

Clinical Research Updates



June 26, 2018

Welcome

- Andy Johns, Sr Associate Vice Chancellor for Research
- Brett Kenney, University Cash Manager, Accounting Services
- Liz Moore, Assistant Director, Office of Industry Contracting
- Christine Nelson, Director, Office of Clinical Trials
- John Roberts, Compliance Manager, Office of Human Research Ethics
- Laura Tuttle, Research Program Manager, NC TraCS

Initiatives to Improve Clinical Trial Contracting Start-up

- Contracting
- Billing Coverage Analysis Assistance
- Budget Assistance

How can the Study Team help?

Be prepared to answer questions on the following

- Record retention
- eCRF completion
- Sponsor invoicing
- Biological samples

How can the Study Team help?

- Conduct a thorough feasibility assessment prior to submission to OIC or IRB

- Be realistic in your accrual projections

Complete the billing coverage analysis and have the budget prepared

- Have a good understanding of what it will cost to conduct the trial

Research Fee Schedule

The UNC Healthcare system is implementing two research fee schedules

- Industry sponsored RFS
- Federal RFS
- Costs and codes given will be based on the designation in BCA spreadsheet
- Only those truly federally funded should receive the federal RFS
- Invoices received from the healthcare system for tests/procedures will be based on the funder in RAMEs

Prepaid Card Program

Brett Kenney
University Cash Manager
Accounting Services



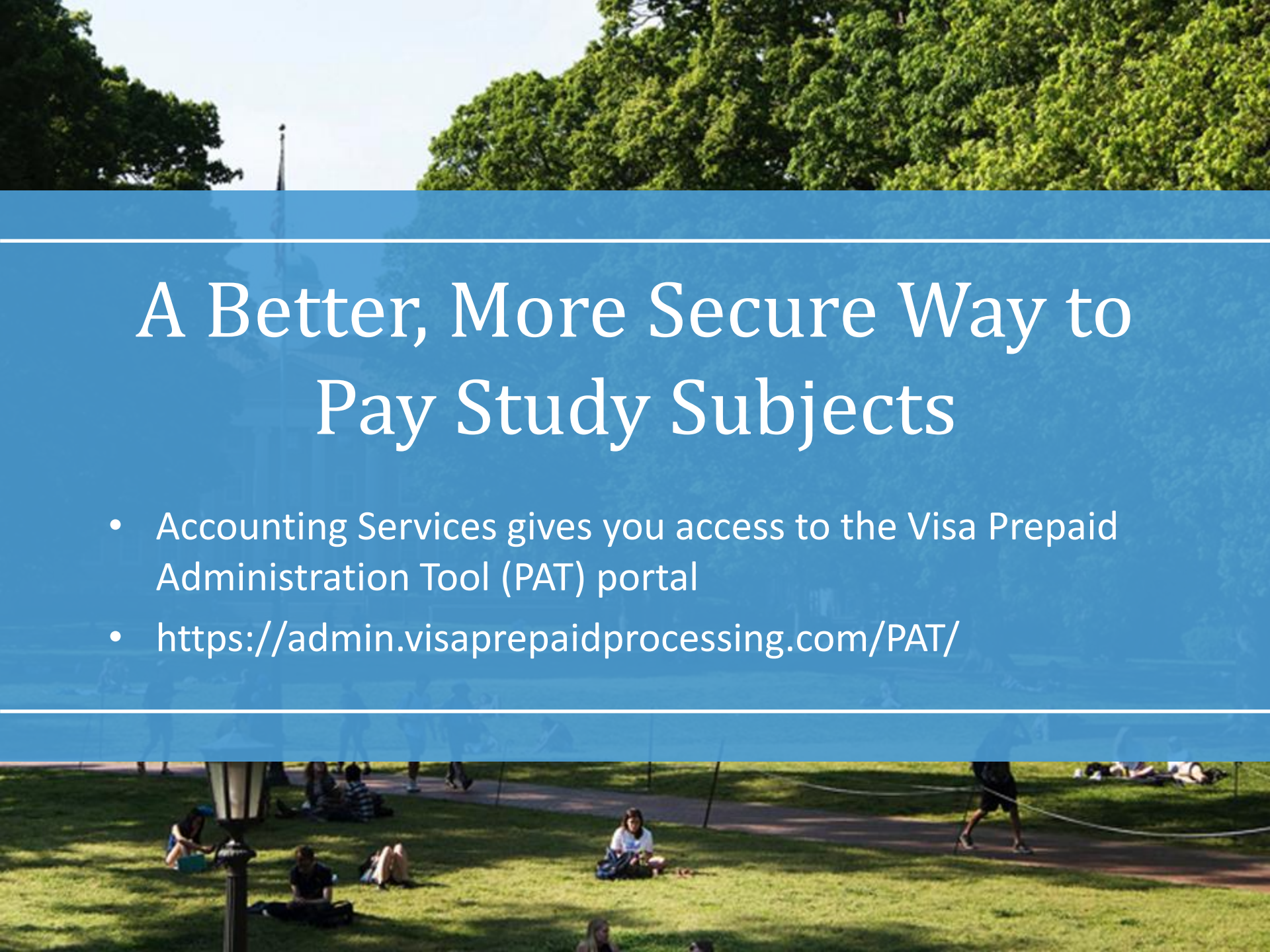
THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Prepaid Card Program

Brett Kenney
University Cash Manager
Accounting Services



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL



A Better, More Secure Way to Pay Study Subjects

- Accounting Services gives you access to the Visa Prepaid Administration Tool (PAT) portal
- <https://admin.visaprepaidprocessing.com/PAT/>



- Accounting Services is phasing out imprest checking accounts in FY 2019
- Prepaid Cards allow you to instantaneously load money onto cards
 - Issue in person
 - Mail to recipients
- Two types of cards – Reloadable Charge (RC) & Anonymous

Prepaid Card Process

1. Request project setup from Cash Management
2. Complete Prepaid Card Setup Form
3. Submit to Cash Manager
4. Request routed through OSR (if a sponsored project)
5. Project is set up in the PAT
6. Order, Load, and Reconcile



Prepaid Card Program – THE GOOD

- No charge to order cards or load money onto cards - project charged the amount loaded
- You can keep an inventory of cards on hand
- PAT runs reports to show what you have ordered and loaded
- Training is available for users/administrators



Prepaid Card Program – THE BAD

- PAT does not interface with ConnectCarolina
- Every new study requires a new set up form
- If you administer different studies, you will have multiple user ids and passwords
- Fees are deducted from the money on the card depending on its use
- PAT users must reconcile their expenses in ConnectCarolina via journal entry by the 15th of the next month



Questions?

Brett W. Kenney
University Cash Manager
Brett.Kenney@unc.edu
919-962-1601



UNC

THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

Research Coordination
& Management Unit



RCMU

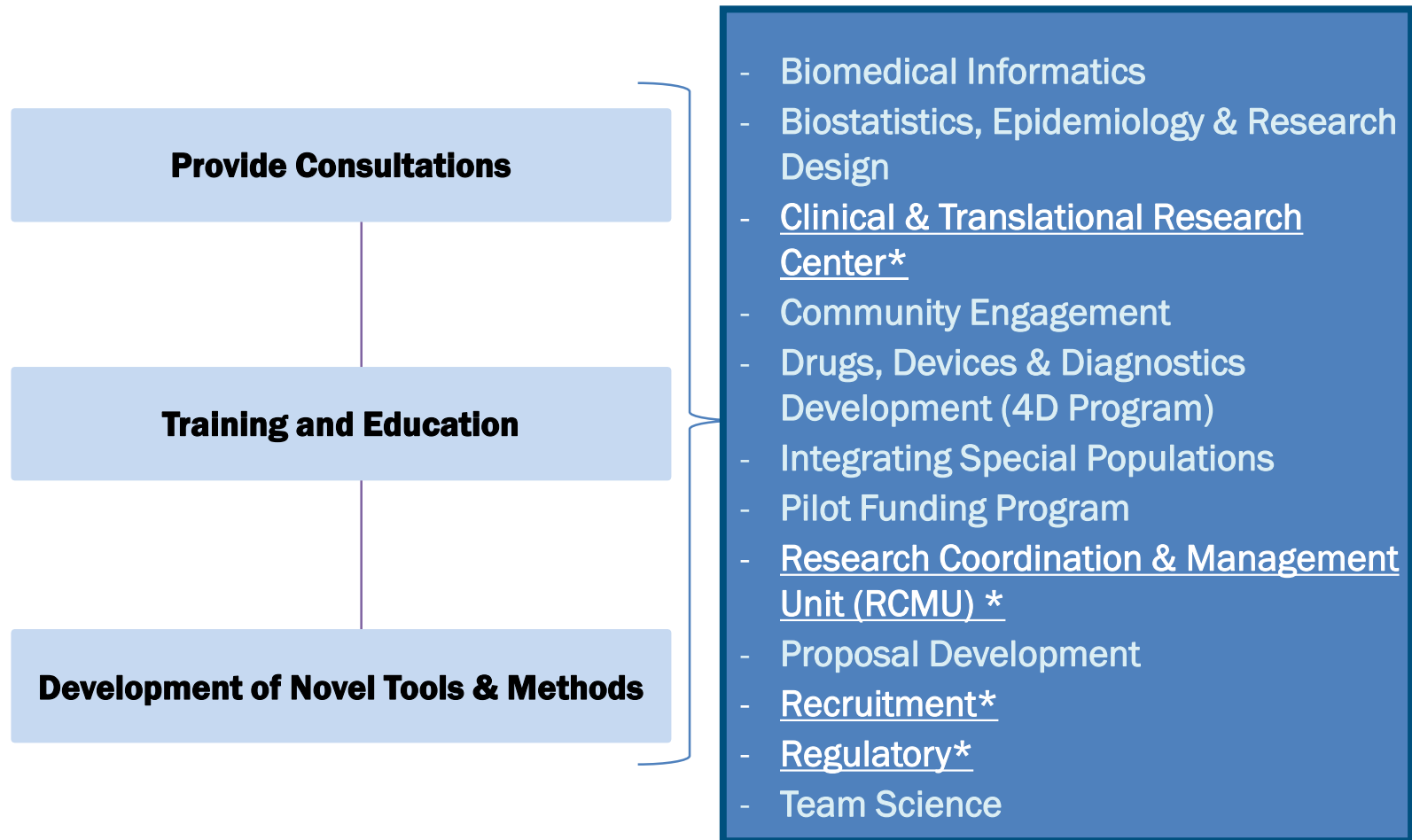
A new service of the NC TraCS Institute



UNC

THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

NC TraCS *Integrated hub of the CTSA at UNC-Chapel Hill*



Research Coordination & Management Unit

Professional, experienced study coordinators equipped to provide a wide range of study coordination activities to UNC and UNCHCS investigators, ensuring regulatory compliance, procedural efficiency, and data collection best practices.



UNC

THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

Identifying and Addressing Needs

Looking for ways to support investigators to conduct more high-quality clinical and translational research with less burden and challenges



Extensive hiring and onboarding process



Project work often doesn't require full-time coordinator



Coordinator training and development takes time and expertise



Managing and maintaining employees can be challenging



UNC

THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

Centrally Managed, Experienced Coordinators



Mentoring



Continuing
Education



Professional
Development

Rigor and Quality



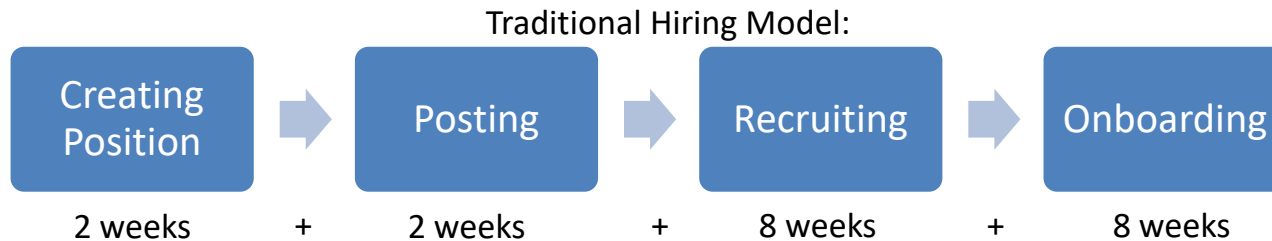
Regulatory
Compliance

Procedural
Efficiency

Data Collection
Best Practices



Quick Start-up



VS

**RCMU coordinator ready to
begin work in days!**

Pay Only for Hours Needed

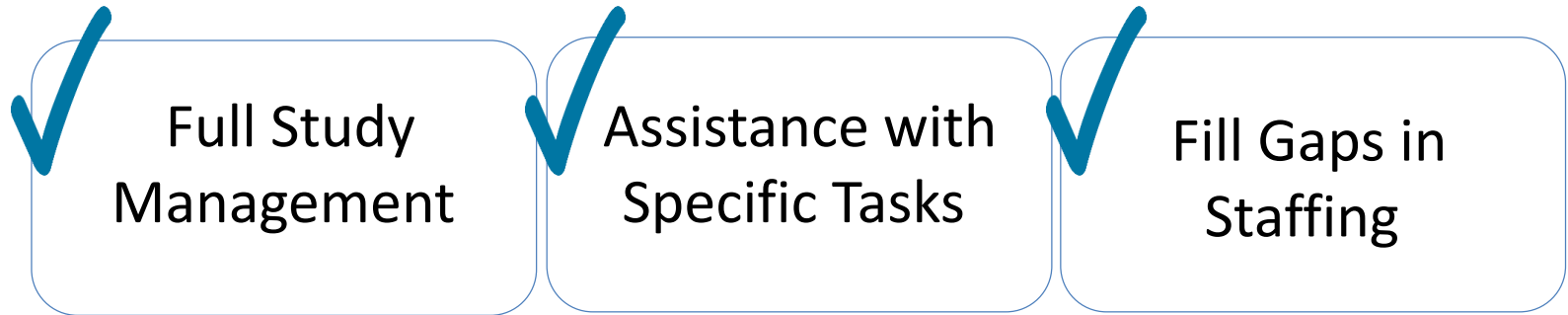
Full-time or % FTE Model

- Estimates are imprecise and variable
- Pay salary for
 - holidays, vacation, sick time
 - general administrative efforts
 - development time

VS

Hourly Model

- Don't pay for hours not worked
- To-the-minute time tracking
- Development activities supported at no direct cost
- Back-up provided at no additional cost



RCMU Model:

- Ideal for projects needing less than 20 hours of effort per week
- Coordinators assigned based on experience, proficiency, interest and availability
- Project manager and coordinator trained on protocol
 - Collaborative approach to ensure quality and best practices
 - Back-up provided to cover absences

Start-Up

- Feasibility assessment
- Regulatory submissions
- Create forms
- Develop budgets
- Train existing staff

Study Execution

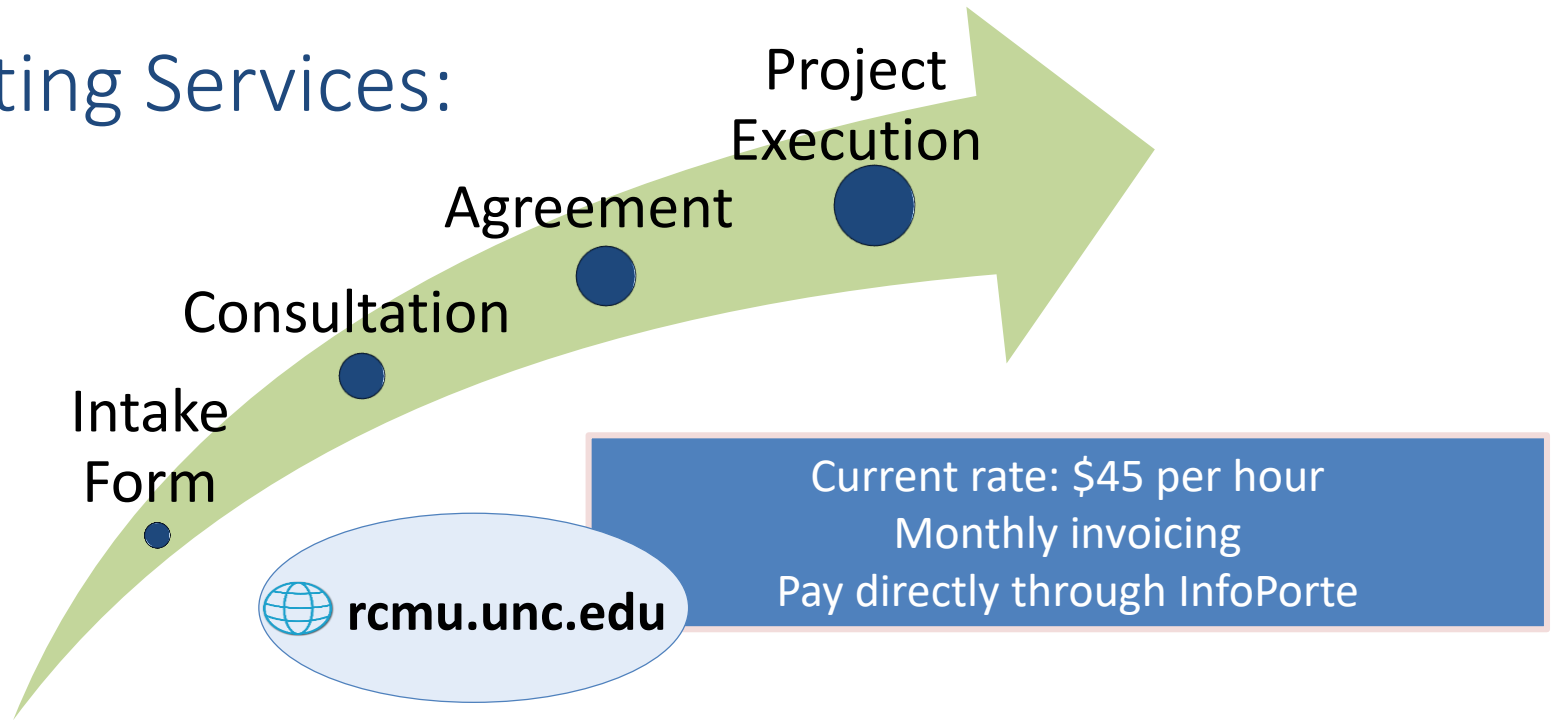
- Recruit and enroll participants
- Conduct study visits
- Collect data
- Process specimens
- Regulatory management

Close-Out

- Perform quality reviews
- Complete and organize records
- Financial close-out
- Manage data queries



Initiating Services:



Utilization since April, 2018

11 Active Projects



10 Principal Investigators



9 Departments



5 Sponsor Types

3 NIH, 3 TraCS, 3 Industry, 1 Foundation, 1 Internal

Project roles include:

- Recruiting participants via email and phone
- Full study coordination
- Project management and staff training
- Study start-up and procedure optimizations



UNC

THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

PI Customer Feedback

- “I thought for sure that there would be no way we could meet our goal. However, now, after seeing how efficient and effective RCMU is, I am confident that we will meet our goal and I am thrilled!”
- “As a junior faculty investigator, I’ve greatly appreciated the RCMU staff’s expertise and experience in clinical research coordination. It’s also been a pleasure working with RCMU and seeing my staff work collaboratively alongside them. I consider them valued members of the study team.”
- “Initial hesitation with “outsourcing” was relieved by knowing Laura’s commitment to excellence and training of her staff.”
- “Truly, this service saved my project and my sanity!!”
- “This project is my first R01 and my baby. It means so much to me. I feel like I’m in good hands with RCMU. To extend the metaphor, I feel like RCMU is the best, most experienced, most responsive, and unperturbable nanny that my research-baby could have. 😊”



UNC

THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

Thank you!

Visit our website:

rcmu.tracs.unc.edu

Contact us directly:

rcmu@unc.edu



UNC

THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Certificates of Confidentiality

John Roberts
Compliance Manager
Office of Human Research Ethics

Certificates of Confidentiality

A Certificate of Confidentiality (COC) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena.



Who may obtain a COC?

- COCs are independent of funding source - research that is **unfunded**, funded by **industry** or a **foundation**, or **federally funded** all may use a COC to provide added protections pertaining to the information collected for research purposes. Although the COC is issued by a federal agency, the research does not have to be federally funded to be issued a COC
- Investigators and research teams not receiving federal funding may decide on their own to apply for a COC or the IRB or sponsor may request they obtain one from NIH depending on the nature of the research
- Research exploring 'Sex, drugs and rock and roll' will often be asked to obtain a COC to protect information about drug use/testing, sexual history or behaviors, and illegal or illicit behaviors. COCs not only protect against forced disclosure of the information collected, but also may encourage subjects to respond truthfully if the information they provide to researchers will be protected from disclosure
- Currently just over 300 active research projects at UNC have applied for and been granted a COC by the NIH, includes biomedical and social/behavioral research projects



Application Process for COC

- Application form provided on COC Kiosk at the NIH website:
<https://humansubjects.nih.gov/coc/index>
- Application packet for NIH includes 4 items:
 - 1) Completed COC application form
 - 2) UNC IRB approval letter
 - 3) UNC IRB approved consent with COC language
 - 4) Assurance letter – provided by UNC IRB when COC request reviewed (check of IRBIS application, COC application, consent)



Relevant Questions in IRBIS Application:

Section A.10 Confidentiality of the Data

A.10.3 Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc? Yes/No

If yes, describe the sensitive data being collected

A.10.4 Do you plan to obtain a federal Certificate of Confidentiality for this study? Please note that all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable information is automatically issued a Certificate of Confidentiality (CoC). You should also select “Yes” if your study is NIH funded and has been issued a CoC under this updated NIH policy. Yes/No





NIH Policy Update



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

NIH COC Policy Updated

- Policy update a reaction to the 21st Century Cures Act, section 2012 <https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf> which in part reads

SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH SUBJECTS.

(a) IN GENERAL.—Subsection (d) of section 301 of the Public Health Service Act (42 U.S.C. 241) is amended to read as follows:

“(d)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

“(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

“(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.



What is new after the NIH policy update?

- NIH funded research no longer has to **apply** for a COC, but is issued one as a term and condition of the NIH award.
- Applies to NIH funded grants, cooperative agreements, R&D contracts, other transaction awards, and NIH intramural research
- Research in which identifiable, sensitive information is collected or used including research that
 - Meets the definition of human subjects research, including exempt research in which subjects can be identified
 - Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable
 - Involves the generation of individual level human genomic data
 - Involves any other information that might identify a person



What is new after the NIH policy update?

- Applies to research funded in whole or in part by NIH, and was
- Commenced or ongoing on or after December 13, 2016 (the enactment date of the 21st Century Cures Act)
- Paper COC document no longer issued for NIH funded research
- NIH policy broadens the idea of *sensitive* research data. Previously considered *sensitive* to be related to 'sex, drugs and rock and roll'. Now *sensitive* essentially = identifiable
- COC is valid during the **funding period** of the NIH award. Research which still needs to apply for a COC (non-federal) will have an expiration date when their COC is issued
- If research continues after the funded period, investigators may apply for extended COC protections as any non-federal project would via an application through the NIH COC Kiosk



UNC IRB's response to policy update

UNC Counsel updated the COC consent language linked to question A.10.4 to be more inclusive of the broadened protections:

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.



UNC IRB's response to policy update (cont.)

Added alternative, shortened language for use in the international setting and some exempt and minimal risk research:

What is a Certificate of Confidentiality?

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.



UNC IRB's response to policy update (cont.)

- Updated IRBIS Application question A.10.4 to include reference to the NIH policy
- Since fall of 2017, UNC IRB has been asking investigators impacted by the NIH policy update to revise their response to question A.10.4 and to insert COC language into any consent forms that remain in use. All initial and renewal reviews of expedited research, and all full board agenda submissions are evaluated for relevance.
- Created a Notice that may be provided to previously enrolled research subjects who continue to participate or will have future visits for research, provided via link from the May 21, 2018 communication to the UNC research community:
<https://research.unc.edu/2018/05/21/nih-policy-change-regarding-certificates-of-confidentiality/>



What should investigator's do now?

If you are an investigator or research team that received NIH funding for your research and your project meets the criteria described in the policy update, you may

- proactively submit a modification in IRBIS to revise question A.10.4 and insert COC language into your active consents
- Review the FAQs on the NIH COC kiosk for additional information about the COC here <https://humansubjects.nih.gov/coc/faqs>
- DO NOT release any information collected for research purposes without consulting the IRB or UNC Counsel first if you have questions
- If you believe you were instructed to reflect issuance of a COC in your IRBIS application in error, please contact the UNC IRB



Resources & Additional Info

- NIH COC kiosk: <https://humansubjects.nih.gov/coc/index>
- COC background information:
<https://humansubjects.nih.gov/coc/background>
- COC FAQs: <https://humansubjects.nih.gov/coc/faqs>
- UNC communication to research community May 2018:
<https://research.unc.edu/2018/05/21/nih-policy-change-regarding-certificates-of-confidentiality/>
- NIH policy change notice:
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>



Questions
