Cultivating the Clinical Research Grant Environment
leveraging DOCR resources for grant administrators and the faculty they support

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November 19, 2014

Session Objectives

• Identify the 3 areas of focus for DOCR in order to help the Duke research community plan for and execute high quality studies
• State key questions to ask of faculty about obtaining appropriate cost estimates for their grant
• Verbalize potential resources available to research administrators
Duke Medicine – Facts and Figures

3 Integrated hospitals using Epic 2014
- Duke University Hospital 924 beds
- Duke Raleigh Hospital 186 beds
- Duke Regional Hospital 369 beds
- 16,318 employees

- 2013
  - Clinical revenues $2.54B, 1.2m outpatient visits
  - 2013 Total research revenues - $651m
  - 2013 NIH funding $284m - ranked 10th

- 1115 investigators and 434 study coordinators in site based research
- About 4000 open IRB studies during FY14
- About 300 NEW clinical studies/year open at Duke University Hospital – another 900 new studies that do not bill
- ~1% of patients enrolled in clinical studies

Clinical Research Revenue by Funding FY11-14

Federal: [Graph showing revenue distribution]
State: [Graph showing revenue distribution]
Foundation: [Graph showing revenue distribution]
Industry: [Graph showing revenue distribution]
Internal: [Graph showing revenue distribution]
Total Revenue: [Graph showing revenue distribution]
Human Research Protection Program

Vice Dean for Clinical Research

Conflict of Interest  Duke Office of Clinical Research  Institutional Review Board  Regulatory Affairs

Epic Build Team  Research Operations  Education and Training  Contracts Liaison

Data Management  Study Start-up  Research Support

Duke Office of Clinical Research
Duke University School of Medicine

The Duke Office of Clinical Research (DOCR)

Three areas of focus:

- Education and Communication

Research Study Support  - Research Management Team (RMT) data management and study coordination

- Study Startup, Management and Closeout
Education and Communication: FY2014

- **Human Subjects Research Training**
  - 1767 faculty/5122 staff
- **Direct training sessions**
  - 139 faculty/2909 staff 150 sessions
- **Research Wednesdays**
  - 34 faculty/1281 staff in 25 sessions
- **Clinical Research Update eNewsletter**
  - 8000+ subscribers to a monthly publication

[Link to Docr Course Descriptions](docr.som.duke.edu/education/docr-course-descriptions)

Research Study Support: FY2014

- **Enhanced Research Management Team (RMT)**
  - Improve tracking of RMT work requests
  - Added 2 data managers and 6 coordinators (including Associate Director)
  - Managed 152 clients (faculty/staff); 203 total projects (133 data; 70 coordinator)

- **Residents, fellows, and medical students certificate training**
  - Partnered with GME to offer clinical research training series for residents/fellows
  - Coordinated clinical research training for 3rd year medical students
  - Allowed RMT to meet with them and jump start proposals

- **Institutional signature process**
  - Site-based industry sponsored contracts - institutional signature moved to DOCR (reduced to 1 business day)
Let’s Be Well RED aims to help India fight the anemia crisis

Gudness iron-rich nutritional bars to every anemic individual in India

Congratulations to Rajvi and Let’s Be Well RED on winning $55,000 at our Grand Finale! Read more about her team and our other finalists below.

RMT stepped in to help turn this into a research project ...
- Protocol development
- CRF design and REDCap build
- IRB setup and submission
- 80 hours
- Cost ~ $3200

RMT Support: Let’s Be Well RED aims to help India fight the anemia crisis

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<thead>
<tr>
<th>Date</th>
<th>Activity</th>
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<tr>
<td>9/17/13</td>
<td>DOCR and IRB consultants reviewed IRB requirements, DTAs, COI, training requirements, templates, logistics of submission to IRB in India and at Duke.</td>
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| 11/19/13   | DOCR consultants reviewed draft protocol and made suggestions regarding protocol development, assessment tools and REDCap database build.  
             |   - Krishna Udayakumar assists with Mumbai IRB application  
             |   - Liz Burns provides statistical consultation               |
| 11/25/13   | DOCR reviewed draft protocol and editions, drafted consent forms, and a mechanism for translation/backtranslations of ICFs and questionnaires. |
| 12/17/14   | IRB submission                                                           |
| 1/8/14     | CT.gov registry                                                           |
| 1/24/14    | Local and Duke IRB approvals                                              |
| 3/11/14    | DOCR completes CRF edits                                                 |
| 3/21/14    | First protocol amendment!                                                |
| 4/7/14     | DOCR completes Study Database                                            |
10,656 Users • 4 minute session avg • 3 pages per visit • 27% bounce rate

Follow us on the DOCR wiki...

https://ori.duke.edu/wiki/category/docr
Operational plan/grant review

Focus:
• Approach
• Human Subjects
• Budget & Budget justification

Perspective:
• Study coordinator – operations EXPERT
• Finance manager
• (reviewer)

Reasons:
• Operational feasibility
• Compliance/regulatory
• Budget

Operational plan – key questions

Participants

Identification & sample
• How/where
• Expected conversion rate
• Way to make more efficient?

Recruitment & retention
• Expected conversion rate
• Expected retention
Operational plan – key questions

Data collection
- Capture methods
- Type – require special storage
- Management – quality assurance, IT support
- Access – who & how
- Storage - where

Operational plan

Put on coordinator/grant manager hat and review the budget justification

Staffing
- Coordinator time
- Data management time
- Other support staff time

Other expenses
- Recruitment
- Travel (staff or investigator)
- Publication expenses
- Other?
The plan in motion

Study start-up offerings

Study initiation process
- Evaluated for all bill risk
- Offered for all
- Recommended for some
  - email
  - in-person (new, complex, issues in the past, etc.)

Study planning process
- All studies that fall outside of CRUs
- Offered and encouraged for those with no billing
Study planning meetings

When
• prior to institutional approval

Who attends?
• study staff (PI, coordinator, others)
• DOCR staff

What happens
• Meet for ~1 hour
• Follow-up email with links/resources
• Satisfaction survey

Study planning meetings

What is covered?

Training
• Human subjects (HSR, CITI)
• Informed consent/Data integrity and security/other DOCR classes
• Study-specific training, logs
• Financial – payment of participants, procuring goods (http://finance.duke.edu/accounting/training/)
• Clinical Research Update Newsletter & Research Wednesdays
Study planning meetings

What is covered?

Regulatory

• Agreements
• Clinicaltrials.gov registration
• IRB communications
• Creation of regulatory binder
• Enrollment log, Delegation of Authority log, CVs / medical licenses of investigators and Key personnel
• Recommended resources (DECO)

Study planning meetings

What is covered?

Study conduct

• Practices consistent with policies
• Recruitment – use DEDUCE/DISCERN?
• Consent – training, watermark, special populations
• Notice of Privacy Practices
• Subject payment
• Handling of specimens
• Mechanisms for reporting progress, escalation
Study planning meetings

What is covered?

*Keeping track of progress*
- Enrollment target
- Milestone/alert levels

*Data management/QA/Analysis*
- Data security (ISO)
- Data in-transit/mobile devices
- Data provenance
- Storage
- Data collection/management – think ahead to table shells
- Access to data – tracking and discontinuing
- QA, Analysis
Study planning meetings

- Tailored to protocol
- Connect to internal resources
- Provides tools/templates
- Educate and link to additional education opportunities
- Constantly evolving as the research environment changes

Thank you!

Duke University School of Medicine

This effort is partially supported by Grant UL1TR001117
from the National Center for Advancing Translational Sciences (NCATS)

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