

Symposium for Research Administrators

Dynamics for Tomorrow's Research Administration



Services, Support and Structure: The New Clinical Research Initiation Process at Duke

Denise Snyder

Duke Office of Clinical Research

Bonnie Funk

Anesthesiology CRU

Lynn Spear

Oncology CRU

Objectives

- Define the clinical research environment at Duke
- Be able to state the role of the Duke Office of Clinical Research (DOCR) in supporting clinical research at Duke
- Understand the impact of Maestro Care (Duke's Epic implementation) on clinical research
- Provide a listing of DOCR resources that are available to PIs at Duke

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Clinical Research at Duke

- Duke's 10 schools, 8 trans-university institutes, and the Duke University Health System together received over \$355MM from the NIH in 2011
- Duke led the nation in industry funding for research with \$215MM, an amount almost double that of the next highest academic institution [NSF 2012]

Table A-1a. Translational Productivity at Duke (2006 vs. 2011).

Type	2006	2011
Invention disclosures	123	242
New license agreements	35	107
US patent applications	55	111
US patents issued	28	52
Annual licensing	\$3.5MM	\$24.1MM

Table A-1b. NIH-funded Interventional Trials at Duke since 2006 (Trials Assigning Subjects to Treatment)

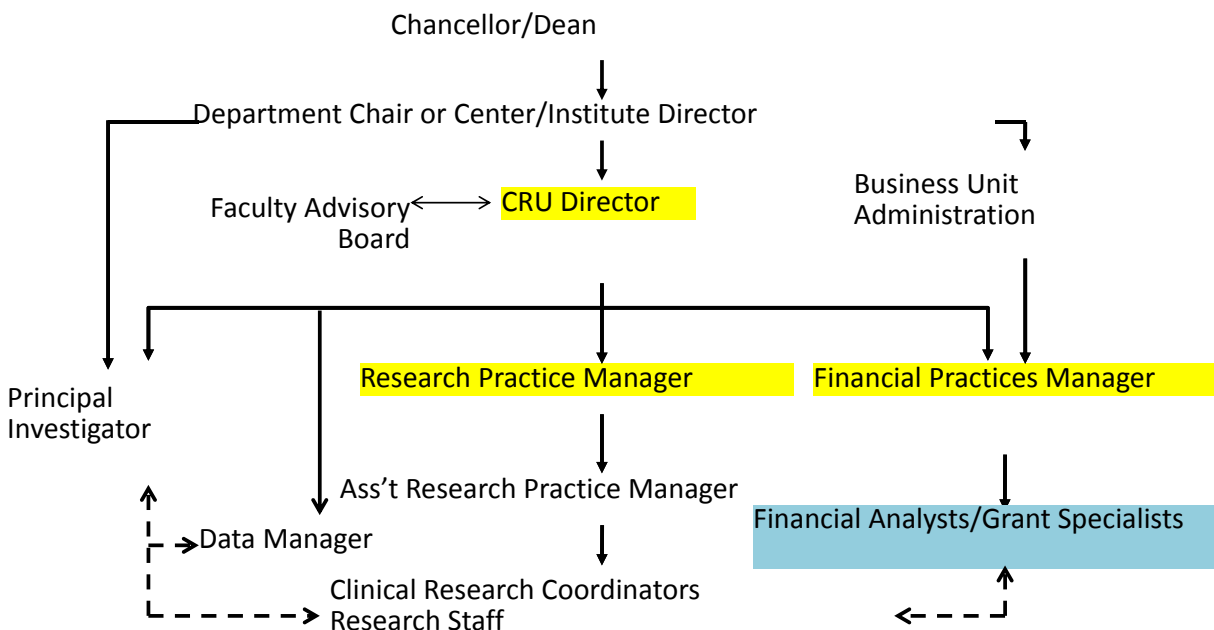
Research Type	NIH-Funded	
	Studies, n	Participants, n
Proof of Concept Unit	80	5,126
Duke investigative site	345	16,634
Coordinating center	75	87,432

Duke's Complex, but Productive, Research Environment

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Clinical Research Unit





Guided Research Navigation & Support

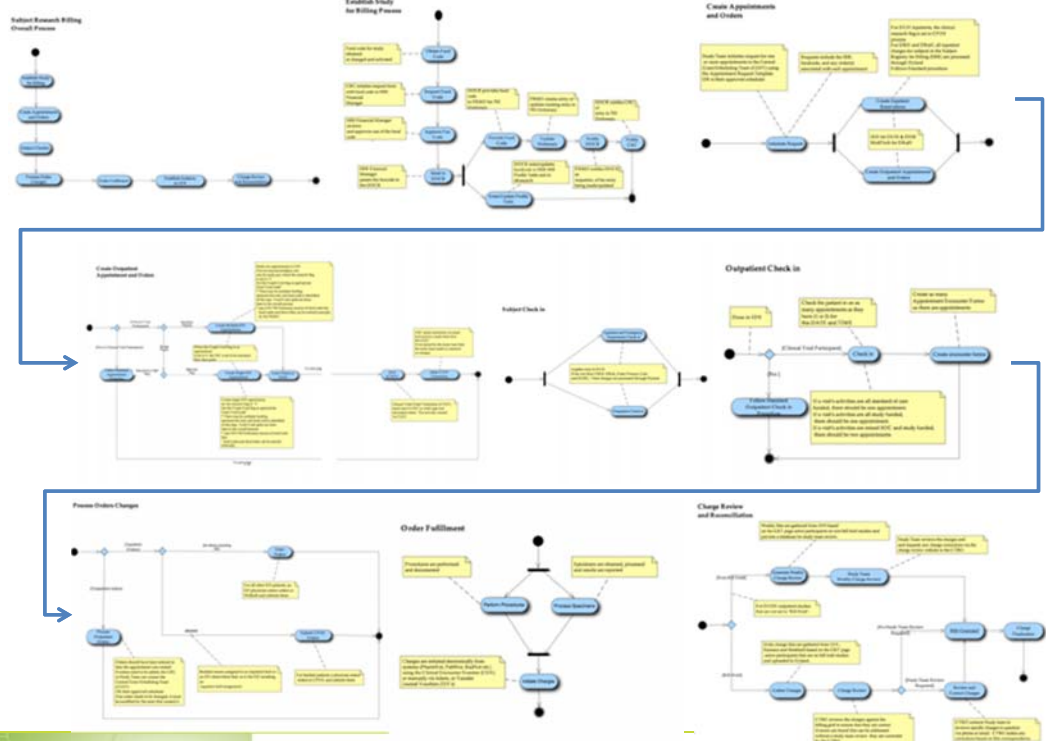
- Responsible for clinical research education, communication, consistent processes, while promoting a culture of integrity and transparency
- Expand the availability of sophisticated research logistics knowledge base to all investigators and study teams – Office of SMEs
- Provide centralized access to disparate research resources and shepherd studies through the study lifecycle
- Create synergistic clinical research support with equitable access to compliant tools and resources
- Improve data provenance by ensuring data trail from initial measurement to final product is explicitly traceable
- Strengthen CRUs through joint partnership

Research Calendaring and Ordering Workgroup

- Mission: Design and Agree upon a functional workflow for the management of Clinical Research at Duke using Epic 2012
- Representation from – Epic, Maestro, DHTS, DOCR, DCI, Deloitte, CRU's, PRMO, Scheduling, Compliance

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Created Maps for Current Workflow..



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Drivers in Future State Research

Workflow using Epic

- No interfaces possible with Velos eResearch or eIRB for Wave 4
- Paramount to create a robust split charge billing mechanism for research and standard of care charges
 - PRMO promoting a single encounter, split billing paradigm. We would have to adjust.
- Need a robust study and subject registry
- Establish central management through DOCR

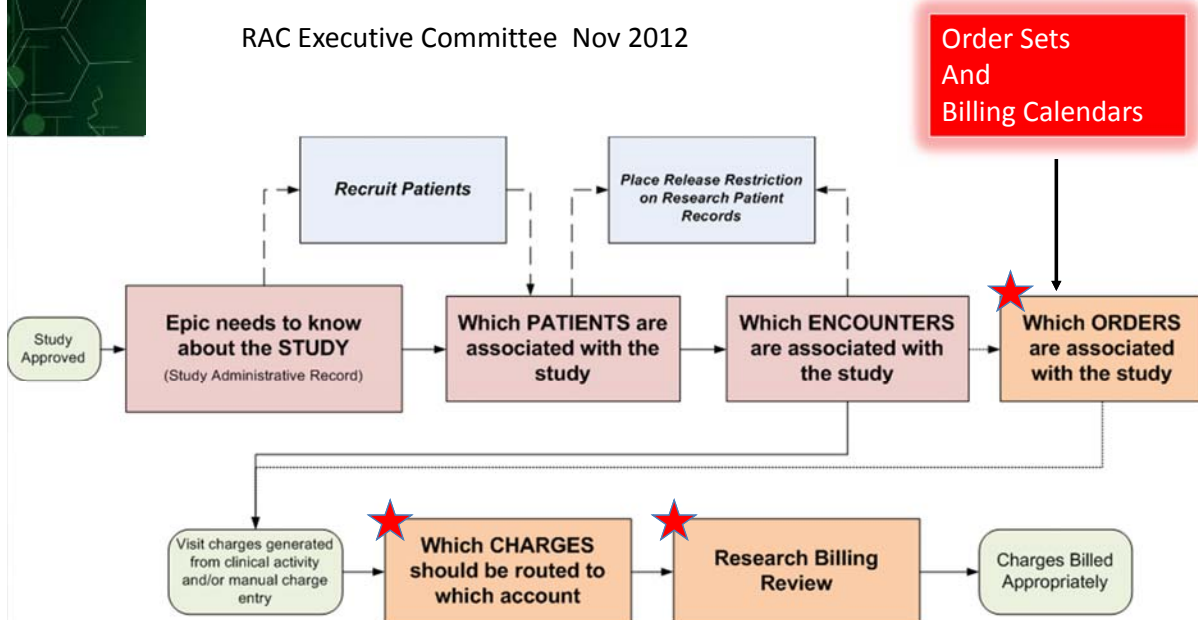
Explored and found considerable functionality for managing clinical studies in Epic 2012 model functionality

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Decision to use Model Epic 2012 Research Functionality

RAC Executive Committee Nov 2012



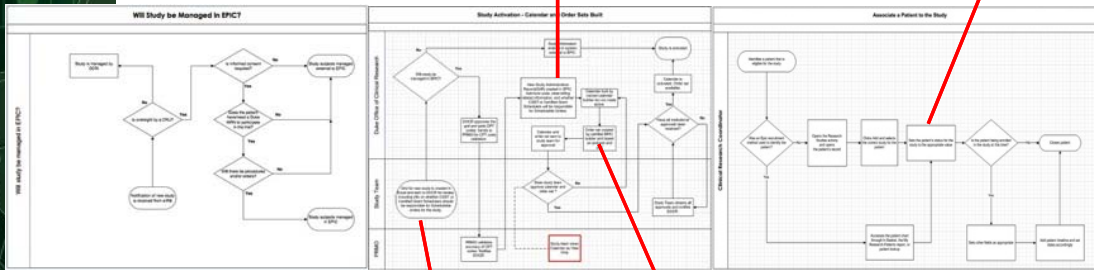
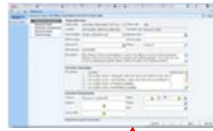
★ = New in Epic 2012

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Future State Workflow Carefully Agreed..

Epic Screens



Study Grid



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Decision to use Billing Calendars and Order Sets

- Epic 2012 enables the creation of a Billing Calendar for non-beacon clinical trials
 - Maps to a visit schedule
 - Chargeable events and items identified, appropriately coded (e.g. V70.7 modifier) and mapped to Payer (sponsor, insurance)
- Linked at build time to an order set for the study
 - Maps orders to chargeable events and items in billing calendar
- As Charges drop, cross-checked against calendar, coded and routed appropriately
- Review process cleans up



Significant advance in billing compliance/reduction in complexity

But Billing Calendars and Order Sets need to be Pre-built...

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Site Actions Browse Page Denise Snyder

MAESTRO
CARE

Maestro Care

News & Announcements
Submit a Maestro Care Support Ticket
Quick Tips & Supplemental Training Materials
Maestro Care Ambulatory
Wave 4 Training Registration
Training Toolkit
Maestro Care Inpatient
DUH Inpatient Training
Training Toolkit
Maestro Care Revenue Cycle
Training Toolkit
Maestro Care Clinical Research
Frequently Asked Questions
Newsletter

MAESTRO CARE IS LIVE!
GO-LIVE UPDATES & INFORMATION

GO-LIVE UPDATES QUICK TIPS & TRAINING TOOLKITS SPECIALTY POCKET CARDS NEWS & ANNOUNCEMENTS

Maestro Care Training Update
Some Maestro Care training classes are available during the week of June 24. If you need to attend Maestro Care training to complete your curriculum, please open a [Service Now ticket](#) and have it assigned to the Maestro Care Training Registration Team.

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Go Live Central Support – Results

- Roles, organization, and scheduling worked seamlessly
- Face-to-face time with study teams formed relationships
- Fostered a connection to the research community
- Go live support organization team continues to interface today to solve problems and plan optimizations

Open Issues

- Need to map build processes within DOCR going forward
- Replacing contractors with permanent staff
 - Data couriering
 - Change management
 - GUI updates/fixes
- Research billing still on 100% bill hold
 - Related to report issues
- Access to Maestro resources
 - Clinical precedence
- Communication



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Open Issues

- Pharmacy
 - Under resourced
 - Paper is viable fallback
 - Users contact directly to circumvent
- Reports
 - Under resourced
 - Lack of research knowledge
- Scheduling
 - Compartmentalized with lack global awareness
- Role of Velos eResearch



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Functionality not addressed by EPIC

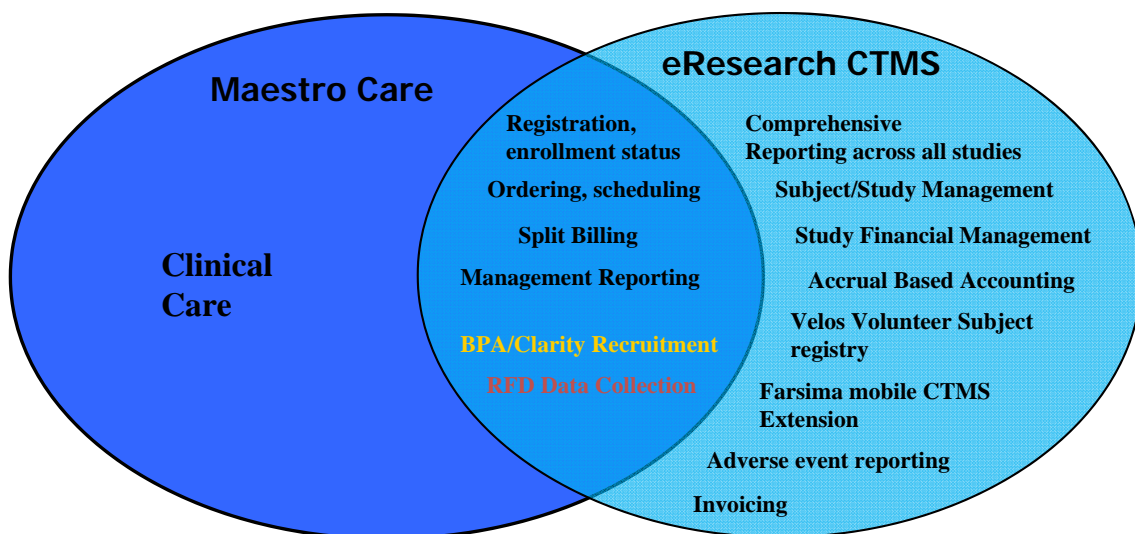
- Financial management of sponsored studies (trial trackers)
- Portfolio management
- Oncology data for reporting
- Multiple sites/Non-Duke patients
- Budgeting
- Management of existing active studies in eResearch



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Site Based Research Maestro Care and Velos (eResearch)



Epic is becoming a Research Patient Management System.

How DOCR helps to facilitate new study start up within the DUHS system

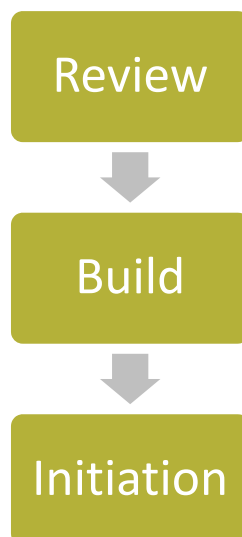
Study Initiation Meeting facilitated by DOCR

- Representatives from Duke Medicine clinical research community meet with study team members to discuss the protocol and identify needs for Maestro care, including order sets and a billing calendar for the PRMO
- Provides a forum to discuss alignment with Duke and national clinical research policy and well as educational and clinical research services within Duke

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DOCR Initiation Process Three Phases



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REVIEW

Study Initiation Meeting

- Review protocol and identify clinical and research-specific activities
- Develop research charge router (identifies standard of care (billable to insurance) & research-only charge or order (billable to grant or generating no DUHS patient charge))
- Review qualifying status and national coverage decision
- Review budget - identifying funding of activities and coverage of related activities
 - Alignment with DUHS financial policies
- CTA and consent for alignment with charges, patient responsibilities, and subject injury language.

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Build

Using the approved research charge router:

- Direct MC order set or treatment plan build
- Facilitate study medication build including Investigational Pharmacies (IDS and ICS)
- Facilitate PRMO's build of the study administration record (RSH) and billing calendar build

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Initiation

After approval by IRB

- Move order set, RSH record and billing calendar into live Maestro Care environment
 - Ensure all IRB approvals obtained
 - Review compliance with study NCT registration (ClinicalTrials.gov)
 - Review and approval of Maestro Care content
 - Special approvals (i.e. CMS approval/waiver for IDE studies is complete)

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DOCR Release

- DOCR is not always the last to sign off for approval, however if there is a Maestro Build, we often are the last release
- This signifies that the study is live in Maestro Care and study enrollment activities can begin once Institutional approval notification is received

(The DOCR button release can be earlier to facilitate study needs with understanding that no enrollment activities can begin until full Institutional approval and protocol is active in Maestro Care.)

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ORA Release

Lindsey Spangler's contract team function

- Applies only to Industry-funded Duke-as-a-site clinical research.
- ORA releases for DCRI agreements.
- To release on DAAS agreements, the following is needed:
 - A Fully executed agreement
 - PI must have completed RCC training

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Get Help Early - DOCR! Identifying Resource Needs

- Research planning & support
- Data management and database development
- Tools, technology and collaboration
 - Safeguard the highest possible degree of integrity
 - Ensure that all methods and practices accelerate the timeline from data collection to data analysis and reporting

Good planning and operationalizing will help ensure success!

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Need Project Assistance?

Research Management Team can help!

Contact DOCR.help@dm.duke.edu

- REDCap eCRF design and REDCap Survey
- MS Access tracking database design and maintenance
- Data cleaning
- Data entry
- Data management/trouble shooting
- Data mining/DEDUCE
- Chart abstraction
- Project management
- Regulatory (IRB) support
- Consent form development
- Research design
- Subject recruitment
- Subject consenting and interviewing
- Subject tracking and follow-up
- Connect with statistical support (B&B)

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Why Partnering with DOCR can help your PIs

- Teamwork approach to problem-solving
- Readily available, research-trained staff
- Navigation experts to increase efficiency for implementation
 - Understanding the regulations and how they apply
 - Whom do you talk to? What do you need to do?
- Improved data quality and data security
- Central documentation - insurance throughout life of project regardless of staff attrition or funding changes
- Tailor effort needs to project – get only what is needed when it is needed
- An active partner in operationalizing the science

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DOCR Educational Offerings

- Instructor-led/on-line classes
- Annual competency requirements
- Maestro Care education
- Research Wednesdays lunch and learn series
- GME Resident/Fellow Research Education series
- Department requests/one-on-one sessions

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- 2nd and 4th Wednesday of every month
- Topics rotate
- Led by subject matter experts
- Upcoming topics found on DOCR website and DOCR newsletter

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Recurring Competency Requirements

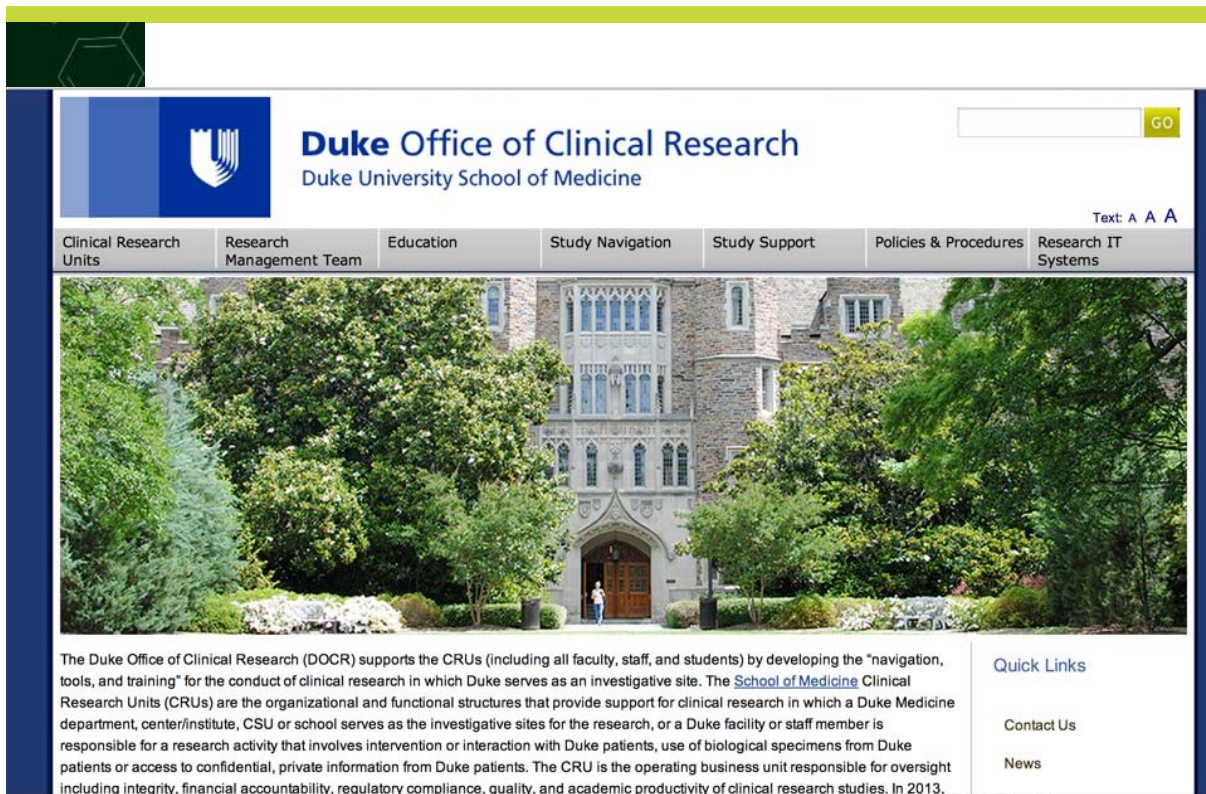
- CITI modules (every 2 years)
 - for DUHS IRB – affiliate with Duke Biomedical research <http://medschool.duke.edu/sites/medschool.duke.edu/files/documents/12.12-rev.-CITI-Access-Instructions.pdf>
- Human Subjects Research at Duke (Annual)
 - Annual requirement for all those involved with human subjects research at Duke
- Urine Pregnancy Screening for Research (Annual)
 - Required for study team members who will be performing urine pregnancy screening for studies
- Phlebotomy Competency for Research (Annual)
 - Required for study team members not otherwise licensed to draw blood on an adult population for research purposes

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The screenshot shows the homepage of the Duke Office of Clinical Research (DOCR). At the top left is the Duke University logo. To its right is the text "Duke Office of Clinical Research" and "Duke University School of Medicine". A search bar with a "GO" button is on the top right. Below the header is a navigation menu with links: "Clinical Research Units", "Research Management Team", "Education", "Study Navigation", "Study Support", "Policies & Procedures", and "Research IT Systems". A large photograph of a Duke University building is centered on the page. Below the photo is a paragraph of text describing the DOCR's role. On the right side, there is a "Quick Links" section with links for "Contact Us" and "News".

Duke Office of Clinical Research
Duke University School of Medicine

Clinical Research Units | Research Management Team | Education | Study Navigation | Study Support | Policies & Procedures | Research IT Systems

Text: A A A

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. The [School of Medicine Clinical Research Units \(CRUs\)](#) are the organizational and functional structures that provide support for clinical research in which a Duke Medicine department, center/institute, CSU or school serves as the investigative sites for the research, or a Duke facility or staff member is responsible for a research activity that involves intervention or interaction with Duke patients, use of biological specimens from Duke patients or access to confidential, private information from Duke patients. The CRU is the operating business unit responsible for oversight including integrity, financial accountability, regulatory compliance, quality, and academic productivity of clinical research studies. In 2013,

Quick Links

- Contact Us
- News

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Duke numbers (rolled out May 2013)

26 researchers (16 recruiting, 10 feasibility) – one researcher from BME has registered

109 “yes” respondents

1,473 volunteers within 50 miles of Duke

Available for IRBs through both DUHS and Campus

Thank you!



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*from the National Center for Advancing
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*Snyder DC et al. Research Management Team (RMT): A
Model for Research Support Services at Duke
University. Clin Trans Sci 2012; 5:464-469.*

Denise Snyder
Associate Dean for Clinical Research
Duke Office of Clinical Research (DOCR)
9th floor Hock Plaza
Office: 919-660-7580 denise.snyder@duke.edu

DOCR.help@dm.duke.edu

