

Clinical Research Update

Duke CTSA
Center for Translational
Science and
Education

DOCR

docr.som.duke.edu
docr.help@dm.duke.edu

November 2017

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DOCR Announces the Launch of New and Improved Website!

We are pleased to announce the launch of the new DOCR website on November 2, 2017!

The [new website](#) provides our visitors an easier way to learn about DOCR services and available resources for clinical research at Duke.

New features include integrated communication with external resources and cross functional research partners. DOCR will be updating content with helpful information, resources, and announcements regarding clinical research successes.

We hope that you find the [new website](#) provides easy access to information and that it meets your research support needs.

OnCore Community News

Several OnCore Champion sessions have been scheduled to continue the dialogue as we develop final training content for each functional role. In the next weeks, Champions will be asked to

participate in the vetting process for training content in preparation for releasing the online modules in December. Instructor lead courses will be open for registration in December. Trainees have the option to complete role based training as eLearning or instructor lead. Details for each course and information about registration will be communicated in early December. Online content will be released for the following roles:

- Administrative Leadership
- CRU Leadership
- Principal Investigator
- Regulatory Coordinator
- Clinical Research Coordinator
- Clinical Research Assistant
- Financial Staff Pre-Award
- Financial Staff Post-Award

Research Community News

NIH Updates to Certificate of Confidentiality Policy

NIH announced that as of October 1, 2017, Certificates of Confidentiality (CoC) are now automatically issued with awards for NIH- funded human subjects research. NIH awardees no longer need to apply for a separate CoC. These certificates protect participant privacy by limiting the disclosure of identifiable information in legal proceedings and to individuals not connected with the research. This policy change is retroactive to studies that were ongoing on/after December 13, 2016.

NIH expects that Certificate of Confidentiality standard language be included in the consent form – updated language is available under the Standard Language section of the IRB website and in the template consent forms.

- **New Studies:** All new NIH-funded human subjects research must include Certificate of Confidentiality Language in the consent form
- **Existing Studies:** Consent forms for existing NIH-funded research that is open to enrollment should be updated with the CoC language at the next renewal or amendment that alters the consent. Re-consent will not be required and the IRB will not require Certificate of Confidentiality language that already appears in consent forms to be updated.

Studies funded by sources other than NIH may still apply to DHHS to obtain a CoC if needed.

More information is available here: <https://humansubjects.nih.gov/coc/index>.

Submitting or Helping Submit NIH Grants in 2018? Big Changes Coming, Stay Informed

The NIH has announced that there will be significant changes to its grant application forms (Forms-E) and application guide instructions for all human subjects research proposals with due dates on or after January 25, 2018. A high-level summary of these changes is available on the [NIH website](#). If correct forms are not used, applications will be rejected without review. **This will be a large adjustment for faculty who apply for NIH research proposals involving human subjects.**

Faculty and their staff who help develop proposals are invited to attend one of three 60-minute sessions. The sessions do not require advanced registration; two have webcast available, with recording accessible shortly after the broadcast.

November 16th, 7:30 AM, Duke North Hospital Lecture Room 2003: [Webcast/recording](#)

November 17th, 9:00 AM, Perkins Room 217

November 20th, 4:30 PM, Duke North Hospital Lecture Room 2003: [Webcast/recording](#)

If you have any questions, please contact researchinitiatives@duke.edu.

Contacting the IRB—the Who and the What

If you have questions about any modifications requested by the IRB, please contact the IRB Specialist who is responsible for your CRU/Department. You can find your IRB Specialist on the IRB web site: <https://irb.duhs.duke.edu/about-us/staff-and-chairs>. If you have concerns or questions about a deferral or disapproval of a study, please contact the Chair of the IRB meeting. In such cases, it is NOT appropriate to contact the IRB Primary Reviewer.

Pathology Review Fees

The Duke Biorepository and Precision Pathology Center (BRPC) will institute a new fee schedule beginning January 1, 2018 for Pathology Reviews. This new fee schedule applies only to Pathology Reviews, which occur early in the IRB Review phase and are not included in BRPC study specific budget teams receive. Pathology Review fees will be invoiced separately to the study team through CoreResearch@Duke. **Please note Pathology Review fees are waived if a Faculty Pathologist is a listed as a collaborator on the protocol.** The new fee schedule is listed below:

- **New Protocol with No Review Needed:** \$0.0 For documentation purposes, an email confirmation will be provided to the study team at the time of determination that Path Review is not needed. There will be no charge associated with this correspondence.
- **New Protocol Qualifying for Automatic Approval:** \$0.0 For new protocols which require a form but meet the criteria for automatic approval (as delineated on the form) -- a signed Path Review will be provided to the study team at the time of Path Review approval. There will be no charge associated with the automatic approval process.
- **New Protocol Full Review:** \$468.00 For new protocols which require a full Pathology review as delineated on the form -- a signed Path Review will be provided to the study team at the time of Path Review approval for documentation purposes. A full protocol review charge will be charged to study-specific fund code (for FY18, this charge will be \$468). All study teams will be invoiced through the CoreResearch@Duke billing system as soon as possible following Path Review approval.
- **Amended Protocol Full Review:** \$90.00 All protocol amendments that change the tissue procurement requirements of the study require revised Path Review approvals. These will be invoiced through the CoreResearch@Duke billing system as a regulatory consultation charge (for FY18, this charge is \$90.00). All study teams will be invoiced through the CoreResearch@Duke billing system as soon as possible following revised Path Review approval.

Office of Sponsored Programs (OSP): Project Balance Netting and Fixed-Price Balances

OSP has announced updates to Duke's post-award financial management processes, which were implemented in October. Reach out to your OSP liaison and/or implementation team representative with any questions.

Project Balance Netting

All reportable sponsored projects that include subcodes established under a parent code with an end date of October 1st or later will follow a standardized approach when expenses do not equal budget on all WBSEs. These procedures will ensure consistent predictable management of balances across all parent w/subs projects, will support the ownership of the project by the parent org, and will minimize financial risk to Duke University.

Factors that will affect the specific steps of this approach include:

- Whether a project is at budget period end (carryforward not automatic) or project period end
- Purpose (rebudget class) of each subcode

A detailed description of this process is available in a [Quick Reference Guide \(QRG\)](#), addressing both the standard procedures and exceptional circumstances.

There is no change to the institutional expectations for GMs to monitor balances during the life of the project, to submit rebudget request forms as appropriate to align budget with PI intent,

and to communicate on critical issues with GMs of subcodes managed in other org units. In all cases when closing a project that includes subcodes, the owning org of the parent retains control of the ultimate disposition of budget and expenses across all project codes; read the QRG closely to determine the correct approach based on the specific factors on each WBSE. The Parent/Child Sponsored Project Management [GAP 200.190](#) has been updated to confirm the project balance netting process at time of closeout.

Fixed-Price Residual Balances

All fixed-price reportable sponsored projects closing with an end date of October 1st or later will be processed based on the new Fixed-Price Residual Balance Transfer [GAP 200.185](#). These standard procedures are being implemented by Duke University to provide a consistent approach to the review and disposition of residual balances on projects based on a fixed-price award amount, and to ensure appropriate management review and risk analysis are performed based on the details of each project.

Key points include:

- There is a minimum award amount threshold (projects with a total award amount of <\$20,000 are exempt from the GAP)
- There is a tiered review structure based on the amount of the residual balance;
 - Balances of ≥25% total award amount or ≥\$50,000 will require owning org management review
 - Balances ≥40% or ≥\$100,000 require School approval
- F&A will be assessed on the residual balance, based on the original proposal budget and assigned F&A rate, and the direct cost portion of the balance will be transferred to the cost object identified on the closeout tasklist.

There will be an associated Quick Reference Guide that provides a helpful graphical summary of this process and links to related resources; it will shortly be [posted here](#).

Opt-Out of Research at Duke?

Not possible! As much as we may want to accommodate a research subject's wishes, we (as individual researchers) cannot guarantee that someone else will not approach the person about being a research subject. Thus, we cannot grant a request to opt-out of being contacted about research.

Have a privacy question? Send it to privacy@duke.edu.

CTSI Funding Programs Open for Applications

CTSI currently has two major funding programs open for applications:

[CTSI Translational Accelerator Funding Agreement](#)

- Up to \$150,000
- Purpose: Support for cross-disciplinary scientific research addressing the development of therapies diagnostics, or devices applicable to human disease, clinical research trials (excluding Phase 2 and beyond), epidemiological studies, and/or community-based research
- Letter of Intent due September 15th, Application due November 6th

[CTSI Transformative Funding Agreement](#)

- Up to \$500,000
- Purpose: Supporting the development of mature research with the potential to attract significant interest for external partnering, thus enabling and accelerating translation of research out of the academic environment
- Letter of Intent due September 15th, Application due November 6th

Duke CTSA KL2 Accepting Applications Beginning November 1

The Duke CTSA KL2 provides mentoring, a scientific and career development curriculum, and the opportunity to conduct clinical or translational research for junior faculty. We are devoted to increasing the diversity of the research workforce, and have committed to supporting at least 50% under-represented minorities with the KL2. Three scholars will be awarded 75% protected effort for 3 years, up to \$20,000/year for research expenses, and \$2,500/year for travel to professional meetings. Funding will start July 2018, and applications are due December 15, 2017. [View more information here.](#)

Translating Duke Health Pilot Project Grants

Translating Duke Health is a platform of resources – including people, services, technology, infrastructure and funding – focusing on areas where Duke Health can have the greatest impact on transformative treatments and prevention strategies.

This endeavor focuses initially on five opportunities selected by convening groups, which included representatives from across Duke.

- Preserving and restoring cardiovascular health
- Enhancing brain resilience and repair in brain disorders
- Ending disease where it begins
- Undertaking the fundamental opportunity of controlling the immune system
- Combating solid tumor brain metastases

Translating Duke Health is a multiyear, multidisciplinary program to capitalize on our collective strengths in research, clinical care and population health to address major health challenges. As part of this initiative, there are a handful of pilot project grants available. For more information about Translating Duke Health and open RFPs, visit www.translatingdukehealth.org.

Tech Fair for Faculty, Instructors, and Researchers November 3rd

OIT is hosting a TechFair for faculty, instructors, and researchers on Friday, November 3rd from 1-4 PM at the Technology Engagement Center (TEC) in the Telecommunications Building.

This open-house style event will feature faculty-oriented table-top demos and practical advice about how to get and use Duke's most important technology services for teaching and learning. Covered topics include: research computing, collaboration tools like WebEx, Box and Office365, CIT services like Sakai and PebblePad, virtual reality demos, academic media services, 3D printing, and hands-on tech help with Sakai. Bring your mobile devices and laptops. Come for food, giveaways, and door prizes, including the coveted Duke OIT mug (while supplies last.) TechFair is in part of the Center for Instructional Technology's NextEd Festival.

ACRP RTP Chapter Fall Conference

The Research Triangle Park Association of Clinical Research Professionals 18th Annual Fall Conference will take place November 9 and 10, 2017, at the North Carolina Biotechnology Center. Sixteen CEUs are available to attendees. For information and to register: <http://www.acrpnet.org/researchtrianglepark>.

ReGARDD Seminar: Developing Monitoring Plans for Investigator-Initiated Clinical Trials

The November ReGARDD seminar will cover the requirements and best practices of establishing, maintaining, and complying with a study monitoring plan for investigator-initiated trials. Join us for this session and go through a real life case example of where adequate monitoring plans can support investigator-initiated trial success.

The session will be held Tuesday, November 14th from 11 AM – Noon in the Duke Albert Eye Research Institute Auditorium. For additional information and to register: <http://tinyurl.com/y98st78m>

Save the Date: 2017 Symposium for Research Administrators November 28th

Please join the research administration community at the 2017 Symposium for Research Administrators on November 28, 2017 at the Durham Convention Center. This year's theme,

Collaboration, Community, Continuous Improvement, reflects the collaborative nature of the research and research administration communities at Duke University and our drive for success.

Date: Tuesday, November 28, 2017

Time: 8:30 a.m. – 3:30 p.m. (registration & breakfast from 7:45-8:30 a.m.)

Location: Durham Convention Center (301 W. Morgan St., Durham, NC 27701)

For registration and session information, contact RCC at rcc-cert@duke.edu.

Save the Date: Basic Science Day November 29th

This year's annual Basic Science Day will be held Wednesday, November 29th in the Trent Semans Center Great Hall. The event will feature Dr. Jennifer Doudna speaking on "CRISPR Systems: Biology and Application of Gene Editing." For a full agenda of the day's events and to register, visit <http://medschool.duke.edu/Basic-Science-Day>.

Office of Sponsored Programs Quarterly Outreach Session

THE OSP EXCHANGE is a 1 hour quarterly session designed to exchange tips, facts, and ideas.

This month's OSP Exchange is specifically targeted to Departmental Grant Managers and their teams. Session participants will take a deep dive into SAP, discovering a wealth of master data/information, and will learn how these details can assist you in the ongoing management of your sponsored project.

Register using the link below.

[November 7th](#) – Sociology and Psychology 130, Karl E. Zener Auditorium, 11:00 AM – Noon (No food or beverages allowed)

If you have any questions or need additional information email sponsoredprograms@duke.edu or call (919) 684-5442.

DOCR News

Clinical Research Appreciation for Faculty and Staff a Success

The 2017 Annual Clinical Research Appreciation Event sponsored by the Duke Office of Clinical Research was a resounding success. Over 600 attendees enjoyed networking with colleagues and meeting with clinical research administrative offices and service providers at vendor tables, along with food, music, dancing, and door prizes. Highlights of the event included remarks by Dr. Adrian Hernandez, Vice Dean of Clinical Research along with remarks from Denise Snyder, Associate Dean of Clinical Research.

Congratulations to the following attendees who were winners of door prizes at the event:

Mallory Simms, GU Clinical Research, beach chair

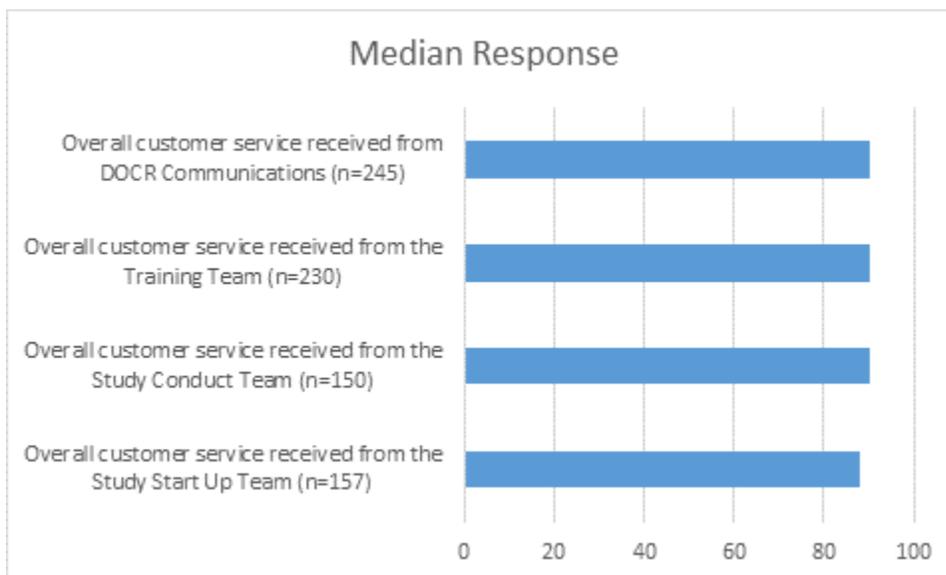
Amanda Kelley, ORC, beach chair

Ronna Zimmer, DUHS IRB, beach tote bag

Anna Sun, Computer Science, beach tent

DOCR Annual Satisfaction Results and Survey Winner Announced

The results of the annual DOCR satisfaction survey [are available](#). The annual satisfaction survey polls the clinical research community regarding use, benefit, knowledge and courtesy of DOCR services and staff. These data are used in DOCR strategic planning to improve services to the research community in the future. This year's survey was taken by a wide range of researchers in a variety of roles. Here is a quick view of Median Responses:



See what your colleagues had to say by [reading the full survey results](#).

Congratulations to Emily Forgey, Heart Center CRU, who is this year's winner of an iPad mini. Emily's name was selected from those who completed the Annual DOCR Satisfaction Survey. Thank you to everyone who completed the satisfaction survey. Congratulations Emily!

Did You Know?

REDCap

REDCap is FREE to use for all Duke faculty, staff, and students, and you can build your own projects at no-cost or contract DOCR expert builders for a percent of effort. The HIPAA compliant web-based Electronic Data Collection Tool is suitable for research projects with low to medium-low complexity data collection requirements and ideal for researchers currently using Excel spreadsheets or MS Access to store data.

REDCap weekly office hours are held on Tuesdays in the Medical Library 212C conference room (Seeley G. Mudd Building) from 10 AM-11 AM.

Office hours are also held the first Thursday of the month, 10:00-11:00 AM in DMP 2W93.

One-on-one REDCap demonstrations and free consultations offered. Full service contract builds also available; contact us at redcap-docr@duke.edu.

Training Opportunities

Upcoming DOCR Training Offerings

DOCR training offerings are available in the [Duke LMS](#). There are 2 easy ways to find all DOCR classes: Enter “DOCR” in the search field and click **Search**, or click the **Category** link, and then click the **DOCR** link. The results display all the offerings currently available from DOCR. Hint: If you want to bookmark the Duke LMS in your browser, edit the bookmark to this address:

<https://lms.duhs.duke.edu/Saba/Web/Cloud>

Detailed information about each offering and direct links to the offering are also available on the [DOCR website](#). Following are the upcoming instructor-led DOCR offerings:

Title	Dates	Time
Research Wednesdays: <ul style="list-style-type: none"> - NIH Updates - Implementation of Changes in the Revised Common Rule, Session 1 (3rd Wednesday in November) - Implementation of Changes in the Revised Common Rule, Session 2 	<p>November 8</p> <p>November 15</p> <p>December 13</p>	<p>1:10 PM – 2 PM</p>
Research Professionals Network: <ul style="list-style-type: none"> - Creating Innovative Solutions to Recruitment and Retention Challenges 	<p>November 16</p>	<p>1 PM – 2 PM</p>

MC Clinical Research 100	November 7, 14, 21, 28 December 5, 12, 19	9 AM - Noon
MC Clinical Research Oncology (Beacon)	November 15 December 7, 19	1 PM – 4 PM
MC Clinical Research Oncology (Beacon) Refresher: Deep Dive	November 2 December 5	1 PM – 4 PM
MC Clinical Research Personalization	November 21 December 21	1 PM – 4 PM
MC Clinical Research Personalization	November 13	9 AM - Noon
Budget Development and Negotiation Training	November 7	10 AM - Noon
Financial Basics for Clinical Research	December 8	9:30 AM – 11:30 AM
IRB Overview	November 14 December 12	10 AM - Noon
Industry Funded Clinical Research Process for Contracts	November 16	9 AM – 11 AM
Phlebotomy Competency for Research	November 9	9 AM – 11 AM
Phlebotomy RENEWAL Competency for Research	November 9	11 AM – 11:30 AM
REDCap: Exporting/Importing and Reports	December 15	11 AM - Noon
REDCap: Learning to Manage Surveys	November 17	11 AM - Noon
Research Database Design Principles	November 3 December 1	11 AM - Noon
Screening and Consenting Subjects	December 18	10 AM - Noon
Study Documentation Regulations and Best Practices	November 9 December 12	10 AM – Noon Noon – 2 PM
Urine Pregnancy Screening for Research	November 14 December 12	1 PM – 2 PM
Workshop: Start Building in REDCap	November 10	10 AM - Noon

	December 8	
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Clinical Research Employee Highlights

- The Anesthesiology CRU welcomes Alice Szydlowska to the team as an Assistant Research Practice Manager.
- The School of Nursing CRU welcomes Megan Arthur to the team as a Research Program Leader.

Partner Resources

DUHS Compliance Office Newsletter

Catch up on news from the [DUHS Compliance Quarterly Newsletter](#).

Subscribe to the Clinical and Translational Science Institute (CTSI) Bi-Weekly Newsletter

Stay up to date on news, funding, and education opportunities in translational science at Duke by subscribing to CTSI UPDATES. Read past newsletters and subscribe at <https://www.ctsi.duke.edu/news/newsletters>.

To be added or removed from the distribution list for the DOCR Clinical Research Update newsletter, please contact the DOCR at docr.help@dm.duke.edu.