to improve the lives of patients, their families and communities through meaningful programs of research
TABLE OF CONTENTS

1. Office of Research Affairs
   - Overview
   - NIH Funding Growth Chart

2. ORA Services and Contacts
   - Details of Services
   - Contact List - Faculty and Staff

3. DUSON Clinical Research Unit Charter

4. Submission Trajectory and Forms for External Funding
   - Trajectory – Concept of Proposal Development
   - Sample Proposal Development Timeline
   - Notice of Intent to Submit
   - Statistical Collaboration and Consultation Request

5. Mandatory Compliance Training for Researchers
   - Investigator Training: Human Subjects Requirements
   - Staff Training: Human Subjects Requirements
   - Investigator Training: Research Cost and Compliance

   - CITI Access
   - NIH eRA Commons Account Information

7. Effort Tracking and Reporting

8. Research Conference - Round Tables - Brown Bags Series

9. Research Administration Terminology

10. Helpful Resources
    - Duke Office of Clinical Research - Website Screen Print
    - Duke Office of Clinical Research: Mission
    - RedCap (Research Electronic Data Capture)
    - Institutional Review Board – Website Screen Print
    - eIRB System – Website Screen Print

1/29/2014
OFFICE OF RESEARCH AFFAIRS

OVERVIEW

LEADERSHIP

Diane Holditch-Davis, PhD, RN, FAAN
Associate Dean of Research Affairs
Marcus Hobbs Distinguished Professor of Nursing

MISSION

We are dedicated to providing the resources needed to support knowledge and discovery that furthers the science of nursing.

FUNCTIONS AND SERVICES

Office of Research Affairs Customers
- Faculty
- Postdoctoral Fellows
- Doctoral and Doctor of Nursing Practice Students
- Duke University Health System Practicing Nurses

Institutional Review Board Membership
ORA coordinates the School of Nursing representation on two of the eleven DUMC Institutional Review Boards with a School of Nursing faculty member serving as chair on a third.

ORA Small Grant Award Program
- Pilot work or other research essential to qualify for large-scale external funding to DUSON
- Research with a health disparities and/or a global health focus
- Short-term bridge funding for established studies submitting for competing continuation or other forms of additional funding
- New investigators launching their research through pilot work

Services
- Proposal writing through preparation of statistical data
- Editorial review
- Budget development
- Submission of external grant funding
- Formatting and communication with
  - Institutional Review Board (IRB)
  - Institutional Animal Care and Use Committee (IACUC)
  - Institutional Office of Research Administration
  - Institutional Duke Office of Clinical Research
  - Institutional Office of Corporate and Research Collaborations (OCRC)
- Research Costing Compliance
- Contract help for data collection and data management through the Research Management Team
- Duke Clinical Research Unit research processes

Staffing
The office is fully staffed with Research Administrators and IRB Specialists. Statistical and Editorial support is available to provide valuable consultation as needed. Please contact us for further information regarding how we can support your research needs.

Questions? Please contact Robbin Thomas, Director, Research Administration, 919-684-3101 or Phyllis Kennel, Director, Clinical and Research Practice, 919-668-5244.
ORA SERVICES

Scientific Consultation
Scientific consultations are offered primarily in the developmental stages of grant preparation. Research mentoring is available for faculty developing a research program or pursuing other scholarly activity. Research Mentor Consultation is available with Dr. Diane Holditch-Davis, Dr. Ruth Anderson, or Dr. Marilyn Hockenberry. To schedule a meeting, please contact the ORA Staff Assistant.

Services and Resources
The Director of Research Administration and Director of Clinical and Research Practice provide support to the Associate Dean for Research Affairs in management of services and resources.

Funding Opportunities
Funding opportunities that are likely to be specific to DUSON interests are posted in the School’s Monday Update. This publication is currently distributed by email to all DUSON faculty and staff. Duke faculty and staff also have free access rights to the Community of Science database in which individuals can set up a customized and ongoing funding search. If you have questions regarding funding announcements or establishing a Community of Science account, please contact the Associate Director for Pre-Award Research Administration.

Grant Submissions
Pre-Award services include assistance with interpretation of funding guidelines, budget development, application submission, system navigation, and response to Just-in-Time requests. Services for agency-sponsored grants and contracts are provided by the Pre-Award Research Administrators. Pre-Award services for ORA-sponsored small grants are provided by the ORA Staff Assistant.

Award Management
Post-Award services include award set-up, financial reporting, projection forecasting, compliance reviews, re-budgeting, effort change requests, non-competing renewal applications, no cost extensions, and agency prior approval requests. Services for agency-sponsored grants and contracts are provided by the Post-Award Grants Management Specialists. Post-award management of ORA-sponsored small grants is provided by the Staff Assistant.

Study Implementation - Clinical and Research - IRB, Human Subjects Protection, Data Security
IRB services include support in navigation of the eIRB system, new study protocols, amendments, renewals, final reports, internal reminders, individual investigator agreements, and understanding exempt/expedited/full board IRB reviews. These services are provided by the Director, Clinical and Research Practice.

Statistical Collaboration and Consultation
ORA-supported statistical services are provided to faculty and staff by the ORA Statistical Team. Services provided include consultation for funded project data analysis, collaboration during grant submission preparation, and unfunded project data analysis (contingent on space available). Principal investigators are encouraged to maintain statistical services during the life of a funded project. As a research team member, the statistician role is defined by the PI. A project that directly funds a statistician is given priority by that Statistical Team Member. Please contact the Director, Research Administration to schedule use of these services.

Editorial Services – Grant Writing Assistance
Investigators are encouraged to use the content expertise and editorial services of Elizabeth Tornquist, PhD, for grant proposals via prior approval from the Associate Dean for Research. Please contact the Director, Research Administration to schedule use of this service.

Editorial Services – Manuscript, Poster, Table, Model, Formatting Assistance
Investigators are encouraged to use the editorial services of Elizabeth (Betsy) Flint, PhD, or Judith Hayes, PhD, via prior approval through the Associate Deans for Academic Affairs and Research Affairs. Please contact the Research Development Coordinator to schedule use of this service.

Duke Office of Clinical Research – Database Creation, Data Collection, Data Management, Project Management
The Duke Office of Clinical Research (DOCR) helps investigators and project managers create a data management plan that takes into account the variables needed to measure project outcomes and work with the research team to implement the work plan. DOCR data managers are skilled in designing relational databases and implementing them in Microsoft Access and REDCap for research or administrative purposes. They can provide a budget estimate for research staffing to principal investigators. This provides a resources to investigators in the School of Nursing who wish to utilize existing personnel resources rather than hiring personnel on their own or working with outside vendors. School of Nursing use of these services is coordinated by the Director, Clinical and Research Practice.

1/29/14
Contact List

Leadership and Management
Associate Dean for Research Affairs
Diane Holditch-Davis, PhD, RN, FAAN
(919) 684-8862
diane.hd@duke.edu
To schedule an appointment with Dr. Holditch-Davis, please contact Leslie Fife, 919-684-5376, or submit a request by email to nursingresearch@mc.duke.edu.

Director, Research Administration
Robbin Thomas
(919) 684-3101
robbin.thomas@duke.edu

Director, Clinical and Research Practice
Phyllis Kennel, MS, RD, LDN
(919) 668-5244
phyllis.kennel@duke.edu

Research Development Coordinators
Ruth Anderson, PhD, MSN, MA, RN, FAAN
(919) 668-4599
ruth.anderson@duke.edu

Marilyn J. Hockenberry, PhD, RN, PNP-BC, FAAN
(919) 684-9330
marilyn.hockenberry@duke.edu

Sharron Docherty, PhD, PNP-BC, FAAN
(919) 668-3836
sharron.docherty@duke.edu

Administrative Support
Staff Assistant
Leslie Fife
(919) 684-5376
leslie.fife@duke.edu

Study Implementation - Clinical and Research
Assistant Research Practice Manager
Nancy Hassell
(919) 668-3256
nancy.hassell@duke.edu

Grant Submissions and Awards - Research Administration
Associate Director, Pre-Award
Jane Halpin, CRA
(919) 684-0348
jane.halpin@duke.edu

Research Administrator, Post-Award
Samuel Morgan
(919) 668-0915
samuel.morgan@duke.edu

Research Administrator, Pre-Award
Julie Yamagiwa
(919) 668-3259
julie.yamagiwa@duke.edu

Research Administrator, Post-Award
Mindy Kempson
(919) 613-4783
mindy.kempson@duke.edu

Statistical Collaboration and Consultation
Janet Levy, PhD
(919) 684-9641
janet.levy@duke.edu

Wei Pan, PhD
(919) 684-9324
wei.pan@duke.edu

Susan Silva, PhD
(919) 681-3004
susann.silva@duke.edu

John Boling, MA
(919) 684-0399
john.boling@duke.edu

Rick Sloane, MA
(919) 660-7515
sloane@geri.duke.edu

Please contact Robbin Thomas at robbin.thomas@duke.edu to request Statistical Collaboration/Consultation. The request form can be found at https://dusonnet.nursing.duke.edu/research-tools/
Clinical Research Unit Charter  
Duke University School of Nursing

Date: 08/30/2013

CRU Director Signature: [Signature]
Unit Head Signature: [Signature]

1. **Scope of Research within the CRU:**
The vast majority of clinical and behavioral research in the School of Nursing CRU resides within the School. Research involving DUHS Nursing will be included in this CRU. The vast majority of externally funded studies are funded by NIH and other federal sources.

2. **Key Personnel:**
   - Director - Diane Holditch-Davis, PhD, RN, FAAN
   - CRU Manager – Research Practices Phyllis Kannel, MS, RD, LDN
   - CRU Manager – Financial Practices Robbin Thomas

3. **Define Clusters & Leadership within Clusters:**

   See last page for organizational chart. While there are areas of expertise in the School of Nursing there is no unit or cluster division.

4. **Clinical Research Unit Research Advisory Committee**

   **Composition:**
   Members of the CRU Research Advisory Committee (RAC) are appointed for two-year terms by the Associate Dean for Research Affairs. The RAC consists of at least five faculty members, students and DUHS nursing representatives. The RAC meets at least four times annually.

   **Function:**
   The committee has developed the following system for overseeing the scientific quality of all active protocols in DUSON. Whenever a new protocol, or a renewal of an existing protocol, is submitted to the IRB through DUSON, the Director of the CRU or designee will review the protocol to make certain that new studies submitted by investigators in the School of Nursing have sufficient scientific merit, an appropriate budget, and adequate resources, including appropriate patients, for the study to be conducted. In addition, when IRB renewals are submitted, the principal investigator will also attest to the fact that satisfactory progress has been made on the project over the past year. The
Clinical Research Unit Charter
Duke University School of Nursing

Director of the CRU will also monitor the success of submitted proposals and seek to assist junior investigators in submitting revisions.

If any questions arise as to the merits or feasibility of a proposed study, the Director of the CRU will consult the Research Advisory Committee to determine if the study should move forward. The Research Advisory Committee will meet at least four times a year to review DUSON’s active research portfolio, develop CRU SOPs and policies, and oversee the activities of all CRU staff as well as the academic productivity of the investigators in DUSON. The Research Advisory Committee with the assistance of the CRU Director and Office of Research Affairs (ORA) staff will also serve as a resource for gathering information about current Federal grant policies and priorities and disseminating this information to the faculty as a whole. ORA staff will be responsible for assisting with this dissemination.

5. CRU Governance and Financial Plan:

The Director of the CRU, who is also the Associate Dean for Research for the School of Nursing, will work with Robbin Thomas, Manager – Financial Practices of the CRU and ORA, and Phyllis Kennel, Manager – Research Practices of the CRU, to assure that PIs are actively involved in the financial aspects of their studies. The CRU Research Advisory Committee will review all CRU activities and advise the Director on their implementation. PIs are expected to review the financial status of their studies on a monthly basis and to work with the CRU’s Manager of Financial Practices and grant specialists to manage the finances of their grants. The Manager of Financial Practices is responsible for updating the School of Nursing’s Associate Dean for Finance and Administration on the status of research funding and the impact of research funding on the finances of the School. The CRU reports directly to the Dean of the School of Nursing, Catherine Gilliss.

The Office of Research Affairs of the School of Nursing provides the funding for the CRU. The School of Nursing CRU acknowledges that there will be additional costs required of the CRU for clinical research efforts within the School. These financial needs may require adjustment in CRU funding in the future.
Clinical Research Unit Charter
Duke University School of Nursing

6. CRU Stakeholders:

Stakeholders include the School of Nursing, its faculty and trainees, and public and private organizations that fund clinical research studies performed at the Duke School of Nursing.

7. Communication Plan:

DUSON will send out research information notifications regarding changes in regulatory requirements, institutional standards and CRU policies for research whenever such changes occur. In addition, the Director of the CRU, the Manager of Research Practices and the Manager of Financial Practices will hold monthly DUSON meetings during which time this information can be discussed.

8. Organization Chart:

SON Clinical Research Unit Structure

[Diagram showing the structure with titles such as Dean, School of Nursing, Executive Vice Dean, Associate Dean for Finance and Administration, Associate Dean for Research Administration/CRU Medical Director, Research Advisory Committee, Principal Investigator, CRU Manager Financial Practices, CRU Manager Research Practices, Grant and Contract Administrators, Assistant Research Practice Manager/QI, Clinical Research Coordinators and other Research Staff]
Research Interest/Program of Research
ORA provides support for Investigators to have a consultative research interest and scientific concept meeting with the Associate Dean for Research or an ORA Faculty Research Development Coordinator to assist in moving programs of research forward. Funding mechanisms, resources, and opportunities for collaboration will be discussed. It is recommended that this step take place in advance of the 16 weeks submission trajectory. Please contact the ORA Staff Assistant to schedule this consultation.

16 Weeks Prior to Agency Deadline
Submit Intent to Submit Form to ORA Statistical Consultation (Required)
Notify ORA of the "Intent to Submit" by submitting the Intent to Submit form to the Director of Research Administration. The form is located on the DUSONnet at https://dusonnet.nursing.duke.edu/research-tools/

Request for Statistical Consultation/Collaboration (Optional)
Statistical Consultation/Collaboration is provided by School of Nursing faculty and staff Statisticians through the ORA resources. To schedule a statistical consultation or to establish collaboration related to a new grant proposal, please submit the Statistical Consultation/Collaboration request form to the Director of Research Administration. The form is located on the DUSONnet at https://dusonnet.nursing.duke.edu/research-tools/

Think Tank Meeting (Optional)
The Think Tank Meeting provides a venue for peers to further the development of the proposal. In order to achieve the best results, it is recommended that the Think Tank Meeting be scheduled 16 weeks in advance of submission and well in advance of the Mock Review. Please contact the ORA Staff Assistant to schedule this meeting.

12-14 Weeks Prior to Agency Deadline
Proposal Development Meeting (Required)
It is recommended that a development meeting be scheduled to include, the Investigator, the Associate Dean, ORA Directors for Research Administration and Clinical and Research Practice, Statistician, and Pre-Award Research Administrator assigned to the proposal submission to discuss the planned proposal. The purpose of this meeting is to determine the staffing and non-personnel resources needed to complete the proposed study. The ORA Staff Assistant will coordinate the schedule for the Proposal Development Meeting.
Office of Research Affairs (ORA) Submission Timeline

16 weeks prior to the agency submission deadline

Start the IRB Process

Begin the IRB protocol in the Duke eIRB system. The initial action will issue a protocol number in ‘presubmission’ status for reference in the grant proposal and allow completion over a period of time. For assistance with regulatory and eIRB system questions, please contact the Director of Clinical and Research Practice with questions. The eIRB is located at https://eirb.mc.duke.edu/eirb/

6-8 Weeks Prior to Agency Deadline

Draft Budget Development (Required)

The Investigator will work closely with the assigned Pre-Award Research Administrator to draft a proposal budget. The Research Administrator will confirm the sponsor’s budget guidelines for allowable cost. Salaries, fringe benefit and indirect costs rates will be calculated by the Research Administrator. The Investigator will obtain quotes for services, equipment, consultants and collaborators that will included as direct cost in the budget.

Early Editorial Review (Optional)

In addition to a final editorial review, an early editorial review can be scheduled upon request and approval by the Associate Dean. Appointments for editorial review can be arranged through the ORA Staff Assistant.

4-6 Weeks Prior to Agency Deadline

Mock Review of final draft/Proposal Revisions (Required for Competing Proposals)

The Mock Review provides a venue for peers to act as reviewers for the proposal. These peers are to offer productive recommendations in response to a near final proposal. In order to achieve the best results, it is recommended that the Mock Review be scheduled 6–8 weeks in advance of submission. The ORA Staff Assistant will coordinate the schedule for the Mock Review.

Institutional Review - Internal Proposal Requirements (Required)

The work on the administrative requirements within the Duke Sponsored Projects System is to occur 4-6 weeks prior to the submission date. These components commonly include the abstract/statement of work, finalized budget, Duke Proposal Approval Form, sub and site agreements, and other relevant requirements based on funding source. The documents will accompany the proposal record as they route for internal approval within Duke. The Investigator will work closely with the Pre-Award Research Administrator to complete the requirement for Institutional review.

Final Editorial Review (Recommended for Competing Proposals)

The editorial review is to be schedule for the final draft of the proposal. Further editorial needs will be determined by the Associate Dean. Appointments for editorial review can be arranged through the ORA Staff Assistant.

3 Weeks Prior to Agency Deadline

Submit Final Documents – Institutional Approval (Required)

Administrative components must be completed 3 weeks prior to the agency due date for the School and Institutional Offices to review, approve, and release for submission. Administrative components include the abstract/statement of work, budget, budget justification, biographical sketches, resources and environment, and any other documents required by the agency. The Pre-Award Administrator assigned to the proposal will facilitate the School and Institutional approval process.

It is always advised that submissions be completed 1–2 weeks prior to the agency due date in order to assure completion, accuracy, and prompt delivery.

Electronic and paper submissions should be transmitted 3 days in advance of the agency deadline to allow for system errors and document delivery. Agency exceptions are rare. A late submission will be rejected.

3/28/14
<table>
<thead>
<tr>
<th>Activity</th>
<th>Target Dates (prior to deadline)</th>
<th>Planned Dates</th>
<th>Date Completed</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Interest/Scientific Consultation with Associate Dean for</td>
<td>18 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Affairs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUBMIT Intent to Submit (ORA form) and forward copy of PR/RFA to ORA</td>
<td>16 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTACT Team Members and Consultants to secure commitments - Think Tank</td>
<td>16 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEETING (optional)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SUBMIT Statistical Consultation/Collaboration Request (ORA form) for ORA</td>
<td>16 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>supported statistical assistance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proposal Development MEETING with Assoc. Dean, Stats, ORA, IRB/QI</td>
<td>14 -12 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>START IRB Protocol</td>
<td>14 -12 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRAFT PROPOSAL Submitted to ORA at least one week prior to</td>
<td>9 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mock Review</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proposal REVISIONS</td>
<td>8-6 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop DRAFT BUDGET with ORA</td>
<td>8-6 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mock Review Meeting Peer review of final draft</td>
<td>6-8 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WORK with ORA to complete internal requirements</td>
<td>6-4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(DPAF, abstract, budget and justification, resources and Biosketches)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PREPARE Final Proposal and submit for Editorial Review</td>
<td>5-4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obtain SUBCONTRACT/CONSULTANT documents if applicable</td>
<td>5-4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FINALIZE BUDGET with ORA</td>
<td>5-4 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INTERNAL DOCUMENTS DEADLINE for completion of internal (SPS) required</td>
<td>3 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>documents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TARGET Deadline for Institutional Approval</td>
<td>1 week</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FINAL Deadline for Electronic Submission</td>
<td>3 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPONSOR DEADLINE for Submission</td>
<td></td>
<td></td>
<td></td>
<td>Forward copy of submitted proposal to ORA</td>
</tr>
</tbody>
</table>
NOTICE OF INTENT TO SUBMIT
Office of Research Affairs
Duke University School of Nursing and Duke University Hospital Nursing Research
Upon completion, submit to Robbin Thomas (robbin.thomas@dm.duke.edu)

Investigator's Name:

Date:

**Funding Source**

**Funding Agency Name:**
For subcontracts, please list the University/Agency who will issue the subcontract to Duke

**Proposal Type:**  ___ New Submission  ___ Resubmission  ___ Other

**Agency Due Date:**
For subcontracts, please list the date that the parent applicant will need Duke’s documentation. Please add an explanation if using a date other than the agency due date (i.e. will be out of town and need to submit early)
Explanation if applicable:

**Proposed Project Dates:** Start/End
Review Agency instructions to confirm that the proposed dates are within the Agency’s earliest possible start date

**Funding Mechanism/Program:**
Program Identification Number (agency Request for Application number – PA or FOA)

Funding Guidelines/Instructions (website)

Faculty Mentor Name(s) (NRSA/Training/Career Development Award mentored programs)

Partnership(s) (Individuals/Universities/Agencies who you will invite for subaward or consultant agreements)

Has the concept been discussed with the Agency Program Officer?  Yes/No

**Protocol, Data, and Material Information**

**Human Subject Research?**  Yes/No
Information: All projects involving human subject recruitment or use of existing data will require the submission and approval of an IRB before the project begins [https://eirb.mc.duke.edu](https://eirb.mc.duke.edu)

**Data or Material Transfer?**  Yes/No
Information: All projects involving the exchange of data or material to or from Duke will require a Data or Material Transfer agreement before the project begins [http://www.duke.edu/web/ost/](http://www.duke.edu/web/ost/)

**Vertebrate Animals Research?**  Yes/No
Information: All projects involving the use of vertebrate animals will require the submission and approval of the IACUC before the project begins [http://vetmed.duhs.duke.edu/IACUC.html](http://vetmed.duhs.duke.edu/IACUC.html)

(continued on the following page)
NOTICE OF INTENT TO SUBMIT

Draft Abstract/Statement of Work

Proposal Title:

Brief description of work:
Please provide below or as an attachment – the agency’s format for abstract or statement of work can be used if desired

PASTE OR TYPE TEXT HERE
STATISTICAL CONSULTATION REQUEST

Office of Research Affairs
Duke University School of Nursing
Upon completion, submit to Robbin Thomas (robbin.thomas@dm.duke.edu)

Requestor’s Name: Date: Email:

Type of Request

Consultation Category  INDICATE ONE
On-Going Assistance with a previously initialized project
Planning Assistance with the preparation of a new protocol or grant application
Implementation Assistance with implementing or initiating of a new project

Funding Status  SELECT ONE
Funded Grant Award, Discretionary Funding, Small Grant, Other
Not Funded Expired Grant Award, Pilot Work, Pre-submission of Grant

Support Level  SELECT ONE
Minimal Minimal involvement with a limited number of brief meetings
Moderate Moderate to engaged involvement to collaboration with the Investigator

Statistician Level  SELECT ONE
Masters Staff Statistician
PhD Prepared Faculty Statistician

Associated Deadlines  INDICATE ALL THAT APPLY
IRB Submission Yes/No Date:
Grant Submission Yes/No Date:
Abstract Submission Yes/No Date:
Presentation Deadline Yes/No Date:
Other Yes/No Date:

NOTE
It is recommended that data management or less complex analyses be done by a data manager or research assistant to encourage the proper use and workflow among the School’s personnel resources.

(continued on the following page)
# STATISTICAL CONSULTATION REQUEST

## Research Question

**TYPE OR PASTE TEXT HERE**

## Brief Description of Statistical Request

**TYPE OR PASTE TEXT HERE**

## Outcome Measures

**Primary Outcome Measure**

**TYPE OR PASTE TEXT HERE**

**Secondary Outcome Measure**

**TYPE OR PASTE TEXT HERE**

1/29/14
INVESTIGATOR TRAINING
MANDATORY COMPLIANCE TRAINING
HUMAN SUBJECTS REQUIREMENTS

Human Subjects Research at Duke

This two-hour overview course covers the different types of human subjects research, outlines study team responsibilities, and describes the regulatory environment overseeing human subjects research at Duke. While this course is a good starting point if you are new to Duke or new to clinical research, registration for the course is open to all members of the Duke clinical research community.

- All faculty listed as Key Personnel must complete the 2-hour in-person classroom review on Human Subjects Protection, OR, complete the review requirement through the on-line module. This review is presented by DOCR and must be completed within 90 days of hire or change to research responsibilities in job role. All faculty have the option of completing the on-line.
- Within 30 days of completion of classroom training (or online training for faculty), a 25-question qualifying assessment must be completed with a passing score of 80% or better.
- All Key Personnel will complete an online module and qualifying assessment annually thereafter.

**Human Subjects Research Website** for registration - [http://docr.som.duke.edu/education/register-trainings](http://docr.som.duke.edu/education/register-trainings)

Date Completed: ________________  Next Action Required: ________________

Investigator Responsibilities

This course, a requirement for PIs, outlines basic information that PIs will need for their work in human subjects research at Duke, including the roles of each administrative office, information about avoiding research misconduct, reporting requirements, the study approval process, principles of confidentiality and privacy, and regulatory requirements for good clinical practice.

**Investigator Responsibilities Website** - [http://docr.som.duke.edu/education/register-trainings](http://docr.som.duke.edu/education/register-trainings).

Enrollment is limited to Duke Staff. The training session is free. Registration is required.

Date Completed: ________________  Next Action Required: ________________

Additional courses may be required based on other roles and responsibilities within a research project. For other available courses offered by Duke Office of Clinical Research, please view either of the above links.
Human Subjects Research at Duke

This two-hour overview course covers the different types of human subjects research, outlines study team responsibilities, and describes the regulatory environment overseeing human subjects research at Duke. While this course is a good starting point if you are new to Duke or new to clinical research, registration for the course is open to all members of the Duke clinical research community.

- All staff listed as Key Personnel must attend a 2-hour classroom overview of Human Subjects Research Protection through the DOCR within 90 days of hire or change to research responsibilities in job role.
- Within 30 days of completion of classroom training (or online training for faculty), a 25-question qualifying assessment must be completed with a passing score of 80% or better.
- All Key Personnel will complete an online module and qualifying assessment annually thereafter.

Human Subjects Research Website for registration - http://docr.som.duke.edu/education/register-trainings

Date Completed: ________________  Next Action Required: ________________

Additional Research Training

Additional Trainings may be required based on the job responsibilities of the research staff. Below are the trainings offered as of 10/3/2012. For registration - http://docr.som.duke.edu/education/register-trainings

Informed Consent
This course outlines the importance of the informed consent process in the protection of human subjects and identifies key regulatory elements that need to be in place during the consent process.

Research Data Integrity/Data Security
This course presents the basic principles of data management and how these principles contribute to data security. The course also addresses key concerns in data security and how to manage these issues.

IRB Overview
This course offers an overview of the DUHS IRB review process, utilization of the eIRB system, the process for submitting new study submissions, amendments, renewals, and deviations, and information on multi-site reporting.

Study Documentation: Regulations and Best Practices
This course outlines the required components of study documentation for all clinical research, defines standard documentation terminology, and applies knowledge of documentation best practices to everyday scenarios faced by study teams.

Research Wednesdays: For more information on hot topics within the research community, policy updates and changes, and new roll-outs and initiatives, employees are encouraged to attend the Research Wednesdays series, held the 2nd and 4th Wednesday of each month. Topics and instructors vary, as the DOCR and the Medical Center Library partner to bring in subject matter experts to share their knowledge.
INVESTIGATOR TRAINING
MANDATORY COMPLIANCE TRAINING
RESEARCH COSTING AND COMPLIANCE (RCC)

Research Cost and Compliance (RCC) Training is required annually of all PIs involved with sponsored research to safeguard financial compliance on how sponsored funds are allocated and managed at Duke University.

IMPORTANT: An award received on a PI's pending sponsored project may NOT be activated until the PI has completed the RCC Training. Upon RCC Training completion, RCC will update SPS which will allow ORA to activate the award.

Accessing the Training Module

To access this web-based training module, go to:

1. Instructions and study material: http://finance.duke.edu/research/training/index.php?crs=307&trn=26
3. Who do I call if I have questions about this requirement? Contact: Julie Cole, Director Research Costing Compliance, 919-681-5850, julie.cole@duke.edu

Date Completed: ________________

Why is this training mandatory?

Duke University is dedicated to the advancement of compliant sponsored research.

In Fiscal Year 2003, Sponsored Projects expenditures at Duke University were approximately $561 million. Federal expenditures for that year were approximately $352 million (63% of the total sponsored projects expense) and have doubled over the last 10 years. They now account for one quarter of the University’s revenue.

As a top recipient of federal research funding in the nation, our commitment to research must be matched with our commitment to being responsible custodians of these funds. We have addressed this responsibility, in part, by instituting strong education programs to meet the needs of different audiences.

PI Education is web-based and designed to meet the demands of Duke faculty engaged in research.

The Business Manager Education includes 4 hours of case study discussions and the Grant/Financial Administrator Training includes an 8 hour lecture on Roles and Responsibilities and University compliance procedures.

A Certification program has been development for Grant/Financial Administrators who work closely with PI's. The purpose of the certification program is to provide Grant/Financial Administrators with a body of knowledge so that they are well trained to manage the PI funds.
CITI RESEARCH ETHICS TRAINING

Collaborative Institutional Training Initiative (CITI)
www.citiprogram.org

Opening/Accessing a Duke Medicine-affiliated CITI account

2. Beside New Users, click on Register Here. (Note: If you already have a CITI username and password, you will need to log in, click on "Affiliate with another institution" on the Main Menu, and follow the instructions below.)
3. From the Participating Institutions drop-down list, select Duke Medicine. Do NOT select "Duke University - Non-medical Research."
4. Scroll down and complete the rest of the page with your personal information and click on Submit. Items with an asterisk are required fields.
5. Complete the next page with your personal information and click on Submit.
6. On the next page, answer 'Yes' to the question "Do you conduct research with human subjects?".
7. On the next page, answer whether or not you conduct research involving children.
8. On the next page, answer whether or not you would like to take the OPTIONAL GCP Course.
9. On the next page, answer whether or not you are an IRB Administrator or an IRB member.
10. On the next page, choose whether or not you would like to affiliate with an additional institution (other than Duke Medicine).
11. This should bring you to the Main Menu page (unless you've chosen to affiliate with an additional institution).
12. Where My Courses are listed on your Main Menu page, the Biomedical Research – Basic/Refresher, Basic Course should be the course listed initially (in addition to other courses such as Research with Children, CITI GCP, or IRB Administrator courses if these courses apply to you).
13. Click the red link (Enter or Re-Enter) beneath Status to the right of Biomedical Research – Basic/Refresher to begin/continue the course.
14. Please complete "The Integrity Assurance Statement" and click on Submit. This will allow you to start taking the courses.
15. Complete the required modules and associated quizzes. You must achieve a score of 80% or higher on all quizzes in order to complete your training. If you want to improve a score on a quiz, you may repeat any quiz. You do not have to complete all modules at one sitting – you can return and finish them at a later date.

The following are the required Bio-medical modules:

1) Basic Institutional Review Board (IRB) regulations and Review Process
2) Informed Consent
3) Vulnerable Subjects - Overview
4) FDA-Regulated Research
5) Vulnerable Subjects - Research Involving Prisoners
6) Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses and Neonates
7) Research and HIPAA Privacy Protections
8) Conflict of Interest in Research Involving Human Subjects
16. To complete any additional courses (such as Research with Children, CITI GCP, or IRB Administrator courses if these apply to you), return to your Main Menu and click the red Enter link next to your course in the My Courses section.

17. **Optional Modules** will be available to you on the Main Menu once you have completed all required modules. The page within Optional Modules lists all courses you can take.

### Printing Course Completion Report

**For verification of completion, you may print and/or download your completion report:**

1. From the Main Menu, under Completion Reports, click on the Print link.
2. Click on Print Completion Report for the course you wish to print.
3. You may also download the completion report by selecting to print to Adobe Pdf.

### Affiliations

**To Remove Affiliation from an Institution:**

If you have selected the wrong institution and have not completed any modules, you can immediately remove that affiliation from your Main Menu. Click on "Remove my Affiliation" and click on "Submit".

**To Add/Change an Institution:**

If you have mistakenly chosen the wrong institution, click on "Affiliate with another institution" on the Main Menu. Follow the prompts and answer all questions with an asterisk.

Date Completed: ________________
NIH eRA COMMONS ACCOUNT INFORMATION

eRA Commons Account Requirement

An eRA Commons account is required to apply for any NIH funding. It is necessary for the account to be in place prior to the start of submission preparation and Pre-Award activities.

eRA Commons Website
https://commons.era.nih.gov/commons/

Creating a New Profile or Affiliation - 8 weeks prior to electronic submission of grant in Grants.Gov

1. ORA staff will do this for you.
2. You will receive an email from the eRA system indicating that an account has been set up. You will be given instructions on how to set up your password and to complete your profile.
Switching Institutions?

Forget Password?

Stick with your existing eRA Commons account!

If you are moving from one institution to another, you do not need to establish a new Electronic Research Administration (eRA) Commons account. Principal Investigators (PIs) should maintain a single Commons account throughout their career. You can simply affiliate your new institution with your existing Commons account.

Likewise, if you have forgotten your password, do not create a new Commons account. There are a few ways to retrieve your account information.

1.) Reset the password yourself at the below link, making sure to follow required password structure very closely.
   [http://era.nih.gov/commons/steps_commons.cfm#step1](http://era.nih.gov/commons/steps_commons.cfm#step1)
2.) Contact your institutional official (i.e. Signing Official or Administrative Official) and have them reset your password. This person is generally in your grants office.
3.) If you have trouble getting a hold of your institutional official, contact the eRA Help Desk for assistance.
   commons@od.nih.gov or [http://era.nih.gov/help/](http://era.nih.gov/help/)

Duplicate Commons profiles can be a headache for applicants and reviewers as well as the NIH. There is currently an effort under way at NIH to collapse duplicate profiles. Maintaining one eRA Commons account throughout your career is not only beneficial to you as a user but also helps the NIH ensure accurate data and reporting.

Advantages of one eRA Commons account:

- A PI’s grant record history will be kept together instead of being split across two or more accounts.
- A reviewer’s service on study sections will be recorded properly and will be accounted for in determining eligibility for continuous submission ([http://grants.nih.gov/grants/peer/continuous_submission.htm](http://grants.nih.gov/grants/peer/continuous_submission.htm)).
- Records maintained by NIH will be more accurate.
- With one account, an applicant’s degree information is in one place and is more likely to be reviewed in consideration for Early Stage Investigator eligibility.

What you can do:

- Request the Signing Official at your new university/organization to use your existing eRA Commons account and affiliate that account with your new university/organization. See the steps for the SO to affiliate the PI via ([http://era.nih.gov/commons/steps_commons.cfm#step3](http://era.nih.gov/commons/steps_commons.cfm#step3)).
- If you realize you have more than one Commons account, contact the eRA Help Desk with a request to merge the accounts into one.
- Keep your Personal Profile in eRA Commons updated. This includes the address fields and the end dates of your employment (for example, employment dates are critical for identifying conflict of interest issues when serving as a reviewer).
The Federal Government requires that the distribution of effort on federal funds must be documented. These regulations require the University to document effort and salary that is either directly or indirectly supported by federally funded projects annually. Effort reporting at Duke University uses two options to meet these requirements. The option for each employee is determined by their payroll status. Monthly or Exempt employees use the ECRT system. Bi-Weekly or Non-Exempt workers certify through their timecard reporting.

The two effort reporting options are as follows:

- **ECRT** - Used for all monthly paid faculty and staff members. Employees are prompted to review their effort distribution on a quarterly basis. This serves as a means to identify errors for correction in a timely manner. Employees will then be prompted at the end of each fiscal year to certify their annual effort. For further information see GAP 200.170 Effort Reporting.

- **Personnel Activity Reporting** - Used for all bi-weekly paid employees. The employee time card is the certification of effort and distribution. For further information see GAP 101.5 Time Reports, GAP 200.170 Effort Reporting.
RESEARCH SEMINAR SERIES

The Research Seminar Series began in 2006 under the leadership of Elizabeth C. Clipp to encourage faculty and staff to present their research to the Duke Nursing community. It is sponsored by the Duke University School of Nursing, Office of Research Affairs and NINR Center of Excellence: Adaptive Leadership for Cognitive/Affective Symptom Science (ADAPT Center).

Presentations are to highlight the quality and rigor of research projects within the Duke Nursing community. Typically individuals do not present more than once in an academic year. In cases of an unanticipated presentation opportunity from guests or faculty, you may contact the Associate Dean for Research to inquire about inclusion in the series.

This series has a distinct focus on Nursing Research and is usually held the second Tuesday, noon-1pmeach month.

Schedule to be announced.

ROUND TABLE AND BROWN BAG DISCUSSIONS

The Office of Research Affairs offers round table and brown bag discussion to explore topics of compliance.

The discussions are usually held noon-1pm and are announced to students and faculty by email and posted in the School’s Monday Update.
**RESEARCH ADMINISTRATION TERMINOLOGY**

**WBSE**
In order to maintain separate accountability for each sponsored project, a minimum of one account number is issued to each sponsored project. An account number is called a Work Breakdown Structure Element (WBSE) in SAP. The WBSE of a sponsored project is located in the Project System under company 0010 (Duke University) in SAP. Sponsored project WBSE begin with the number 2 or 3 and consists of 7 digits.

**Clinical Trials Pharma/NIH**
Clinical Trials are an organized medical study of a new or existing drug, medical device or biological treatment on human subjects, for the purpose of identifying the potential beneficial effect on treating human illness and/or determining safety and efficacy. In order for a grant or contract to be considered a Clinical Trial, the following aspects must all be true:
- Testing a device, drug, or biological compound on human subjects
- Has a protocol reviewed and approved by the Institutional Review Board (IRB).
- Focuses on clinical pharmacological, pharmacokinetic and/or other pharmaco-dynamic effects, and/or seeks to identify the agent’s safety and efficacy.

**Contract Pharma**
An agreement between the University and another entity to provide an economic benefit for compensation paid. The agreement is binding and creates a quid pro quo relationship between the University and the entity. The Sponsor may require an accounting of the use of funds and/or a specific deliverable(s).

**Cooperative Agreement**
The Federal Grant and Cooperative Agreement Act of 1977 defines the cooperative agreement as an alternative assistance instrument to be used in lieu of a grant whenever substantial Federal involvement with the recipient is anticipated. The difference between grants and cooperative agreements is the degree of Federal programmatic involvement rather than the type of administrative requirements imposed.

**Cost Sharing**
That portion of total project costs not borne by the Federal government. GAP 200.140, Cost Sharing on Sponsored Programs provides additional information.

- **Cost Sharing – Mandatory**
  The portion of the University’s contribution to a sponsored project, which is required by the terms of the project. It must be included or a proposal will receive no consideration by the sponsor.

- **Cost Sharing – Voluntary**
  Resources offered by Duke in sponsored project proposals, which are not a specific sponsor requirement.

- **Cost Sharing – Voluntary Committed**
  Resources that are committed and budgeted for in a sponsored agreement. Salary amounts in excess of the NIH salary cap are considered voluntary committed cost sharing. The fringe benefits associated with that portion of the salary amount in excess of the NIH salary cap are also considered voluntary committed cost sharing.

- **Cost Sharing – Voluntary Uncommitted**
  Expenses that are over and above that which is committed and budgeted. This effort is included in annual effort certification, but not identified with a specific project. An example of voluntary uncommitted non-effort cost sharing is expenses that are incurred above the awarded amount. This overdraft or over-expenditure is then absorbed by the University.

**Effort Certification**
We document the distribution of effort and salary that faculty and employees expend either directly or indirectly in support of federally funded projects. GAP 200.170, Effort Reporting provides additional information. The two Effort Reporting systems used at Duke are as follows:

- **ECERT** - Used for all monthly paid faculty and staff members.
- **Personnel Activity Reporting** - used for all bi-weekly paid employees. Employee time card is the certification of effort and distribution.
Facilities & Administrative (F&A) costs
F&A costs are "costs that are incurred for common or joint objectives and, therefore, cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity." Examples include: salaries wages and fringe benefits for clerical and administrative positions not allowable as direct costs, memberships, subscriptions, library books, periodicals, office supplies, equipment, janitorial services, photocopying charges (for general business use), postage, repair & maintenance, sanitation services, local telephone service, utilities, etc. GAP 200.330, Facilities and Administrative (Indirect) Costs on Sponsored Projects provides specific guidelines regarding F&A costs.

Gift
An unconditional contribution received by the University for either unrestricted or restricted use in general operations for which the University has made no commitment of resources or services, other than possible agreement to the designation of the use of the gift by the donor. The contribution is a nonreciprocal transfer; therefore, the University has no obligation to report results to the donor, or to provide them with a financial accounting of the usage. For assistance with making the determination of Gift versus Grant please contact the ORA Grants Management Team.

Grant
Non-specific grants
Those received by the University in support of specific programs or projects, but did not result from a specific grant proposal. No specific resources or services are committed and no accounting for the use of the funds is required.
Specific grants
Those received by the University resulting from approved grant proposals for specific programs and projects. The University commits resources or services as a condition of the grant. The grantor will likely require an accounting of the use of funds and reporting of results.

Post-Award
Post-Award covers the financial and administrative activities required after a program or project has been awarded. The Office of Research Affairs Post-Award Administrator will be your primary contact for these issues. They will facilitate the hands-on financial and administrative activities throughout the life of the project. The Office of Sponsored Programs (OSP) is the institutional office responsible for post-award administration of the University’s sponsored projects. OSP’s responsibilities include preparing and submitting financial and other non-scientific reports to Sponsors on sponsored projects, monitoring for compliance with Sponsor and Duke requirements, assuring reimbursement of project expenditures, providing training and support to departmental administrators, coordinating award documentation and approval processes.

Pre-Award
Pre-Award is the period of proposal development and negotiation prior to the sponsor’s award. The Office of Research Affairs Pre-Award Administrator will be your primary contact for these issues. Institutional Pre-Award administration is performed by two pre-award offices: the Office of Research Support and the Office of Research Administration. The pre-award offices are responsible for sponsored projects from the proposal stage through the acceptance of the award. In addition, the pre-award offices are involved when an action or request has the potential of amending or modifying the award document, or a prior written approval is required.

Prior Approval
Certain activities may be indicated in the award as requiring prior written approval before they can occur. All requests that require prior written approval must be submitted through the Pre-Award office. After reviewing the award document and Sponsor guidelines, the pre-award office determines whether prior written approval can be obtained internally or whether the Sponsor’s approval is required. If Sponsor approval is required, the Pre-Award office submits the request to the Sponsor. If approval can be given internally, the Pre-Award office has the authority to give internal approval. Once the approval is obtained, the Pre-Award office forwards a copy of the approval to relevant parties.

Program Income
Income earned by a sponsored project from activities which are directly supported by the sponsored project. Example: A conference grant charges registration fees that result in an excess of funds not provided by the sponsor. Most sponsors require
that program income be used to further the project and be reported. In some cases any anticipated program income must be disclosed in the proposal. GAP 200.290, Program Income - Federal Grants and Contracts provides additional information.

**Subaward or Subcontract**
This is an agreement entered into by an institution (Prime) and a third party (Subrecipient) when funds are to be awarded to the Subrecipient. A Subcontract is the term used when the original project was in response to a contract mechanism. A Subaward is the term used when the original project was in response to a Grant or Award mechanism. Proposals for Sub-Agreements are incorporated in the main application as a mini proposal. The agreement documents are negotiated by the pre-award office. When both parties have signed the agreement, funds can be transferred to the Subrecipient.

**Unallowable Costs**
Certain types of costs are not allowed to be charged to sponsored projects, either as a direct cost or an F&A cost. Federal grants have a predetermined list of unallowable expense types as identified in OMB Circular A-21. They also can have project specific restrictions indicated in the program announcement or the award. Non-Federal sponsors will have individual restrictions. GAP 200.320, Direct Costing on Sponsored Projects provides specific guidelines regarding unallowable costs.

**Discretionary/Current Unrestricted – Allocated Funds 451-xxxx**
The University sets these funds aside for specific purposes. They are not restricted by any outside source. Unspent balances are carried forward to the next fiscal year.

   45X – Educational and General  
   XX1 – Instructional and Departmental Research*

*Departmental research refers to general research performed in a department for which there is no separate budget or accounting.
Mission:

- To foster a collaborative environment assisting study teams in navigating all regulatory and institutional requirements for clinical research.

What we do:

- The Duke Office of Clinical Research (DOCR) supports the CRUs (including all faculty, staff, and students) by developing the navigation, tools, and training for the conduct of clinical research in which Duke serves as an investigative site. DOCR provides the following services to the research community:
  - The Research Management Team (RMT) is available through DOCR to help you with your research needs. We want to remove the burden of hiring, managing and training research and data management staff and allow you to focus on your scientific expertise.
  - Education: DOCR offers many free educational courses for new and established employees in the clinical research community that are available for registration through our departmental website. We also hold a Research Wednesdays lunchtime session twice per month featuring subject matter experts and hot topics from the research community.
  - Study Navigation: Our office provides guidelines and resources for Study Start-Up, Study Management, and Study Closeout to the research community.
  - Contracts: DOCR facilitates obtaining signature for industry-funded, Duke-as-a-site clinical research contracts, and we are available to help study teams navigate their contracts through the Duke system.
  - Maestro Care: DOCR coordinates training and resources for Maestro Care users in the clinical research community and also holds study initiation meetings which are required for studies that need a Maestro Care billing calendar and order set/Beacon build.
  - ClinicalTrials.gov: DOCR is available to help you identify whether your study needs to be registered on ClinicalTrials.gov and will also guide you through both the registration and results reporting processes.
  - Communication: DOCR sends a monthly Clinical Research Update newsletter that provides helpful information and updates to the research community at Duke.

For additional information about DOCR:

- Send an e-mail to DOCR.Help@dm.duke.edu.
- For more information about RMT, or to schedule a free consultation, contact Sue Budinger at susan.budinger@duke.edu.
- Call the DOCR help line at 919-681-6665.
- CTSA Grant Number UL1TR001117
REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. REDCap is managed by DOCR (Duke Office of Clinical Research), located in the School of Medicine. DOCR provides research and data management support to investigators across Duke.

Advantages to utilizing REDCap for your research studies and quality improvement projects:
1) A robust database for capturing your data.
2) An intuitive interface for data entry.
3) Real time single-field data validation.
4) Audit trails for tracking data manipulation and export procedures.
5) Automated export to common statistical packages (Excel, SPSS, SAS, Stata, R).
6) Procedures for importing data from external sources.
7) Data entry using a web interface from multiple sites into a single database housed behind the Duke firewall.

The cost of using REDCap:

Two models are available for using this instance of REDCap.

- **Option 1: DOCR Build**
  DOCR will build a database to your specifications, based on the needs of your project. The only cost to you is the percentage of effort needed to complete the work. Many researchers prefer the efficiency and reasonable cost of this model, since it requires minimal effort of the research team.

- **Option 2: Study Team Build**
  For study teams that possess internal resources capable of building REDCap databases and who only want to use the DOCR-validated instance to house their REDCap database, there is a limited support assessed per project monthly at 0.5% FTE (half percent effort per month) to cover maintenance, updates, and security.

How to get started using REDCap:
Contact DOCR at redcap-docr@duke.edu. A Research Manager from DOCR will meet with investigators and research teams to determine project needs and timelines and provide a written estimate.

Benefits of using REDCap:
1. DOCR’s instance of REDCap has been systematically tested and validated.
2. School of Medicine supports several infrastructure costs associated with DOCR’s instance of REDCap. These costs include dedicated servers, daily backups, application updates, and software validation.
3. DOCR pre-project consultations are free. Talk to us – DOCR’s data managers and analysts can help you find the best data collection solution for your project.
4. Contracting with DOCR is often less expensive than hiring your own staff because you do not have to find, hire, and train staff, or worry about staff turnover.
5. If you decide to build your own database for the nominal annual fee, then:
   a. DOCR will answer your questions about REDCap.
   b. DOCR will keep you notified of changes in the system.
   c. DOCR will manage your user accounts and data access groups, including reminding you to conduct an annual review of your database users.
6. If you contract DOCR to build a database, the following also will apply:
   a. DOCR will follow a professional design methodology to build your database.
   b. DOCR will document the steps taken to build your database.
   c. DOCR will help you find and use common data standards for your area, if they exist.
   d. If you are ever audited, DOCR can supply database and system documentation.

For more information on REDCap, contact us at redcap-docr@duke.edu.
Duke eIRB Electronic System