REBOUNDING WITH RESILIENCE

2023 SYMPOSIUM FOR RESEARCH ADMINISTRATORS

CONCURRENT SESSION | MARCH 15, 2023

Human Subjects Project Management for Non-Industry Grant Manager

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Session Objectives

- Explore the answers to frequently asked questions related to human subjects focused in several areas:
  - General Clinical Trials
  - PHS Human subject forms
  - ASSIST Human Subjects Records for RPPRs
  - ClinCard
  - Budgeting for human subjects
  - General questions

What kind of human subjects research are you most familiar with?

General Human Subjects Research

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GATE 00
ROW AA
SEAT 01X

1. How do I know if what I am working on is Human Subjects Research?

- Ask yourself a couple of questions:
  - Is the project "research"?
  - Does it meet the definition of "human subjects" research?
    - Defined by: research involving existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are identifiable.
  - The NIH has a decision tool that can assist investigators and grants staff to determine whether it's human subjects research, may be considered exempt from Federal Regulations or it is not considered human subjects research at all.
    - Tool: https://grants.nih.gov/policy/humansubjects/hs-decision.htm

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2. What are some examples of types of Human Subjects Research?

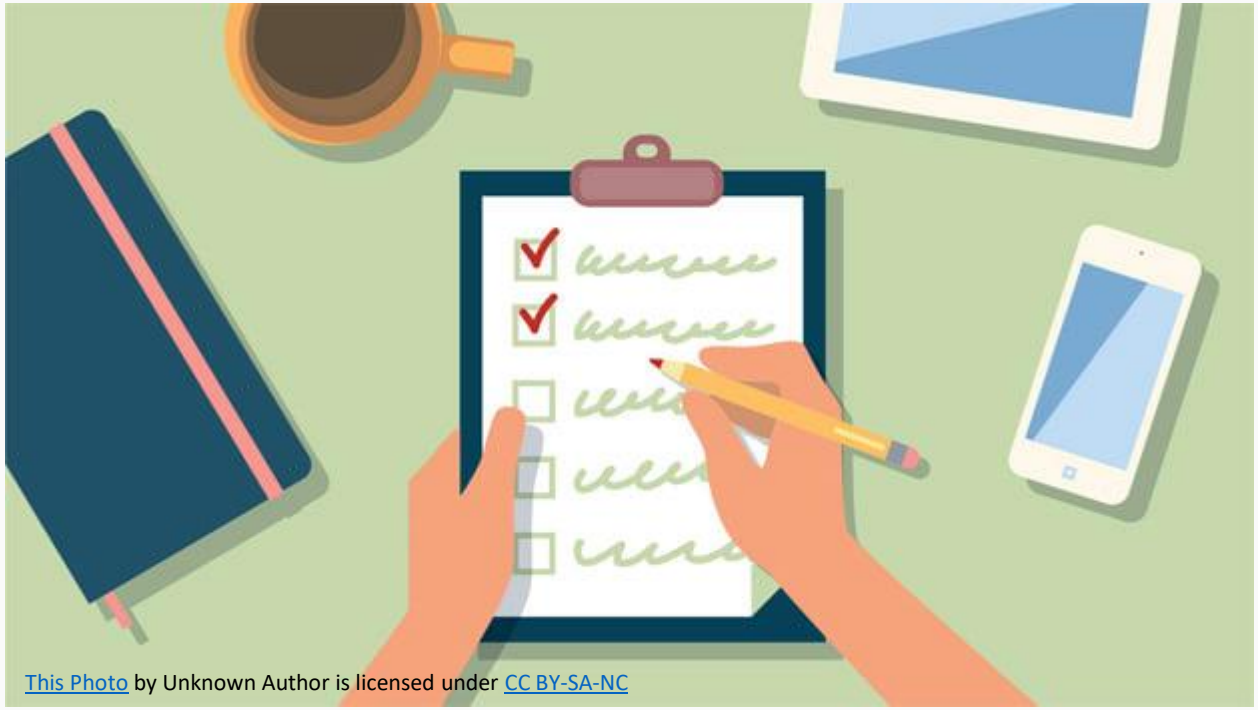
- Analysis of Existing Data or Specimens
- Observational Studies
  - Records observations and analyzes data, without assigning participants to a specific intervention or treatment
  - Might look at natural history, variations in disease progression, or risk factors
- Interventional Studies
  - Manipulation of the subject or the subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.

3. Are there different definitions of a Clinical Trial?

- Yes. Examples include:
  - ***NIH*** *defines a clinical trial* as a research study in which one or more human subjects (aspect 1) are prospectively (aspect 2) assigned to one or more interventions (which may include placebo or other control) (aspect 3) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (aspect 4). All four aspects must be present to be defined by the NIH as a clinical trial.
  - ***ClinicalTrials.gov*** *defines clinical trials as* a type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.
- FAQs for determining NIH clinical trial status are helpful here: https://grants.nih.gov/faqs#/clinical-trial-definition.htm?anchor=header11537
- For Duke specific CT.gov questions, reach out to DOCR-CTGOV@dm.duke.edu

4. What is the purpose of CT.gov?

- ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world. CT.gov is managed by the U.S. National Library of Medicine
- **2017:** NIH implemented a new policy, "NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information"
  - All studies funded in whole or in part by NIH that meet NIH's definition of 'clinical trial' must register and submit results on CT.gov, as a term and condition of the award
- **2021:** NIH introduced RPPR system validations with CT.gov to help monitor compliance with the policy



PHS Human Subjects Forms

How do you collect information for Human Subjects Studies Tab?

1. Does the human subjects form still need to be filled out if the PI is only using existing data?

- Yes, if the question to whether the study will involve human subjects is marked yes, then the forms should be completed

2. When is human subject research considered exempt from IRB review?

- Exemption is reserved for benign research that poses little to no risk to participants. You can find the definition of the exemption categories on the IRB protocol form.
- The IRB is the only entity who can determine that a study is exempt from review (ie: not a PI).

3. What is the difference between Exemption #4 and Non-Human Subjects Research?

- Exemption 4: involves the collection/study of data or specimens if publicly available, or recorded such that subjects cannot be identified
- Under some circumstances, research involving only unidentifiable/de-identified or coded private information or biological specimens is not human subjects research because investigators cannot readily ascertain the identities of the individuals to whom the data or samples belong.
- https://campusirb.duke.edu/resources/guides/defining-research-human-subjects
- https://campusirb.duke.edu/irb-policies/exempt-research

ASSIST Human Subjects Records for RPPRs

1. I am working on an RPPR and received a warning regarding G.4. How do I address this?

- When submitting an RPPR, NIH expects an update on human subject participation.
  - Within the RPPR, navigate to section G.4 and click through to the associated ASSIST record.
  - If the ASSIST record is in “submitted” status, you will need to work with your pre-award rep to update the status to “work in progress” before the PI or grant manager can edit the record.

2. Common Warnings/Errors Related to G.4

- “G.4.b No cumulative enrollment data has been provided to Study #XXXX, is this correct? If enrollment has not begun, you may proceed and submit the RPPR. If participants have been enrolled, navigate to section G4.b and update inclusion enrollment data…
  - Check with the PI to determine if enrollment has begun. If it has, the date of first enrolled subject should be entered. If enrollment has not started, ensure the "anticipated date" of the first enrolled subject is in the future
- "G.4.b Updates to Inclusion enrollment report(s) have not been made for study #XXXX. If updates are needed, navigate to G.4.b of the RPPR to access this study and update inclusion reports."
  - If enrollment has started, PI/study team needs to add the enrollment data into the cells provided online, or utilize the provided Participant Level Data Template to upload enrollment details.

3. Which fields are part of the system validation? ClinicalTrials.gov and the RPPR

ASSIST		ClinicalTrials.gov	
*Section	Field	Section	Field
Section 1	Study Title	Study Identification	Brief Title
Section 2	Conditions or Focus of Study	Conditions	Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study
	Eligibility Criteria	Eligibility	Eligibility Criteria
	Age Limits		Age Limits
	Recruitment Status	Study Status	Overall Recruitment Status
Section 4	Detailed Description	Study Description	Detailed Description
	Primary Purpose	Study Design	Primary Purpose
	Interventions	Arms and Interventions	Interventions, including Intervention Type and Intervention Name(s)
	Study Phase	Study Design	Study Phase
	Intervention Model		Interventional Study Model
	Masking		Masking
	Allocation		Allocation
	Outcome Measures	Outcome Measures	Primary Outcome Measure Information
Section 6	Study Primary Completion Date	Study Status	Primary Completion Date
	Study Final Completion Date		Study Completion Date
	Enrollment of the first participant		Study Start Date

*Section under 5.1 Human Subjects & Clinical Trials Information Form

While these fields are part of the system validation, not every field will flag an RPPR error if there is a discrepancy

4. Which errors will hold up my submission? ClinicalTrials.gov and the RPPR

- Most validation errors we see are related to discrepancies in the **Study Start Date** and **Completion Date** fields
  - These dates have very specific definitions in CT.gov
  - The CT.gov definitions should always be used when determining the appropriate dates for entry in the RPPR
- Primary and Study Completion dates refer to final **data collection** for the study outcome data. They are not related to the status of the IRB or the grant
- DOCR assists study teams in making sure the dates on CT.gov are accurate

ClinCard

1. What are the expenses associated with the ClinCard? Are they allowable on federally sponsored research projects?

- Yes, please budget for the use of Duke ClinCard!
- Cost of the Card
  - One time cost of $4.90 of issuing the card to the research participant
  - This is not an allocable cost and cannot be applied to individual federally funded grants (because the card can be used across multiple studies).
    - Clinical Research Units will charge this fee to their Hub Code instead.
- Load Fees
  - $1.15 Load Fee per transaction. We suggest minimizing load fees by bundling transactions.
  - The load fee can be charged to all funding sources, including federal grants.

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2. How do I know who to ask in my department about budgeting for ClinCard fees?

- Your department will have a Department Administrator in charge of setting up all protocols with ClinCards.
- They may ask you to provide an estimate for the number of subjects so they can make sure to have the correct number of cards on hand.

3. I get a new fund code for my reportable sponsored project, how does that get updated?

- The Site Administrator needs to submit a form to update the fund code on the project in ClinCard so that the correct fund code is used when the payments are authorized.
- Make sure to reconcile the new fund code on the Personal Data Disclosure form submitted to you by the CRC/research team to process ClinCard approval in the ClinCard system.

4. Are there specific general ledger accounts for Duke ClinCard expenses?

- Are there specific general ledger accounts for Duke ClinCard expenses? Yes!
- 622510 – Experimental Subject Payments, ClinCard (used to record the cost of the payment)
- 622520 – Experimental Subject Load Fee (used to record the cost of the load fee incurred by the milestone payments)
- 622530 – Experimental Subject Card Fee (used to record the cost of the card for use by the study)

6. What type of back-up documentation do we need for ClinCard payments?

- ET&R has established a shared folder on the protected directory for departments utilizing gift cards/ClinCards to pay experimental subjects.
- You must have access to the Protected Directory to process ClinCard payments.
- Prior approval from ET&R is required for gift cards, non-monetary items, SSN waivers. No PHI should be uploaded into SAP. The approval from ET&R is provided via email and you should have that on file for reference.

ClinCard Resources:
- GAP 200.420, Processing Payments to Research Participants
- Training Resources: https://finance.duke.edu/travel/resources/experimental
- For questions regarding payments to research participants: clincard-request@duke.edu

Budgeting for Human Subjects

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1. What are some of the things I need to consider while budgeting for human subjects research?

- Determine financial feasibility
- Determine actual costs to conduct the study
- Account for inflation for studies across multiple fiscal years
- For federal prime budgets, always use our negotiated F&A rate
- If budget is provided to you (sometimes with capitation budgets), determine if the sponsor's budget proposal covers actual costs of the study
  - If you were given the amount from the sponsor, put a note in the proposal memo field.
  - Communicate this on the Closeout Tasklist

2. How should I get patient care costs to include in a budget?

- In the SOM, work with your PI, RPM, and/or FPM to obtain the correct CPT codes, then each expense can be found by your FPM or manager within the Chargemaster
- Report includes both Technical and Professional pricing. Don't forget to include both when building a budget!

Charge Master Pricing Look Up Report

*Radiology procedures have codes, separate from CPT codes, that may impact how a procedure/test is budgeted. Bypassing the Radiology review process may increase the risk of incorrect/under budgeting of a Radiology procedure/test.

**Bypassing the Revenue Manager for pricing of bundled procedures may increase the risk of missing all items associated with the procedure.

Report run: 03/08/2023

Charge Master Version: 2 - 07/31/2020

Event Description	Item Code	Item Description	Retail	Research
Event Type: Lab				
12-Lead ECG (Initial Preventive Examination)	76101280	HC IPPE MEDICARE SCREEN ECG(PDC)	$ XX.XX	$ XX.XX
12-Lead ECG (Initial Preventive Examination)	G0403	PR EKG FOR INITIAL PREVENT EXAM	$ XX.XX	$ XX.XX

2. How should I get patient care costs to include in a budget?

- Research rate is the amount that will be charged to your fund code
- Retail rate is the amount used when negotiating a margin in an Industry budget
- Patient care costs, charged through Maestro Care for Federal clinical research will not incur F&A (MTDC)
- Patient care costs, charged through Maestro Care for Industry clinical research will be charged F&A (TDC)

3. What about labs? What are they and how do they get charged to my project?

- Lab tests ordered through Maestro Care and resulted through DUHS labs will be charged to your grant through Maestro Care. For Federal sponsors, F&A will not be applied (MTDC)
- Lab tests sent out to a vendor and not resulted through Maestro Care will be charged to your grant. F&A charges will apply.
- It is important to ask the question if you see "labs" in your PI's budget.
- All activities through a SOM service center (including labs, imaging, etc.) will incur F&A

4. How do I know what F&A rate to use? (federal = 61%)

- Federal Rate = 61%
- You should not circumvent the research F&A rate by using a different activity type if the activity is truly research.

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5. What should our concerns be with data storage? If a proposal has a large dataset purchase or data analysis piece, should we be building in cost for storing data on secure servers?

- Yes. If data is coming into Duke, the owner of data will consider how sensitive the data is and establish security minimums for securing data.
- There may or may not be a need for additional storage security for the data, however that is dependent upon each dataset.

6. Can you charge institutional IRB fees to federal projects?

- Federal, foundation/nonprofit studies are exempt from IRB review fees
- You can charge the effort associated (for example, CRC, RPL, PI) with submitting/amending IRB protocols to the associated grant/contract, if the sponsor allows.

General Questions

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1. Who needs to complete Section 6 of the close out tasklist (for Human Subjects)?

- Neither SOM or Campus AMT rely solely on the programmatic attribute to do a Tasklist review. Programmatic attributes should be verified by the department after the project is started up – same as validating any other master data point, it shouldn't wait until closeout.
- We are relying on the GMs to understand the nature of the research prior to doing the Tasklist. Whether that's clinical or exempt or totally non clinical, what matters most is what work occurred and did we have all the approvals in place for this work to occur. That should be understood by the GM during the life of the grant and not something that is news at closeout.
- Trick of the Trade: Pay attention to the G/Ls of expenses in SAP. You can mark N/A to human subjects, even if the program attribute is SCI and you have an IRB, if there are **no human subjects expenses**.

2. As a Grant Manager, how do I make sure to accurately fill out Section 6 of the Closeout tasklist?

- For clinical trials, you'll need to work with the person in your unit (most likely the FPM) to run the appropriate reports and verify for you.
- If the human subject research does not enroll subjects or have patient care charges, the answers to some of the questions will be "N/A - No patient care charges".

3. What is the procedure for Non-Industry Sponsored Clinical Research Codes?

- The CRU is to ensure a process is in place to be notified of study closure.
- Once the Study Team attests that the study is complete, the CRU, along with the grants administrator, must determine if WBSE closeout is appropriate.
  - All studies that are funded by this WBSE are complete
  - The financial reconciliation & closeout is complete
  - Closure (Deactivation) of the WBSE is appropriate
- Workflow:
  - For the SOM, the workflow for the Electronic Closeout Tasklist, should include the Research Practice Manager (or Assistant Research Practice Manager or Clinical Research Coordinator III Lead) and Financial Practice Manager (or Primary Grant Manager) as additional approvers if they are not already in the workflow.
  - For campus, the ETL is reviewed by the department first (GCA's GCM). Once approved by the dept, it moves to CAMT for review and approval

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3. What is the procedure for Non-Industry Sponsored Clinical Research Codes?

- CAMT/ORA will review the Closeout Tasklist, and Obligation Worksheet (if applicable), and follow up with the submitter regarding any questions or issues that require resolution before approving the Closeout Tasklist.
- Once completed/approved, the Closeout Tasklist is imaged and available for retrieval. Once all required forms are completed, OSP can complete their review and submission of the final financial action (invoice and/or report), and close the WBSE.

4. Do we all use the same IRB for review?

- No, just like we have separate pre-award offices we have separate IRB offices for review.
- Campus primarily uses Campus IRB (CIRB) but dependent upon the research being performed, they may be required to go through DUHS IRB. See link for further details. https://myresearchpath.duke.edu/selecting-appropriate-irb-guidance
- https://campusirb.duke.edu/campus-institutional-review-board

Questions?

Thanks for attending this session. As you exit, you will be able to complete a brief survey. If you have additional feedback or questions, please contact OERAF at ResearchFinanceEd@Duke.edu.