring
2) **Personal qualities**: enthusiasm, altruism,
3) Act as a **career guide** for mentee
4) Support **personal/professional balance**
5) **Leave a legacy** of how to be a good mentor

Cho C, Ramanan R, Feldman MD. AJM 2010
Mentoring Partnership Agreement

Working in partnership, we are entering this mentoring relationship. It is our expectation that this partnership will foster professional growth and career development. In order to ensure that the mentoring relationship will be a mutually regarding and satisfying experience, we agree to the following:

1. Maintain confidentiality in this relationship and
   Mentor ___________ and ___________ Mentee

2. We are committed to sustain this relationship for at least one (1) year from this date.
   ___________ Mentor ___________ Mentee

3. We are committed to meet together: weekly ______ monthly ______

4. We have established the following goals for this mentoring relationship:
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________

5. The skill areas to be enhanced or developed through this partnership are:
   ____________________________________________________________
   ____________________________________________________________
   ____________________________________________________________

6. Each of us has outlined expectations for the mentoring relationship. Initial Initial

7. We have discussed and agree to a “No-Fault” conclusion if necessary. Initial Initial

Mentor ___________ Date ___________ Mentee ___________ Date ___________

Check box if you are lead mentor [ ]
K to R Club Attendance for Mentee Presentations

- 4th Tuesday of each month at 5pm in BEB 102
- Each scholar is required to attend
- Each scholar is required to present twice a year
  - Mentor must be present during his/her mentee’s presentation
  - Mentors are strongly encouraged to attend all K to R club meetings
Mock Study Section Participation by Mentors

- Mock Study Sections Participation is required by mentee and mentor.
  - Prior to external grant submission scholars will submit a grant for review by a mock study section
  - Mentors will fulfill the role as reviewers for the K Program mock study section
  - Scholars will also attend and participate in mock study sections
Meeting & Reporting Deadlines

- Meet with mentee at least monthly
- Meet with K program directors quarterly/every 6 months (depending on specific K program)
- By end of Year 2, scholars are expected to have submitted an extramural grant application
- Year 3 – resubmission of an extramural grant application if applicable
Summary of Mentor Responsibilities

- Help develop the skills needed to promote the career of the mentee
- Ensure that a mutually agreed upon set of expectations and goals are in place at the outset of the mentoring period and work with the mentee to create an individual development plan (IDP)
- Strive to maintain a relationship with the mentee that is based on trust and mutual respect
- Promote all ethical standards for conducting research including compliance with all institutional and federal regulations
Mentor Responsibilities

- Ensure that the mentee has sufficient opportunities to acquire the skills necessary to become an expert in the area of investigation.
- Provide the mentee with the required guidance and mentoring, and seek the assistance of other faculty and departmental / institutional resources when necessary.
- Encourage the interaction of the mentee with fellow scientists both intra- and extramurally and encourage the mentee’s attendance at professional meetings to network and present research findings.
- Ensure that the research performed by a mentee is submitted for publication in a timely manner and that the mentee receives appropriate credit for the work.
Mentor Responsibilities

- Make available to the mentee, as appropriate, data from previous or ongoing projects that are related to the mentee’s area(s) of interest
- Commit to being a supportive colleague to mentees as they transition into the next stage of their career and to the extent possible, throughout their professional life.
- Play a fully involved role in the K Program
- Attend the Annual CTSA Mentor Training Program
Optimizing the Practice of Mentoring

- An Online Curriculum for the Professional Development of Research Mentors – through the University of Minnesota’s CTSI
- Registration is Free – [ctsi.umn.edu/education/mentoring](ctsi.umn.edu/education/mentoring)
Mentoring Defined

On the course home page, you spent a few minutes reflecting upon an image that represents your point of view about mentoring. During the reflection, did you think about a specific mentoring experience? Did you consider how you define the term “mentoring?”

In this course, our working definition of mentoring\(^1,2\) is as follows:

Mentoring is a collaborative learning relationship that proceeds through purposeful stages over time and has the primary goal of helping a mentee to acquire the essential competencies needed for success in a research career.

Navigation Tip: To proceed through this section, “What is Mentoring,” click each topic to the left (in grey). When done, click another section in the navigation bar at the top of the screen.

Resources


The Importance of Relationships

At the core of mentoring is an interpersonal relationship that is developed via a series of ongoing interactions between a mentor and a mentee. Simply put, a mentoring relationship can be understood as a learning environment. For this reason, a mentor’s consistent application of strategies to build and nourish a healthy relationship with a mentee is crucial, and should be given more attention than other specific roles and responsibilities.

“It is through the personalized interaction between mentor and mentee that self-reflection occurs, career goals are set, specific competencies to be gained are identified, encouragement is given, challenges are presented, and new opportunities are explored.”

FOOTNOTES

1. ^ (Bland et al., 2009, p. 92)

REFERENCES

Needs Assessment and Goal Setting

Sudie Back, PhD
Professor
Department of Psychiatry & Behavioral Sciences

Staff Psychologist
Ralph H. Johnson VAMC
What ARE Your Training Needs??

Compare where you are NOW to where you want to be when you finish the K program.

- Skills to run clinical trials?
- Expertise with basic science models?
- Collaborative interdisciplinary team?
- Advanced statistical knowledge?
- More publications?
- Independent funding?
Tip #1: Work Closely with Your Mentor

- Review the Baseline Needs Assessments and Goals form with your mentor
- Update periodically – e.g., 3-6 months
- It's a TEAM sport
Tip # 2: Visit Appointment, Promotion and Tenure (APT) Website
## Instructor

**Faculty Tracks**

<table>
<thead>
<tr>
<th>Instructor</th>
<th>Academic Inv</th>
<th>Academic Inv/Ed</th>
<th>Academic CI</th>
<th>Clinician Ed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of educational requirements necessary to enter a career in academic research, teaching and/or clinical care.</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Aptitude for an academic career based upon recommendations of mentors.</td>
<td>R</td>
<td>R</td>
<td>R</td>
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</tr>
<tr>
<td>Career goal to function independently in an academic environment as an investigator, teacher, and/or clinician.</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Developing experience with preparation of research protocols and grant applications.</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Demonstrated interest in teaching.</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Early experience with preparation of publications and presentations related to research.</td>
<td>R</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Fulfilled educational requirements for certification by appropriate specialty board.</td>
<td></td>
<td></td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Demonstrated interest in high quality clinical care.</td>
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<td></td>
<td></td>
<td>R</td>
</tr>
</tbody>
</table>
### Assistant Professor

<table>
<thead>
<tr>
<th></th>
<th>Academic Investigator</th>
<th>Academic Inv/Ed</th>
<th>Academic Clinician</th>
<th>Clinician Educator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear commitment to an academic career in research, teaching and/or clinical care.</td>
<td>R</td>
<td>R</td>
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</tr>
<tr>
<td>Commitment to and potential for performing independent laboratory and/or clinical research.</td>
<td>R</td>
<td>R</td>
<td>R</td>
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</tr>
<tr>
<td>Receipt, active pursuit or development of the skills necessary to apply for local, regional and national grants.</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Developing skills for directing or contributing to publications related to research, teaching and/or clinical care. (Participation in interprofessional teaching and inter-disciplinary research encouraged)*</td>
<td>R*</td>
<td>R*</td>
<td>R*</td>
<td>R*</td>
</tr>
<tr>
<td>Active in training of students and/or post-graduates.</td>
<td>R</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Strong interest in teaching .</td>
<td></td>
<td>S</td>
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<tr>
<td>Contributions as first author on refereed publications.</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>S</td>
</tr>
<tr>
<td>Contributions as author on refereed publications.</td>
<td></td>
<td>R</td>
<td>R</td>
<td>S</td>
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<tr>
<td>Capable of managing most clinical problems in the appropriate discipline, but may seek assistance from senior faculty when dealing with complex problems.</td>
<td></td>
<td>R</td>
<td>R</td>
<td>S</td>
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<tr>
<td>Carry a heavy clinical load</td>
<td></td>
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<tr>
<td>Establishing recognition through candidacy or membership in appropriate professional and scientific organizations.</td>
<td>R</td>
<td>R</td>
<td>R</td>
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</tbody>
</table>
# Associate Professor

<table>
<thead>
<tr>
<th>Associate Professor</th>
<th>Academic Investigator</th>
<th>Academic Inv/Ed</th>
<th>Academic Clinician</th>
<th>Clinician Educator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continues to meet all the criteria for Assistant Professor with a record of achievement in research, teaching, and/or clinical service. (Participation in interprofessional teaching and inter-disciplinary research encouraged)*</td>
<td>R*</td>
<td>R*</td>
<td>R*</td>
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<tr>
<td>Record of excellence in high quality patient care, teaching and/or research</td>
<td>R</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Established independent investigator with major impact in planning/development of research project. Involved in teaching activities, including formal lectures, grand rounds, and/or continuing medical education.</td>
<td>R</td>
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<tr>
<td>Principal investigator on significant research grants</td>
<td>R</td>
<td></td>
<td>S</td>
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<tr>
<td>Co-investigator on research grants.</td>
<td></td>
<td>R</td>
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<tr>
<td>Local, regional or national grant support for independent research or development of teaching methods, or health care delivery methods, or clinical care systems</td>
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<tr>
<td>Poor recognition for research activities including invitations to present work at other universities, workshops and scientific conferences.</td>
<td>R</td>
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<tr>
<td>Direct involvement in research.</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Organization of clinical services to provide a setting for medical education and a data base for clinical research.</td>
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<tr>
<td>Active in training of students and/or post-graduates.</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Serves as Course Director for one or more major professional courses</td>
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<tr>
<td>Important contributor to course development or course direction.</td>
<td></td>
<td>R</td>
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<tr>
<td>Superior evaluations of teaching by students, residents, peers, course directors, dept. chairs.</td>
<td>S</td>
<td>R</td>
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<tr>
<td>Nominated for or recipient of teaching awards.</td>
<td></td>
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<tr>
<td>Presentations at national/international meetings.</td>
<td>R</td>
<td>R</td>
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</tr>
<tr>
<td>Continued publication of reviews, chapters, textbooks, peer reviewed papers, and/or innovative teaching materials (new curricula, educational programs, syllabi, video materials, computer programs, etc.) that influence the science and practice of medicine at the regional &amp; national levels</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Continued publication of important and original clinical and/or laboratory investigations with significant authorship.</td>
<td>R</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Total publications with significant authorship since last promotion</td>
<td>≥10</td>
<td>≥10</td>
<td></td>
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<tr>
<td>Total publications with authorship since last promotion</td>
<td>≥5</td>
<td>≥5</td>
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<tr>
<td>Development of new teaching materials, such as curricula, educational programs, textbooks, syllabi, computer programs and video tapes</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Established reputation inside and outside local institution as an authority in a clinical specialty or for leadership in primary care</td>
<td>S</td>
<td>R</td>
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<tr>
<td>Contributions to committees at department, college, university, community, state, regional, national and international levels</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Leadership role in department and hospital as a section or division head, or program director</td>
<td>S</td>
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<tr>
<td>Active involvement in local and national professional organizations</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Election to scientific organizations in discipline</td>
<td>S</td>
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</tbody>
</table>
Tip # 3: Identify Short-Term Steps to Reach Long-Term Goals

- Submit 4-5 papers each year
- Present at 2-3 national conferences each year
- Become members of A & B committees – dept, university, local, national levels
- Apply for pilot funding
- Submit an R-series grant
Addressing Your Goals and Training Needs

- Meetings with Mentor
- Other Sources:
  - Grant Writing Course
  - Mock Study Section
  - Office of Research Dev Retreats
  - Masters of Science in Clinical Research (MSCR)
  - CCRT: Core Curriculum in Research Training
Tip #5: Keep the Path Clear...

WHAT YOU DON’T NEED:
Too many committees
Too many meetings
Too many projects
Too many courses you’re taking
Too much courses you’re teaching
Too many people you are mentoring or supervising
Too many mentors
PLAN

- **P**urpose
- **L**inking
- **A**ction and
- **N**eeds
### Building Interdisciplinary Careers in Women's Health (BIRCWH)

#### NEEDS ASSESSMENT

<table>
<thead>
<tr>
<th>Scholar:</th>
<th>Year:</th>
</tr>
</thead>
</table>

| Primary Mentor: | Secondary Mentor: |

**Instructions:** Please rank the following items from 1 to 5 for your skill level (1 = few skills in this area, to 5 = strong skills in this area), and importance to your career development (1 = little importance, to 5 = great importance).

<table>
<thead>
<tr>
<th>Knowledge and skill areas</th>
<th>Level of skill</th>
<th>Importance to career development</th>
</tr>
</thead>
</table>

### Research Design and Methods
- Critically evaluate addiction research literature: 4 [5]
- Formulate hypothesis and operationally define variables: 4 [5]
- Knowledge of sampling techniques, sample size issues, and power: 3 [5]
- Understand validity and reliability: 3 [5]
- Knowledge of different types of research designs: 4 [5]
- Knowledge of different assessment methods: 4 [5]

### Data Collection, Management and Analysis
- Construct a plan for data collection: 2 [5]
- Knowledge of how to create and maintain data files: 3 [5]
- Understand commonly used statistical tests: 3 [5]
- Knowledge of available statistical packages: 3 [5]
- Interpret p-value and statistical output: 4 [5]

### Disseminating Research Findings
- Attend an addiction research conference: 3 [5]
- Submit an abstract for presentation at a research conference: 3 [5]
- Present a poster or symposium at a research conference: 3 [5]
- Prepare, submit, and revise a manuscript for publication: 3 [5]
- Integrate findings into the existing literature: 3 [5]
- Orally communicate research findings/public speaking: 3 [5]

### Human Subjects Protection and Research Ethics
- Principles of good research practice/ responsible conduct of research: 4 [5]
- Ethical considerations in conducting drug abuse clinical research: 3 [5]

### Other

#### Research Administration
- Knowledge of how to secure and maintain IRB approval: 4 [5]
- Prepare and manage research budgets: 4 [5]
- Knowledge of Phase I-IV clinical trials: 1 [5]
- Supervise research staff, liaison with clinical personnel: 3 [5]

#### Grant Writing
- Knowledge of addiction research funding sources: 3 [5]
- Knowledge of grant forms, cycles and review process: 4 [5]
- Grantsmanship skills: 3 [5]

#### Knowledge Areas in Addiction
- Clinical aspects of substance use disorders: 4 [3]
- Treatment of substance use disorders: 4 [2]
- Neurobiology of addiction: 2 [5]
- Race, ethnicity, culture and addiction: 2 [5]
- Gender and addiction: 2 [5]
- Public health and prevention research: 2 [5]

#### Computer Skills
- Searches, software and file sharing: 5 [5]

### Other

---

**BIRCWH Scholar Signature**

7-8-07

**Primary Mentor Signature**

Date

**Secondary Mentor Signature**

Date

**BIRCWH Program Member Signature**

Date
Building Interdisciplinary Careers in Women’s Health (BIRCWH)

ANNUAL RESEARCH GOALS

Scholar: ___________________ Year: __________
Primary Mentor: ___________ Secondary: __________

Annual Research Goals
(e.g., Learn more about research ethics and human subjects protection; Gain experience with data entry, management, and statistical analysis; Learn more about funding opportunities and grant writing; Apply for funding for pilot study; Attend the CPDD conference):

Statistical genetics course at UAB
Clinical trials training at NIH
Genetics statistics training at Harvard
Gender-specific review paper

Research Skills To Target This Year
See Needs Assessment Template (e.g., Manuscript writing; Conference poster or oral presentation skills; Statistical analysis; Research design and methodology, Human subjects protection, Grantsmanship):

Statistical genetics analysis
Complex statistical modeling
Clinical trials training
DNA extraction

Research Projects and Other Activities To Be Involved In This Year:
Co-PI ARC project
PTSD/ substance abuse data analysis
National survey
BIRCWH Project

Research Training Components to Complete This Year
(e.g., CITI course, Core Clinical Research Training Course, Grant Workshop, IRB course, Formal coursework):
ORWH online Sex & Gender Course
Core clinical research training September 2009
Annual ORWH Meeting
World Congress of Psychiatric Genetics Meetings
Association of Cognitive Behavioral Therapies
Association for Human Genetics

BIRCWH Scholar Signature __________ Date __________
Primary Mentor Signature __________ Date __________
Secondary Mentor Signature __________ Date __________
BIRCWH Program Member Signature __________ Date __________
# Building Interdisciplinary Careers in Women's Health (BIRCHW)

## Needs Assessment

<table>
<thead>
<tr>
<th>Scholar:</th>
<th>Research with vulnerable populations</th>
<th>Perform studies according to approved IRB or IACUC protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Mentor:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary Mentor:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Instructions
- Please rank the following items from 1 to 5 for your skill level (1 = few skills in this area, to 5 = many skills in this area), and importance to your career development (1 = little importance, to 3 = great importance).
- Not applicable

## Knowledge and skill areas

### Research Design and Methods
- Critically evaluate relevant research literature
- Formulate hypotheses and operationally define variables
- Knowledge of sampling techniques, sample size issues, and power
- Understand validity and reliability
- Knowledge of different types of research designs
- Knowledge of different assessment methods

### Data Collection, Management and Analysis
- Construct a plan for data collection
- Knowledge of how to create and maintain data files
- Understand commonly used statistical tests
- Knowledge of available statistical packages
- Interpret p-value and statistical output

### Disseminating Research Findings
- Attend a relevant research conference
- Submit an abstract for presentation at a research conference
- Present a poster or symposium at a research conference
- Prepare, submit, and revise a manuscript for publication
- Integrate findings into the existing literature
- Orally communicate research findings/public speaking

### Human Subjects or Animal Protection and Research Ethics (as appropriate)
- Principles of good research practice/ responsible conduct of research
- Ethical considerations in conducting drug abuse clinical research
- Elements of informed consent document

## Research Administration
- Knowledge of how to secure and maintain IRB approval
- Prepare and manage research budgets
- Knowledge of Phase I-IV clinical trials
- Supervise research staff, liaison with clinical personnel

## Grant Writing
- Knowledge of relevant research funding sources
- Knowledge of grant forms, cycles and review process

## Grantmanship skills

## Knowledge Areas in Research Area
- Clinical aspects of relevant disorders
- Treatment of relevant disorders
- Neurobiology of CNS disorders
- Race, ethnicity, culture and relevant disorder
- Gender and relevant disorder
- Public health and prevention research
- Computer Skills
- Searches, software and file sharing

### Other

---

BIRCHW Scholar Signature Date

Primary Mentor Signature Date

Secondary Mentor Signature Date

BIRCHW Program Member Signature Date
Building Interdisciplinary Careers in Women's Health (BIRCWH)

ANNUAL RESEARCH GOALS

Scholar: __________________________ Year: __________
Primary Mentor: __________________ Secondary: ______________

Annual Research Goals
(e.g., Learn more about research ethics and human subjects protection; Gain experience with data entry, management, and statistical analysis; Learn more about funding opportunities and grant writing; Apply for funding for pilot study; Attend the CPDD conference):

Two first-authored papers
Two additional papers with others
Devote some time to reading to broaden research perspective

Research Skills To Target This Year
Seq Needs Assessment Template (e.g., Manuscript writing, Conference poster or oral presentation skills, Statistical analysis, Research design and methodology, Human subjects protection, Grantmanship):

Present at 1-2 meetings per year
Neurocognitive data analysis

Research Projects and Other Activities To Be Involved In This Year
Manuscript writing
Collaboration with research team
Attend monthly SCOR & BIRCWH meetings

Research Training Components to Complete This Year
(e.g., CIT course, Core Clinical Research Training, Grant Workshop, IRB course, Formal coursework):
The Science of Sex and Gender in Human Health online course

BIRCWH Scholar Signature __________________________ Date
Primary Mentor Signature __________________________ Date
Secondary Mentor Signature __________________________ Date
BIRCWH Program Member Signature __________________________ Date
Final Tip: Be sure to celebrate each accomplishment!
Thank you

- Kathleen Brady, MD, PhD
- NIH Support
  - F31 DA00607
  - T32 DA007288
  - K23 DA021228
  - R25 DA020537
  - R01 DA030143
Program Resources

MARC CHIMOWITZ
KATHLEEN BRADY
DAN LACKLAND

JULY 11, 2014
Grant/Career Development

Graduate Programs PhD/Med Student
- Basic Grant Training
  - K-awards for PhDs
- Ethics-RCR

K-Awardee Junior Faculty
- Career Development Series*
  - Time Management
  - Career Trajectories, etc.
- Grant Writing and Mgmt Course*
- K to R Club
- Focused Mentoring
- RPG Retreats

Mid to Senior Level
- Mentor Training/Retreat
- Multi-site Trials
- Mentoring Website*

STAR Consults and Pilot Project Funds
* To Be Developed
Institutional K awards

- BIRCWH – focused on research careers in women’s health – Year 6
- CTSA KL2 – focused on translational research training - Year 5
- COM K12 – focused on clinical to translational research
- NIDA K-12 – Clinician Scientists in Substance Abuse - Year 1
- HCC K-12 – Career development for Clinical & Translational Oncology Program
- AHRQ – focused on PCORI – in development
Institutional K awards

**Common elements**
- 40-75% minimum time for research
- Research/travel budget
- 2-3 years funding (accelerated trajectory)
- RCR

**Added elements**
- Orientation
- K to R club
- SOCRATES
- Grant writing course
- Mock study sections

**Program-specific elements**
GRANT PREPARATION ACTIVITIES

- Course – September/October
- Mock Study Sections
  - December for February submission
  - April for June submission
- K to R club
  - All scholars present
- Pilot project funds
  - SCTR, SCOR, Hollings
- STAR consults
GRANT WRITING COURSE

- Monday's 9/8 – 10/27, 1:15–2:45pm
- Faculty: Brady, Chimowitz, Back, & McGinty
- Will follow text for first 4 weeks
  - Scholars to review material
  - Faculty facilitator
- Weeks 5-8 review individual timelines, specific aims
GRANT WRITING COURSE

- **WEEK 1 – SEPT 8\textsuperscript{th}**
  - Picking a great idea
  - Creating your timeline
  - Conceptual overview & outline

- **WEEK 2 – SEPT 15\textsuperscript{th}**
  - Specific Aims
  - Significance & Innovation

- **WEEK 3 – SEPT 22\textsuperscript{nd}**
  - Training plans & career goals
  - Expected outcomes/Potential pitfalls
  - Summary

- **WEEK 4 – SEPT 29\textsuperscript{th}**
  - Literature Review
  - Prelim Studies
  - Research Design

- **WEEKS 5-8 – OCT 6\textsuperscript{th}-27\textsuperscript{th}**
  - Review of Individual abstracts and timelines

- **Participants:**
  - Zachary Adams
  - Linnea Freeman
  - Gonzalo Revuelta
  - Cristina Lopez
  - Satish Nadig
  - Lindsay Squeglia
  - Erin McClure
  - Qing Li
• Mid to end of Year 2
• Full Application submitted 3 weeks before
• Faculty primary and secondary reviewer
• Trainees review and attend session
K to R Club Attendance for Mentee Presentations

- 4th Tuesday of each month at 5pm in BEB 102
- Each scholar is required to attend
- Each scholar is required to present at least *once an academic year
  - Mentor must be present during his/her mentee’s presentation
  - Mentors are strongly encouraged to attend all K to R club meetings

*Refer to your Mentee expectations for your specific program to see how many times you need to present.
Society of Clinical Research and Translational Early Scientists (SOCRATES)

- For Junior Faculty to Present Research Projects in Front of Peers, Senior Researchers, Statisticians and Epidemiologists
- To Meet Researchers in Other Departments & Foster Collaboration Across Multiple Subspecialties at MUSC
- To Discuss Ways to Enhance Clinical and Translational Research Across the Campus
- To Provide Information on Research Opportunities (e.g., grant announcements)
B & BS and SOCRATES Joint Meetings

- Informal forum to present research ideas, grant proposals to a mixed audience for feedback and collaboration.
- Twice Monthly meetings:

Contact barrettd@musc.edu or mchimow@musc.edu or halushpv@musc.edu
SCOR/BIRCWH Meeting Attendance

- 2\textsuperscript{nd} Tuesday* of each month at 10am in RMOB 140 (125 Doughty Street)
- Each scholar is required to attend
- Each scholar is required to present once per year
  - Mentor must be present during his/her mentee’s presentation
  - Mentors are strongly encouraged to attend all meetings at which BIRCWH scholars present

The Master of Science in Clinical Research

MEDICAL UNIVERSITY OF SOUTH CAROLINA (MUSC)
CHARLESTON, SOUTH CAROLINA
USA
Master of Science in Clinical Research (MSCR)

- **Program**
  - Design based on US National Institute of Health (NIH) definition of Clinical Research with modifications based on NIH and NCRR core competencies
  - adheres to the Association of Clinical Research Training (ACRT) – now the National Center for Advancing Translational Sciences (NCATS) recommended 52 core competencies for clinical research training programs.
  - is the pivotal educational program for the South Carolina Clinical and Translational Research Institute

- **38 Academic Credit Hours**
- One year, full time
- Multi year, part time
- **Locations to study**
  - Distant Education blended format – currently under development
  - MUSC campus
NCATS/CTSA Core Competencies in Clinical & Translational Research

I. Clinical & Translational Research Questions
II. Literature Critique
III. Study Design
IV. Research Implementation
V. Sources of Error
VI. Statistical Approaches
VII. Biomedical Informatics
VIII. Clinical Research Interactions
   I. Regulatory Support & Knowledge Competencies
   II. Responsible Conduct of Research Competencies
IX. Scientific Communication
X. Cultural Diversity
XI. Translational Teamwork
XII. Leadership
XIII. Cross Disciplinary Training
XIV. Community Engagement
Curriculum

• Ethics
• Clinical epidemiology
• Clinical biostatistics
• Computer programming
• Leadership
• Design of clinical trials
• Comparative Effectiveness
• Critical review of contemporary clinical research
• Pharmaceutical industries overview
Goals of the MSCR

- Leaders of research teams called ‘team science’ (e.g., basic researchers, clinicians, nurses, biostatisticians, epidemiologists, trialists, bioinformaticians, CROs, CRAs, etc)
- Career development and advancement in clinical research
- Building research programs with the pharmaceutical industry
- Training to become future leaders
Teaching & Delivery

- MUSC MSCR faculty
- Combination of delivery formats
  - Power Point & Tegrity
  - Skype
  - Chat rooms
  - Onsite visit by MUSC faculty
- All courses are taught in English
- Traditional classroom lectures
- Audio / Video Conferencing
- Case study based learning
- Seminars / Group discussions
- Directed self-study
- Individual and group projects
Assessment

- Combination of the below
  - Online Quizzes / Examinations
  - Case study presentations
  - Workshop participation
  - Discussions
  - Project work
  - Individual Assignments
  - Group Presentations
Degree

- Awarded by Medical University of South Carolina
- Master of Science in Clinical Research
Office of Research Development and Types of NIH & Agency Grants Available

July 11, 2014

Joann F. Sullivan, Ph.D.
Director
Office of Research Development
BSB Room 101
sullivan@musc.edu
Session ‘Line-Up’

• Research Administration at MUSC

• Office of Research Development

• Research Funding Opportunities: Which ones are right for me?
Key Research and Development Offices in the MUSC Organization

President

Vice President for Academic Affairs & Provost

Associate Provost for Research

Office of Research & Sponsored Programs
- Proposal Processing
- Negotiation
- Award Administration
- Regulatory Compliance

Office of Research Development
- Funding Opportunities
- Proposal Development

Office of Research Integrity
- Human Research
- Animal Care & Use
- Biosafety
- Scientific Integrity
- Conflict of Interest

Vice President for Finance & Administration

Grants & Contracts Accounting
- Fiscal Management
- Reporting

Office of Development
- Major Gifts
- Planned Gifts
- Annual Fund
- Capital Campaigns

Human Resource Management

Procurement

Alumni Affairs

Foundation for Research Development
- Intellectual Property
- Technology Transfer
- Cooperative Research
- Economic Development

Health Sciences Foundation
- Fund Management
- Investments

Associate Provost

Office of Research & Sponsored Programs
- Proposal Processing
- Negotiation
- Award Administration
- Regulatory Compliance

Office of Research Development
- Funding Opportunities
- Proposal Development

Office of Research Integrity
- Human Research
- Animal Care & Use
- Biosafety
- Scientific Integrity
- Conflict of Interest

Vice President for Development

Office of Development
- Major Gifts
- Planned Gifts
- Annual Fund
- Capital Campaigns

Human Resource Management

Procurement

Alumni Affairs

Foundation for Research Development
- Intellectual Property
- Technology Transfer
- Cooperative Research
- Economic Development
The Lifecycle of an Award

1. Conception of idea
2. Search for Funding
3. Proposal Creation
4. Budget Creation
5. Award Accepted
6. Setting up Award by GCA
7. Post Award Administration
8. Award Close Out and Audit
9. Submission To Sponsor
10. Review by Sponsor
11. Routing & Approval
MUSC
Office of Research Development

Joann F. Sullivan, Ph.D.
Director & Professor
843-792-0870
email

Karen Harper
Program Manager
843-792-0871
email

Wanda K. Hutto, CRA
Assistant Director
843-792-0867
email

Heather Ferguson
Grants Coordinator
843-792-0872
email
What do we offer?

- Research Funding Alerts
- Pivot (aka Community of Science)
- Grantsmanship Workshops
- Research INKlings
- Institutional “Boilerplate” and Databases
- Collaborative Proposal Development
- *Research Project Grant (RPG) Retreats*
- *Library of Sample Proposals*
Three Basic Steps

• Find Funding Opportunities
• Do Your Homework
• Prepare a Competitive Proposal
Find Funding Opportunities

• SIGN UP for ORD Research Funding Alerts
  <www.carc.musc.edu/ordalerts/>

• SET UP personalized searches using COS Pivot
  <pivot.cos.com>

• SUBSCRIBE to NIH Guide for Grants and Contracts
  <http://grants.nih.gov/grants/guide/listserv.htm>

• SCAN proposalCENTRAL
  <https://proposalcentral.altum.com/>
Do Your Homework

• Know the “culture” of your funding source

• Take a course in NIH 101

• Do some searching (http://report.nih.gov/)
Billions of constant FY 2014 Dollars

Source: 1975-1994 figures are from the NSF federal funds survey; remainder is from AAAS R&D reports. FY 2014 are estimates, FY 2015 is the President’s request. © 2014 AAAS.
NIH Institutes and Centers (IC)

27 Institutes and Centers (IC)
<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Acronym</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA</td>
<td>National Institute on Alcohol Abuse and Alcoholism</td>
<td>NIAAA</td>
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<tr>
<td>AG</td>
<td>National Institute on Aging</td>
<td>NIA</td>
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<tr>
<td>AI</td>
<td>National Institute of Allergy and Infectious Diseases</td>
<td>NIAID</td>
</tr>
<tr>
<td>AM</td>
<td>National Institute of Arthritis and Musculoskeletal and Skin Diseases</td>
<td>NIAMS</td>
</tr>
<tr>
<td>AT</td>
<td>National Center for Complementary and Alternative Medicine</td>
<td>NCCAM</td>
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<tr>
<td>CA</td>
<td>National Cancer Institute</td>
<td>NCI</td>
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<tr>
<td>DA</td>
<td>National Institute on Drug Abuse</td>
<td>NIDA</td>
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<td>DC</td>
<td>National Institute on Deafness and Other Communicative Disorders</td>
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<tr>
<td>DE</td>
<td>National Institute of Dental and Craniofacial Research</td>
<td>NIDR</td>
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<td>National Institute of Diabetes and Digestive and Kidney Diseases</td>
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<td>National Institute of Environmental Health Sciences</td>
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<td>National Eye Institute</td>
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<td>National Human Genome Research Institute</td>
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<td>NS</td>
<td>National Institute of Neurological Disorders and Stroke</td>
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<td>National Center for Research Resources</td>
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<td>CT</td>
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<td>CIT</td>
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<td>John E Fogarty International Center</td>
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<td>MD</td>
<td>National Institute on Minority Health and Health Disparities</td>
<td>NIMHD</td>
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<td>EB</td>
<td>National Institute of Biomedical Imaging and Bioengineering</td>
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<tr>
<td>TR</td>
<td>National Center for Advancing Translational Sciences</td>
<td>NCATS</td>
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National Institutes of Health Budget, 1998-2015
budget authority in billions of constant FY 2014 dollars

Source: AAAS Report: Research and Development series and agency budget documents. FY 2014 figures are latest estimates, FY 2015 is the President's request. © 2014 AAAS
## Common NIH Support Mechanisms

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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>R</td>
<td>Research Projects</td>
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<tr>
<td>K</td>
<td>Career Development Programs</td>
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<td>R&amp;D-Related Contracts</td>
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<td>Program Projects and Centers</td>
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<td>Training Programs</td>
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<tr>
<td>U</td>
<td>Cooperative Agreements</td>
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</table>

### Grant Number

1 R01 DA 012921 - 04
Prepare a Competitive Proposal

• Get copies of similar proposals from colleagues
• Read and re-read the RFA or program announcement
• Persistence pays -- learn from your critiques
• Reviewing can be a game of comparison between proposals
• Have someone double check your proposal
• Like a college paper, the *appearance* of your proposal can make the difference
• Write to left and right brain reviewers
Research Funding Opportunities: Which ones are right for me?
INDIVIDUAL RESEARCH TRAINING & CAREER DEVELOPMENT

<table>
<thead>
<tr>
<th>Stage of Development</th>
<th>Mechanism of Support</th>
</tr>
</thead>
</table>
| **Senior**           | Senior Scientist Award (K05)  
                        | Academic Career Award (K07)  
                        | Method to Extend Research in Time (MERIT) Award (R37) |
| **Middle**           | Mid-Career Award in POR (K24)  
                        | Independent Scientist Award (K02)  
                        | Exploratory/Developmental Grant (R21) |
| **Early**            | Research Project Grant (R01) |
| **Post Doctoral**    | Small Grant (R03)  
                        | Mentored Career Development Awards (K01, K08, K23, K25) |
| **Graduate Student** | Postdoctoral Training Support (T32, F32, K12, K22, K99/R00)  
                        | American Heart Postdoctoral Fellowship |
|                      | Dissertation Research Grant  
                        | American Heart Pre-doctoral Fellowship |
|                      | Pre-doctoral Individual NRSA (F30, F31)  
                        | Pre-doctoral Training Grant (T32)  
                        | NSF Pre-doctoral Fellowship |
Mentored K Awards: Which One?

- **K01**: Mentored Research Scientist Development Award
- **K08**: Mentored Clinical Scientist Development Award
- **K22**: Research Career Award for Transition to Independence
- **K23**: Mentored Patient-Oriented Research Development Award
- **K25**: Mentored Quantitative Research Development Award
- **K99/R00**: NIH Pathway to Independence (PI) Award
- **K12**: Institutional Mentored Research Scientist Development Program
# R01 vs R03 vs R21

<table>
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<th>R03</th>
<th>R21</th>
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<td><strong>Budget</strong></td>
<td>$250K/yr</td>
<td>$50K/yr</td>
<td>$275K/2 yrs</td>
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<td><strong>Period of Support</strong></td>
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<td>2 yrs</td>
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<td><strong>Participating I/Cs</strong></td>
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<td><strong>Preliminary Data</strong></td>
<td>Required</td>
<td>Not required</td>
<td>Not required, but allowed</td>
</tr>
</tbody>
</table>
| **Characteristics**    | • Long term  
                        • Increased knowledge in well-established area | • Pilot or feasibility studies  
                        • Secondary analysis of existing data  
                        • Small, self-contained project  
                        • Methodology development  
                        • Technology development | • Novel  
                        • Exploratory  
                        • Breaking new ground  
                        • New directions |

R03: [http://grants.nih.gov/grants/guide/contacts/parent_R03.html](http://grants.nih.gov/grants/guide/contacts/parent_R03.html)
FIRST R01s

NEW INVESTIGATOR (NI): A PD/PI who has not previously competed successfully for an NIH-supported research project (excludes R00, R03, R21, R55, and so on).

EARLY STAGE INVESTIGATOR (ESI): New Investigators within 10 years of completing their terminal research degree or within ten years of completing their medical residency.

“… My hope is that institutions will continue to look for ways to reduce the duration of graduate and postdoctoral training and to find new ways to enable new investigators to compete successfully for extramural funding.”

Sally Rockey, PhD, Deputy Director for Extramural Research, NIH
Figure 1. Average Age of Principal Investigators with MD, MD-PhD, or PhD at the time of First R01 Equivalent Award from NIH, Fiscal Years 1980 to 2011

[Graph showing the average age of principal investigators with MD, MD-PhD, or PhD at the time of first R01 equivalent award from NIH, fiscal years 1980 to 2011.]
R01-Equivalent grants, New (Type 1)
Success rates, by career stage of investigator
# PERSISTENCE PAYS OFF

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Research Project Grants</th>
<th>R01s</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Submission No.</td>
<td>Success Rate</td>
</tr>
<tr>
<td>2011</td>
<td>A0</td>
<td>10.1</td>
</tr>
<tr>
<td></td>
<td>A1</td>
<td>36.2</td>
</tr>
<tr>
<td>2012</td>
<td>A0</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td>A1</td>
<td>38.7</td>
</tr>
<tr>
<td>2013</td>
<td>A0</td>
<td>9.3%</td>
</tr>
<tr>
<td></td>
<td>A1</td>
<td>31.5%</td>
</tr>
</tbody>
</table>
New Developments

• NIH Updated Policy for Application Submission: Following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate due date.

• NIH Co-funding for IDeA States: For R01 (and R15) applications, the NIGMS will provide support (up to 75% of total cost not to exceed $280K, 2 years) to applicants whose proposals received excellent ratings through the peer review process but fell short of the I/C’s pay line.
## FOUNDATION GRANTS: MUSC’s TRACK RECORD

<table>
<thead>
<tr>
<th></th>
<th>FY2010</th>
<th>FY2011</th>
<th>FY2012</th>
<th>FY2013</th>
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<td>132</td>
<td>145</td>
<td>183</td>
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<td><strong># of Foundation Entities</strong></td>
<td>73</td>
<td>76</td>
<td>79</td>
<td>91</td>
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<tr>
<td><strong>Total Award Amount</strong></td>
<td>$10,676,888</td>
<td>$10,661,224</td>
<td>$14,161,427</td>
<td>$16,448,287</td>
</tr>
</tbody>
</table>
Department of Defense
Congressionally Directed Medical Research Programs
(http://cdmrp.army.mil/funding/default.shtml)

- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- Duchenne Muscular Dystrophy
- Gulf War Illness
- Lung Cancer
- Multiple Sclerosis
- Neurofibromatosis
- Ovarian Cancer
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Peer Reviewed Orthopaedic
- Prostate Cancer
- Spinal Cord Injury
- Tuberous Sclerosis Complex
OUR CALL TO ACTION…

Take advantage of all possible resources available!

Network, Communicate and Collaborate!
The NIH Public Access Policy

Neil Thakur, Bart Trawick, Katie Funk
June 26, 2014

Website: http://publicaccess.nih.gov

Randal Davis
SCTR Project Director
Most Important Info:

Call SCTR SUCCESS Center and Request an NIH Public Access Consult (Randal and Becca):

Phone: 2-8300
Email: success@musc.edu

**Also, for RPPR – Susan Greene in ORSP

MUSC’s Secret Weapons for NIH Manuscript Submission System: Jennifer Peterson and Becca Barry

MUSC’s Secret Weapon for ALL Journal-related Submission Questions: Teri Lynn Herbert (Library)
Today’s Discussion: The NIH Public Access Policy

1. The Basics
2. Awardee Tasks
3. Enhancing Compliance
4. NIHMS: Processing Manuscripts
5. My NCBI Features: A Primer
6. Compliance Monitoring for Institutions
7. Ways Institutions Can Ensure Compliance
1) The Basics:

- The Policy
- Its Implications
The Policy Applies to Any Manuscript That…

Is peer-reviewed;

Is accepted for publication in a journal on or after April 7, 2008;

And, arises from:

– Any direct funding from an NIH grant or cooperative agreement active in Fiscal Year 2008 or beyond, or;

– Any direct funding from an NIH contract signed on or after April 7, 2008, or;

– Any direct funding from the NIH Intramural Program, or;

– An NIH employee.
**Final Published Article**
- Journal’s authoritative copy of the paper
- Includes peer review modifications plus copyediting and formatting changes
- *Submitted by Publishers/Journals to PMC (Methods A&B)*

**Final Peer-Reviewed Manuscript:**
- Author’s final manuscript of a peer-reviewed paper accepted for journal publication
- Includes all modifications from the peer review process
- *Submitted by Authors and Publishers/Journals to PMC (Methods C&D)*
PubMed vs PubMed Central (PMC)

Free resources developed by the U. S. National Library of Medicine

PubMed.gov

• Biomedical journal citations + abstracts
• Some links to full text articles at PMC and publisher websites.
• Unique identifier: PMID followed by a series of numbers.

VS

PMC

• Digital archive of full-text, peer-reviewed journal papers.
• Unique identifier: PMCID followed by a series of numbers.
Or, another way to think about it:

PubMed.gov VS is analogous to PMC

TV Guide VS PBS

http://publicaccess.nih.gov/
2) Awardee Tasks

• Address Copyright
• Posting Papers
• Documenting Compliance
Institutions and investigators are responsible for ensuring full compliance with the Public Access Policy.

Make sure the copyright transfer agreement allows the final peer-reviewed manuscript to be submitted to NIH.

We encourage authors to consider
- Who will submit the paper and/or approve the submission?
- What version of the paper will be made available on PMC?
- When will it be submitted and when will the paper be made public on PMC?
The 4 ways papers make their way into PMC:

- **Method A**: Publish in a PMC-participating journal.
- **Method B**: Arrange to have a publisher deposit the final published article in PMC.
- **Method C**: Submit the final peer-reviewed manuscript to the NIHMS.
- **Method D**: A publisher begins the submission process for a manuscript via the NIHMS.

**Link to find Method A & B journals and publishers:**
http://publicaccess.nih.gov/submit_process.htm

**NOTE: Method B** - Did you make arrangements with one of the journals or publishers listed below to have the final published version of your paper posted directly to PubMed Central (i.e. pay an open access fee)?
If yes, you are using **Submission Method B**.
If no, submit your paper through the NIHMS. See **Methods C and D Best Practices**
Posting Papers: Methods A and B straight to PMC

A

Journal deposits the published version of all NIH-funded articles in **PMC**.

B

Author arranges for Publisher to deposit published version of specific article in **PMC**.

**Final published article in PMC**
Methods C&D: Manuscript submission to the NIHMS

Who can deposit manuscripts in the NIHMS?
• An Author
• A Delegate: anyone given access to the author's files
• The Publisher

Remember:
Only Authors can approve the submission and web versions of the manuscript. Awardees need an NIHMSID *upon acceptance for publication.*
Methods C&D: Manuscript submission to the NIHMS

1. **Deposit manuscript files** - An NIHMSID is assigned to the submission.

   **C** Author or delegate submits final peer reviewed manuscript to the NIHMS.

   **D** Journal publisher submits final peer reviewed manuscript to the NIHMS.
2. **Author approves PDF receipt**, gives permission to NIH to process the manuscript: **Methods C and D**.

**Author Approval**

C

Author or delegate submits final peer reviewed manuscript to the NIHMS.

D

Journal publisher submits final peer reviewed manuscript to the NIHMS.

NIHMS sends **author** an email asking author to approve the submitted materials for processing.
3. **Author** approves PMC-formatted manuscript for public display: **Methods C and D**.

**Author Approval**

- **Author or other** submits final peer reviewed manuscript to the NIHMS.
- **NIHMS** sends author an email asking author to approve the submitted materials for processing.
- **Author** reviews and approves the PMC-formatted manuscript.

**Manuscript archived in PMC**

*After submission is complete, NIHMS emails the citation with PMCID to author and PIs*
## Posting Papers: Summary

<table>
<thead>
<tr>
<th>Version of Paper Submitted</th>
<th>Final Published Article</th>
<th>Final Peer-Reviewed Manuscript</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission Process</td>
<td>Publisher posts the paper directly to PMC</td>
<td>Papers are <strong>required</strong> to be submitted via the NIHMS <strong>upon acceptance for publication</strong>. The NIHMS converts them to the PMC native format.</td>
</tr>
</tbody>
</table>
| Deposit Files              | • **Method A Journals** post NIH supported papers automatically  
                              • Authors must make special arrangements for **Method B journals and publishers** to post the paper | • Manuscripts must be submitted to the NIHMS **upon acceptance for publication**  
                              • Authors or their designee must submit **Method C** papers to the NIHMS  
                              • **Method D publishers** will submit papers to the NIHMS |
| Approve Submission         | Publisher                | Author, via NIHMS |
| Approve PMC web version    | Publisher                | Author, via NIHMS |
| Responsible Party          | NIH awardee              | NIH awardee |
| To cite papers, from acceptance for publication to 3 months post publication | PMCID or “PMC Journal- In Process” | PMCID or NIHMSID |
| To cite papers, 3 months post publication and beyond | PMCID | PMCID |
How to cite papers in press (epub ahead of print), or within 3 months of publication...

For Method A and B Journals, use “PMC Journal - In Process”.

For Method C and D Journals, use the NIHMSID.

**NIHMSIDs will not be accepted 3 months after publication.**
- PMCIDs are assigned around the time of publication.
- Use the PMCID once it is assigned.
How to cite papers archived in PMC

– When citing a paper in NIH applications, proposals, and progress reports, include the PMCID at the end of the full citation.
– Applies to papers that fall under the Policy and are authored or co-authored by you.

Example

3) Enhancing compliance

- Scope
- My NCBI, RPPR and PHS 2590
(NOT-OD-12-160) For non-competing continuation with a start date of July 1, 2013 and beyond

- Awards will be placed on hold until grantees have demonstrated compliance
- My NCBI is required to report papers, when electronically submitting progress reports using the Research Performance Progress Report (RPPR)
- PDF reports generated from My NCBI are required, when submitting paper progress reports using the form PHS 2590 (replaces publication section)
**Trigger:** When a grantee submits a RPPR to NIH that associates 1 or more publications with the award for which the public access compliance status is “Noncompliant”.

**Recipients:** to the PD/PI, with a cc to the AO, SO, GMS, IC mailbox, and PO.

**Response:** The grantee may respond to the eNotification via email or through the Progress Report Additional Materials (PRAM) link.
Example: PRAM for Public Access

Progress Report Additional Materials

Public Access Compliance

<table>
<thead>
<tr>
<th>Grant Number:</th>
<th>5K23HD123456-03</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD/PI Name:</td>
<td>JEFFERSON, THOMAS</td>
</tr>
<tr>
<td>Project Title:</td>
<td>A New Model for the Delivery of Well-Child Care</td>
</tr>
<tr>
<td>PRAM submitted on:</td>
<td>10/04/2012 01:19 PM</td>
</tr>
</tbody>
</table>

This is a sample of text entered in response to noncompliant publications submitted as part of the RPPR...
4) NIH Manuscript Submission System: Processing manuscripts
Each Login route has its own NIHMS account
Submitters must continue to use the same login method for subsequent visits to NIHMS.
Submit + author approval

Document conversion

author approves web version

Load to PubMed Central
Method C
Author or delegate deposits manuscript files in NIHMS
Which articles?
Manuscripts that meet the criteria of the NIH Public Access Policy
When?
At the time the paper is accepted for publication
Author responsibility?
Deposit files
Associate funding
Approve deposit
Review & approve PMC web version

Method D
Publisher deposits manuscript files in NIHMS
Which articles?
Manuscripts that meet the criteria of the NIH Public Access Policy
When?
At the time the paper is accepted for publication
Author responsibility?
Notify publisher of NIH support
Associate funding
Approve deposit
Review & approve PMC web version
Manuscript files submitted to NIHMS

Manuscript tagged in XML

Manuscript in available in PMC (after embargo)
Three Steps for Authors in NIHMS

1. **Submitter deposits files**
2. **Author approves submission**
3. **QA of submitted materials**
4. **Taggers convert files to XML**
5. **NIHMS generates standard format documents**
6. **QA of XML/HTML/PDF versions**
7. **Author reviews PMC web version**
8. **Approved documents are sent to PMC (once final citation information available)**

**Conversion Process**

- Notification sent to assigned reviewing author
- Notification sent to assigned reviewing author
Submitter Deposits Files

**NIH Manuscript Submission System**

**Review and Approve Submission**

This PDF Receipt is a concatenated document of all the files (excluding supplementary files) that you have uploaded. (Details)

**PDF Receipt**

- By checking this box I certify that this manuscript submission includes all referred supplemental materials.
- What if the PDF Receipt has not generated properly or I need to change the files?

<table>
<thead>
<tr>
<th>Grants/project (Grantee)</th>
<th>Grant/project #</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iona Grant</td>
<td>123581321</td>
<td>Progressive grant</td>
</tr>
<tr>
<td></td>
<td>8675-309</td>
<td>80s music study</td>
</tr>
</tbody>
</table>

**Choose reviewer**

Please designate a reviewer for the submission. The reviewer must be an author of the manuscript. The reviewer will be responsible for approving the PMC-ready web version of this manuscript (the 2nd and final approval). If the reviewer’s name is not already present as a choice, you may provide contact information for this individual in the last row.

- Select
  - Me (Iva Manuscript)
  - Iona Grant
- First Name
- Last Name
- Email

**Release delay**

Release to PubMed Central 12 months after publication in the journal.

Go to Manuscript List

Prev: Summary Approve

The National Institutes of Health Manuscript Submission (NIHMS) system is a service of NCBI.

Help & F.A.Q. Contact Us Privacy notice Disclaimer Accessibility
Review of NIHMS submission statement

Submission Statement

**Manuscript Title:** Introduction to the Special Issu on Social and Motivational Processes in After-School Settings: Bridging Gaps Between Theory, Research and Practice

**Accepted for Publication in:** The Journal of early adolescence

I am an author of this manuscript, and I am providing it to the National Institutes of Health (NIH) to make publicly available in PubMed Central immediately after its official date of publication in the journal.

I confirm that:

**Publication and Copyright Agreements** — In any agreements that I have made with the journal, I have retained the right to deposit this version of the manuscript with PMC, so that it may be appropriately tagged and made available to the public on the PMC web site; or, I otherwise am legally authorized to deposit this manuscript for the purposes described.

**Confidentiality** — The manuscript may contain confidential information that must not be publicly disclosed prior to publication of the paper in the named journal.

**Peer Review** — The version I am depositing has been peer reviewed and accepted for publication and includes all modifications resulting from the peer review process.

**Funding** — The manuscript is the result of research supported, in whole or in part, by direct costs funded by NIH.

Return to PDF review  Change Release Date
Review and Approve Web Version of Manuscript

Please review the PubMed Central-formatted version of your manuscript.

This is the final step in the manuscript submission process.

What should I do?

Review

<table>
<thead>
<tr>
<th>Grants</th>
<th>Grant #</th>
<th>Title</th>
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<tr>
<td></td>
<td>R01 CA118953</td>
<td>Improving Outcomes Assessment in Chronic Graft versus Host Disease</td>
</tr>
<tr>
<td></td>
<td>U54 CA163438</td>
<td>Immune Mediated Disorders After Allogeneic Hematopoietic Cell Transplants (HCT)</td>
</tr>
</tbody>
</table>

history

Go to Manuscript List

Request Corrections

Approve
5) My NCBI: a Primer
My NCBI is a free account system that provides customized services for many NCBI databases, such as PubMed.

**Key features for our discussion:**

- Can be linked to eRA Commons accounts
- Commons-linked users can associate publications with NIH grants
- Tracks NIH Public Access compliance
- The only way to enter publications into RPPR
- Creates the publications section (Section E) of PHS 2590s
Signing in to My NCBI

Results: 1 to 20 of 404989

1. Dietary carotenoid-rich pequi oil reduces plasma lipid peroxidation and DNA damage in runners and evidence for an association with MnSOD genetic variant -Val9Ala.
   Miranda-Vilela AL, Akimoto AK, Alves PC, Pereira LC, Gonçalves CA, Klautau-Guimarães MN, Grisolia CK.
   PMID: 20082261 [PubMed - as supplied by publisher]

2. Predictors of 3-Year Mortality in Subjects over 95 Years of Age. The NonaSantfeliu Study.
   Formiga F, Ferrer A, Montero A, Chivite D, Pujol R.
   PMID: 20082056 [PubMed - as supplied by publisher]
Signing in to My NCBI

Sign in to NCBI

Sign in with

Google

NIH Login

See more 3rd party sign in options

Sign in directly to NCBI

NIH funded investigator?

Extramural NIH-funded investigators looking for NIH Public Access Compliance tools should sign in using the "NIH Login" button. Use your eRA Commons credentials on the subsequent sign in page. Once signed in, navigate to the My Bibliography section.

Documentation for using these features is located in the Managing Compliance to the NIH Public Access Policy section of the NCBI Help Manual.


Account Troubleshooting FAQ

Expired email confirmation link message
Multiple My NCBI accounts
Link eRA Commons, University, or other account to your NCBI account
Adding PubMed Citations

1. Predicting microRNA modulation in human prostate IDentifier (SID1.0).
   Albertini MC, Olivieri F, Lazzarini R, Pilolli F, Galli F, Marzoli MR, Procopio AD.
   PMID: 21334455 [PubMed - as supplied by publisher]
   Related citations

   Leung BM, Wiens KP, Kaplan BJ.
   BMC Pregnancy Childbirth. 2011 Feb 3;11:12.
   Free full text Related citations
Adding PubMed Citations

   Related citations

   Related citations

   Related citations

   Related citations

Related PubMed Citations

- Pediatric Voice Analysis: Comparison of 2 Computerized [JAMA Otolaryngol Head Neck Surg...]
- When students from different professions are co-located: the importance [J Interprof Care, 2014]
- An Exploration of Substance Abuse Course Offerings for Students in Curr [Subst Abus, 2014]
- Advances in lupus genetics and epigenetics. [Curr Opin Rheumatol, 2014]

Updated weekly

Award View option for eRA-linked users

My NCBI » My Bibliography

This bibliography is public (make it private) | Edit settings for My Bibliography | Save My Bibliography

Display Settings: Award view, Sort by public access compliance, group by citation type

View
- List
- Print
- Award
- PMID List

Sort by
- Date (new to old)
- Author (A to Z)
- Title (A to Z)
- Public Access Compliance
- Reverse

Grouping
- None
- By citation type
- Award

Funding: No funding has been associated with this citation. Add award

http://publicaccess.nih.gov/
Public access status codes

• **Working Through the Myriad Issues with Yellow and Red Dot Pubs**
  - The My NCBI instructions do not provide detailed solutions for all of the non-compliant issues that you will encounter

• **Missing Publications**
  - If using filters in “My Bibliography,” ensure that you select ALL NIH grant numbers including those grant numbers that include the project year (-01, -02, etc)
  - When searching PubMed, make sure you search using wildcards before and after your grant number (%UL1TR000062%)
  - Conduct a manual cross check between a PubMed search and the publications listed in My Bibliography (we ran searches with our grant numbers and our reportable investigators names)
• **Working with Yellow and Red Citations**
  
  - Add funding to those citations that are missing the grant award (ex: some citations that are indexed in PubMed and show the grant number but which haven’t been entered into NIHMS will not always show the grant number in My Bibliography)….click “Add or Delete Award” beneath the affected pub on the My Bibliography screen and choose your CTSA award from the list
  
  - Contact the NIHMS Help Desk to remove a grant association for those publications that appear in My Bibliography but are listed in journals that are not peer reviewed
  
  - To discern where a yellow status publication has stalled….click on the NIHMS link beneath the citation on the My Bibliography screen. **NOTE:** citations that are Epub ahead of print are still “in press” and are not considered published until they are actually printed in the respective journal and receive page numbers and volumes..contact your Program Officer before reporting on your APR
PI adds a new citation to their My Bibliography

Journal Articles


Public Access Compliance: Edit Status
NIH Funding: No funding has been associated with this citation.
Add award

Did the NIH support this citation, in whole or in part?

- Yes
- No

The NIH Public Access Policy requires scientists to submit final, peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. (See Determine Applicability for full details.) Please submit the final manuscript sent to your publisher or indicate that this publication is exempt from the policy.

We do not have a record of this citation in NIH Manuscript Submission system (NIHMS). Please choose from the following:

- Begin submission in the NIHMS.
- This citation has been submitted. NIHMS ID: [enter ID]
- Arrangements have been made for a publisher on this list to send the final article directly to PubMed Central. (Method B)
- This citation does not need to be submitted under NIH Public Access because:
  - Publication was not peer reviewed.
  - Publication was accepted for publication before April 7, 2008.
  - Publication was written in a script other than Latin (e.g., Russian, Japanese).
  - Publication was not directly supported by NIH funds active in FY08 or beyond.

Save & Close
PI adds a new citation to their My Bibliography

Journal Articles


Public Access Compliance: Edit Status

NIH Funding: No funding has been associated with this citation.

Add award

Assign Awards

Use the checkboxes to assign awards to the selected citations:

My awards:
- R01 EB006062 - Metal-Enhanced Fluorescence Sensing
- R01 EB006521 - Plasmon-Controlled Fluorescence and Cardiac Markers
- R01 HG002555 - Metallic Surfaces and Particles in DNA Analysis
- R13 RR017508 - CFS Course on Fluorescence Spectroscopy
- R21 EB009861 - Biohazard Detection Using Metal-Enhanced Fluorescence
- R21 HG005090 - DNA Sequencing Using Intrinsically Bound Fluorescence
- RC1 GM091081 - Sub-Wavelength Imaging of Intracellular Metal Ions

Other awards:
- R01 GM038060 - Sequencing the Polysaccharide Component of Proteoglycans
- R21 EB00509 - Measurement of CCR5 and CCL3L1 on Single Cell by Fluorescent Metal Nanoparticle
- R25 CA180078 - Training Program in Pediatric Cancer Epidemiology and Control
- U01 DK082505 - Right Lobe Living Donor Liver Transplantation in Adults
- UL1 RR25755 - CTSA INFRASTRUCTURE FOR AIDS RESEARCH

Save Cancel
Compliance management with My NCBI

- My Bibliography
- eRA
- PubMed
- NIHMS
- PMC

- Manuscript files in any format
- Progress reports (RPPR, etc)
- Full text XML + Final article PDF

http://publicaccess.nih.gov/
NIH Manuscript Submission System Status: Available

1 Publications

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award? ☐ Yes ☐ No

If yes, select from the table below to affiliate publications with this progress report.

If you need to login to your NCBI account please use this link: My NCBI

Display on RPPR
## Publications Reported for this Reporting Period

<table>
<thead>
<tr>
<th>NIH Public Access Compliance</th>
<th>Citation</th>
</tr>
</thead>
</table>
How My NCBI Reduces PI Workload

• **Automated and Collaborative Methods to Track Publications**
  – Import citations directly from PubMed
  – Automated matches of manuscript citations to PubMed records
  – NIHMS paper-grant suggestions
  – Recommendations from other authors
  – Paper-grant associations by other PI authors

• **Year round management**

• **Live Public Access compliance status for every record**

• **Delegation**
Appendices
Resources

About the Public Access Policy:
- For Sponsored Programs: [http://publicaccess.nih.gov/sponsored.htm](http://publicaccess.nih.gov/sponsored.htm)
- Training materials for PIs and other communications: [http://publicaccess.nih.gov/communications.htm](http://publicaccess.nih.gov/communications.htm)
- **Questions**: [PublicAccess@NIH.GOV](mailto:PublicAccess@NIH.GOV)

The NIH Manuscript Submission System:

PubMed Central:
- Information for Publishers: [http://www.pubmedcentral.nih.gov/about/pubinfo.html](http://www.pubmedcentral.nih.gov/about/pubinfo.html)
• NIH Guide Notice NOT-OD-08-033

• NIH Guide Notice NOT-OD-09-071 announces the policy is permanent, per the Consolidated Appropriations Act, 2009
REDCap – An Overview

Joint K Orientation
July 11, 2014

Stephanie Oppenheimer
SUCCESS Center
What is REDCap?

- Online, secure electronic data capture system
- Thousands of projects and end-users @ MUSC
- Worldwide consortium
How can REDCap support your study?

- Supported resource
- Security features
- Suited for multi-site studies
- Supports data collection format and surveys
- Data exchange options
Creating a project

https://redcap.musc.edu  [no ‘www’]

Log in with netid and password

Click “Create New Project”
Creating a project

Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title:

Purpose of this project:
(How will it be used?)

Start project from scratch or begin with a template?

Choose a project template:

<table>
<thead>
<tr>
<th>Template title</th>
<th>Template description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Demography</td>
<td>Contains a single data collection instrument to capture basic demographic information.</td>
</tr>
<tr>
<td>Classic Database</td>
<td>Contains six data entry forms, including forms for demography and baseline data, three monthly data forms, and concludes with a completion data form.</td>
</tr>
<tr>
<td>Human Cancer Tissue Biobank</td>
<td>Contains five data entry forms for collecting and tracking information for cancer tissue.</td>
</tr>
<tr>
<td>Longitudinal Database (1 arm)</td>
<td>Contains nine data entry forms (beginning with a demographics form) for collecting data longitudinally over eight different events.</td>
</tr>
<tr>
<td>Longitudinal Database (2 arms)</td>
<td>Contains nine data entry forms (beginning with a demographics form) for collecting data on two different arms (Drug A and Drug B) with each arm containing eight different events.</td>
</tr>
</tbody>
</table>

Create Project  Cancel
Building a data collection form

Medical University of South Carolina
SCTR - Office of Biomedical Informatics Services

Main project settings
- Use longitudinal data collection with repeating forms?
- Use surveys in this project?

Design your data collection instruments & enable your surveys
Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method), in which you may use either method or both. You may then enable your instruments to be used as surveys in the Online Designer.

Quick links: Download PDF of all data collection instruments OR Download the current Data Dictionary

Go to Online Designer
Building a data collection form

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. **NOTE:** While in development status, all field changes will take effect immediately in real time.

<table>
<thead>
<tr>
<th>Data Collection Instruments</th>
<th>Survey options:</th>
<th>Add new instrument:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument name</td>
<td>Fields</td>
<td>View PDF</td>
</tr>
<tr>
<td>My First instrument</td>
<td>14</td>
<td>Enable</td>
</tr>
<tr>
<td>My Second instrument</td>
<td>0</td>
<td>Rename, Delete</td>
</tr>
</tbody>
</table>

**VIDEO:** How to use this page
Building a data collection form

Current instrument: **My First Instrument**

**Variable: record_id**

**Record ID**

NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.

**Variable: is_flavor_yn**

Do you have a favorite flavor of ice cream?

**Variable: is_flavor_choice_all**

Which of the following do you consider a favorite flavor?

- Chocolate
- Pistachio
- Strawberry
- Vanilla
- Other

CHECK ALL THAT APPLY

**Matrix group: favors**

Do you consider any of the following a favorite flavor of ice cream?

- Variable: once
- Chocolate
- Yes
- No

- Variable: pistachio
- Pistachio

- Variable: straw
- Strawberry

- Variable: van
- Vanilla
Building a data collection form

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the Field Types video (4 min).

Field Type: Checkboxes (Multiple Answers)

Field Label

Which of the following do you consider a favorite flavor?

Choices (one choice per line)

1. Chocolate
2. Pistachio
3. Strawberry
4. Vanilla
99. Other

Variable Name (utilized during data export)

ic_fav_choice_all

Required?* □ No □ Yes
* Prompt if field is blank

Identifier? □ No □ Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment

Right / Vertical (RV)

Field Note (optional)

CHECK ALL THAT APPLY
Small reminder text displayed underneath field

How do I manually code the choices?

Looking for Branching Logic? Try clicking the icon for this field after clicking the Save or Cancel button below.

Save  Cancel
**Building a data collection form**

---

**Do you have a favorite flavor of ice cream?**

- Yes
- No

**The following questions demonstrate both the single field and the matrix field type.**

**Which of the following do you consider a favorite flavor?**

- Chocolate
- Pistachio
- Strawberry
- Vanilla
- Other

**Do you consider any of the following a favorite flavor of ice cream?**

<table>
<thead>
<tr>
<th>Flavor</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chocolate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pistachio</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strawberry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vanilla</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other favorite flavor</td>
<td>Mint chocolate chip</td>
<td></td>
</tr>
</tbody>
</table>

**How many times a week do you eat ice cream?**

- 3

**Total intake of ice cream**

- 156 times per year

**Email**

- oppenhei@musc.edu
Selecting modules

Main project settings
- Use longitudinal data collection with repeating forms?

Design your data collection instruments & enable your surveys
- Add or edit fields on your data collection instruments (survey and forms).
- Quick links: Download PDF of all data collection instruments or Download the current Data Dictionary
- Go to Online Designer or Data Dictionary
- REDCap Shared Library
- Check For Identifiers to ensure all identifier fields have been tagged.

Define your events and designate instruments for them
- Create events for re-using data collection instruments and/or set up scheduling.
- Go to Define My Events or Designate Instruments for My Events
Selecting modules

Since you have defined multiple events on the Define My Events page, you may now select which data collection modules you wish to utilize for each event by using the table below. This allows you to enter data on any data collection instrument for any given project record. Any and all data collection instruments can thus be used for any event defined.

Click the **Begin Editing** button to change the relationships below by designating which forms you wish to use. When you are finished making changes, click the **Save** button to finalize your changes.

<table>
<thead>
<tr>
<th>Data Collection Instrument</th>
<th>Event 1</th>
<th>Event 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>My First Instrument</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>My Second Instrument</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
Selecting modules
Selecting modules

Manage Survey Participants

Public Survey Link  Participant List  Survey Invitation Log

The Participant List option allows you to send a customized email to anyone in your list and track who responds to your survey. It is also possible to identify an individual's survey answers, if desired, by providing an identifier for each participant (this feature must first be enabled by clicking the 'Enable' button in the table below). More details

Participant List belonging to "My Second Instrument" - Event 1

Displaying 1 - 2 of 2  Add participants  Compose Survey Invitations  Export list

<table>
<thead>
<tr>
<th>Email</th>
<th>Participant Identifier</th>
<th>Link</th>
<th>Invitation Scheduled?</th>
<th>Invitation Sent?</th>
<th>Responded?</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:123@abc.com">123@abc.com</a> (ID 2)</td>
<td>Disabled</td>
<td>☑</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><a href="mailto:oppenhei@musc.edu">oppenhei@musc.edu</a> (ID 1)</td>
<td>Disabled</td>
<td>☑</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Adding a user to a project

### Basic Rights
- **Expiration Date** (if applicable)
- **Project Design and Setup**
- **Manage Survey Participants**
- **Calender**
- **Data Export Tool**
- **Data Import Tool**
- **Data Comparison Tool**
- **Logging**
- **File Repository**
- **User Rights**
- **Data Access Groups**
- **Graphical Data View & Stats**
- **Data Quality**
  - [What is Data Quality?](#)
- **API**
  - [What is the REDCap API?](#)
- **Reports & Report Builder**

### Data Entry Rights
NOTE: The data entry rights "only" pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.

<table>
<thead>
<tr>
<th>Access</th>
<th>Read</th>
<th>View</th>
<th>Edit survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>My First Instrument</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>My Second Instrument (survey)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### New User Notification
- [Notify user of their project access via email?](#)
Collecting data

Are you sure you wish to leave the DEVELOPMENT stage? If you proceed, the project will be moved to PRODUCTION status so that real data may be collected. By leaving the checkbox checked below, all current collected data, calendar events, and uploaded documents will be deleted, otherwise all will remain untouched as the project is moved to production.

Have you checked the Check For Identifiers page to ensure all identifier fields have been tagged?

- Delete ALL data, calendar events, documents uploaded for records/responses, and (if applicable) survey responses?

Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will then need to be approved by a REDCap administrator before taking effect.

YES, Move to Production Status  Cancel
Making sense of the data
Making sense of the data

Which of the following do you consider a favorite flavor?:
- Refresh Plot

<table>
<thead>
<tr>
<th>Total (N)</th>
<th>Missing</th>
<th>Unique</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 (60.0%)</td>
<td>1</td>
</tr>
</tbody>
</table>

Missing values: 2
Counts/frequency: Chocolate (1, 100.0%), Pistachio (0, 0.0%), Strawberry (0, 0.0%), Vanilla (1, 100.0%), Other (1, 100.0%)
Making sense of the data

Report Builder
You may use this page to build and save custom reports, which will query the project in real time and display the resulting data in a table format. Once created, you may view your reports at any time as well as modify or even delete them. Your saved reports will be displayed on the right-hand menu as links, which can be clicked to display the report.

Edit Existing Report
You may edit an existing report by changing any of the fields below or by selecting new fields/variables that you want to include in the report. You may add as many new fields to your report as you wish. When you have completed making the changes, click the Save Changes button at the bottom.

<table>
<thead>
<tr>
<th>Name of Report:</th>
<th>Chocolate Ice Cream Lovers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field Name / Label</td>
<td>Limiters (optional)</td>
</tr>
<tr>
<td>Field 1</td>
<td>record_id (Record ID)</td>
</tr>
<tr>
<td>Field 2</td>
<td>icecrm_fav_yr (Do you have a favorite...)</td>
</tr>
<tr>
<td>Field 3</td>
<td>ic_fav_choice_all (Which of the follo...)</td>
</tr>
<tr>
<td>Field 4</td>
<td></td>
</tr>
<tr>
<td>Order the Results (optional)</td>
<td></td>
</tr>
<tr>
<td>First by</td>
<td>choc (Chocolate)</td>
</tr>
<tr>
<td>Then by</td>
<td></td>
</tr>
</tbody>
</table>
Best Practices

- include all stakeholders in development
- start from the end
- include a statistician from the beginning
- be consistent with your IRB approval
- be selective with user rights
- use surveys for direct participant entry
Best Practices

- test your *entire* project before moving it to production
  - Does the format facilitate easy data entry/export?
  - Can you create the reports you need?
  - Do the branched and calculated fields work?
  - Have you set up surveys properly?
- move your project to Production for extra security when ready to collect project data
Need REDCap assistance?

- for those roadblocks or how-to questions that come up as you build your project
  redcap@musc.edu – Ask a question

- for one-on-one assistance with your project
  https://sparc.musc.edu – SPARC Request Consult
  [located under the SCTR Services provider button]
Questions ?
South Carolina Clinical & Translational Research (SCTR) Institute

- Established in 2006 in response to the NIH Clinical & Translational Science Award Program
- The largest NIH initiative of the last decade
- Provides integrated resources to advance interdisciplinary, translational, innovative research
- “Advance the health of the nation by transforming patient observations and basic discovery into clinical practice”
SCTR’s mission is to facilitate clinical and translational research by providing research support services, research training and improving access to research-related resources.

CTSA Clinical & Translational Science Awards

The Clinical and Translational Science Awards (CTSA) is a registered trademark of DHHS.
The “Front Door” to SCTR services
SCTR SUCCESS Center Free Consultations

- Research Navigation
- Regulatory Consultations & Training
- Participant Recruitment
- Grants, Contracts & Budget
- Community Engagement
- Biomedical Informatics
- Biostatistics
- Clinical Research Ethics
- Novel Technologies & Mobile Apps
- Comparative Effectiveness (PCOR)
- Drug & Device Development
- Intellectual Property, Records of Invention & Patents
- Center for Innovation & Entrepreneurship - Faculty Startups, Commercial Market Analysis
- NIH Public Access Policy

Intake or Online Request Form
SUCCESS Center Consultations

- **Research Navigation**
- **Regulatory Knowledge and Support**
  - Hands on training and consultation
  - State-wide eIRB project management
- **Participant Recruitment**
  - Strategies, planning & partnerships
  - Budget
  - Materials
- **Grants & Budget Development**
- **SPARC Request Hands on Training**
Community Engagement

- Collaboration
- Research design
- Communication and dissemination
- Social/cultural advisors
- Community site training

4th Cohort of the Community-Engaged Scholars Program, 2013
• Provide methodological expertise to translational researchers
• Stimulate methodological development in the areas of study design and biostatistics
• Examples of requests
  – Sample size / power estimation
  – Analyses of preliminary data for a grant
  – Development of analysis plans
  – Assistance with manuscript preparation
  – Grant review
  – Survey design
  – 1 on 1 didactic teaching
SCTR Training, Education, and Career Home (TEACH)

- Society for Clinical Research & Translational Early Scientists (SOCRATES)
- Tools for Mentors & Mentees
- Core Clinical Research Training
- Master of Science in Clinical Research (MSCR)

TL1 trainees at Mayo Clinic
For more information visit sctr.musc.edu
Clinical Data Warehouse (CDW)

- **MUSC electronic clinical data**
  - OACIS and Epic clinical data repository
  - Patient demographics, ICD-coded diagnoses, CPT-coded procedures, and laboratory test results

- **CDW Data request committee**
  - Review the clinical data needs of your research project
  - Provide advice on requesting IRB approval to obtain clinical data from the CDW
  - Discuss options for clinical data abstraction, reporting and storage to meet your research needs
• https://sctr.musc.edu/index.php/research-tools/redcap
• Secure, web-based data capture application for research studies
• Intuitive interface for data entry (with data validation)
• Audit trails for tracking data manipulation
• Automated export for data downloads to common statistical packages
• Other features include:
  – branching logic
  – calculated fields
  – data de-identification
  – survey capabilities
• Free consultations to guide you in database/survey development
SC research.org is the South Carolina Research Studies Directory designed specifically to help people, like you, locate research studies in which to participate. If you or someone you know is interested in being a volunteer, search this website to find out more information.

Not finding the type of study you're looking for? Try the national research matching participant website researchmatch.org

Search Studies:
(example Cancer, Smith)

GO

Browse by Institutions
Browse all Keywords
Browse all Researchers

Investigator Access

SC research.org
South Carolina Research Studies Directory

SCTR
SCTR Clinical & Translational Science Awards
Translating Discoveries to Medical Practice

CTSA
Clinical & Translational Science Awards

Health Sciences South Carolina
- 500+ Volunteers in SC
- 3 Active promotion campaigns
- 27 Researchers at SCTR
  - 7 Recruitment
  - 20 Feasibility
- 8 Active studies
- 5,312 Volunteers contacted
- 1,245 ‘Yes’ respondents
Push Study Calendar into EHR
Funding Opportunities

- Pilot Projects
- Community Engaged Scholars
- Research Nexus Translational Awards
- Vouchers
- External Research Funding Opportunities
- TL1 Awards
- KL2 Awards
SCTR Research Nexus Fee Based Research Support

- Research Opportunities & Collaborations
- Research Coordination and Management
- Research Laboratory and Biorepository
- Research Center
- Body Composition and Pulmonary Function Testing
- Clinical Nursing and Nutrition

Patrick A. Flume and Royce Sampson at the 2013 SCTR Research Nexus Open House
Research Opportunities & Collaborations

- Identify industry-funded clinical trials
- Sponsor and Contract Research Organization (CRO) outreach
- Pair trial opportunities with MUSC Investigators
- Assistance navigating the site selection process

Research Opportunities & Collaborations program manager, Signe Denmark, and Quintiles Site Relationship Manager, Kelsey Morgan.
Contact Signe at 843.792.4146 or denmarks@musc.edu
Research Coordination and Management

- Trained and experienced research and nurse coordinators
- Services include:
  - Study coordination
  - Project coordination
  - Regulatory management
  - Data management
  - Recruitment
  - Budget development
  - Study record and drug storage
  - Quality assurance reviews
- Available for full, partial, or gap support
- Inpatient, outpatient, and outlying clinics

Senior research coordinators, Cullen McWhite and Laura Fields, working in the SCTR Research Nexus with a study patient.
Research Laboratory and Biorepository

- **Laboratory**
  - Processes biological specimens
  - Packaging and shipping to Central Laboratories
  - Nucleic acid extraction
  - ELISA protocols
  - Develop/customize protocols

- **Biorepository**
  - Process/store biological specimens collected under IRB-approved protocols
  - Retrieval for IRB-approved studies
  - Plasma, DNA, urine
Research Center

8 examination rooms and 3 procedure rooms

Dental suite

Pulmonary Function Testing (PFT) suite

Body composition suite with BodPod and Hologic Discovery A Dexscan
Clinical Nursing and Nutrition

- Clinical Nursing services include:
  - Conduct study protocol procedures
  - Secure specimens
  - Administer medication
  - Gather critical data at bedside
  - SOC nursing support, as needed

- Nutrition services include:
  - Collect and assess macro and micro nutrient intake
  - Provide nutrition education in individual or group sessions
  - Coordinate nutrient specific meals and/or snacks
SCTR Research Nexus Standard of Care (SOC) Services

- Provider based clinic for the Medical University Hospital Authority
- Ability to bill 3rd party payers (insurance companies) for SOC services provided during research visits
- Increased satisfaction for participants, investigators and research teams
- High quality continuum of care provided in one location
Contact the SCTR Research Nexus

SCTR Research Nexus
MUSC Clinical Sciences Building, Suite 214
843-792-8300
academicdepartments.musc.edu/sctr/nexus

Request services via sparc.musc.edu
Keep In Touch

• **SCTR Weekly Research e-newsletter:**
  – Each week receive a calendar of events, announcements & notes regarding research happenings at MUSC & beyond.

• **Monthly Research Lunch-N-Learn**
  – 3rd Wednesday of Month, 12pm-1pm, special presentations are sponsored to offer training, information & discussion.

• **More Ways to Stay Connected:**

/sctrinstitute
/photos/sctrinstitute/
/sctrinstitute
/sctrinstitute
SUCCESS Center
SCTR RESEARCH CONSULTATIONS

843-792-8300
success@musc.edu
sctr.musc.edu