CLINICAL TRIALS-CLINICAL RESEARCH COORDINATOR- FREQUENTLY ASKED QUESTIONS

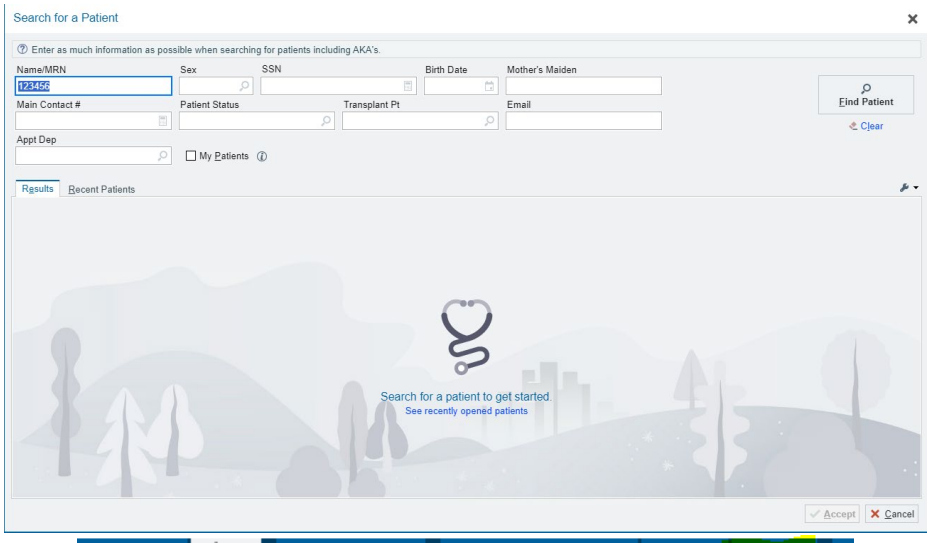
Revised May 30, 2025

OVERVIEW – CRC FAQ

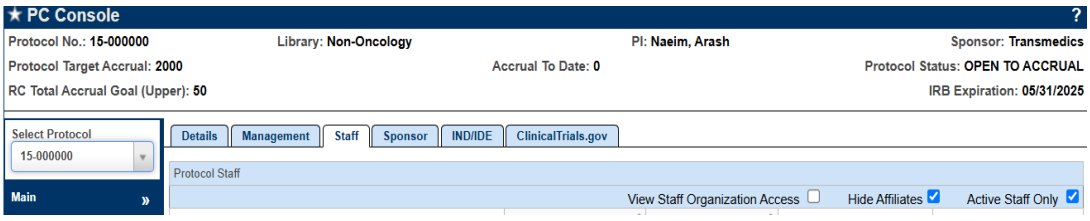
- **Description:** This provides answers to basic questions and scenarios that can come up in the Clinical Research Coordinator role at UCLA.

FREQUENTLY ASKED QUESTIONS

1. **Where can you find patients previous health records/doctors notes?**
   - Login to **CareConnect** > Go to **Chart** > Search for Patient's MRN and Select their chart > Click the **Chart Tab** > Select the **Notes** or **History tab**.



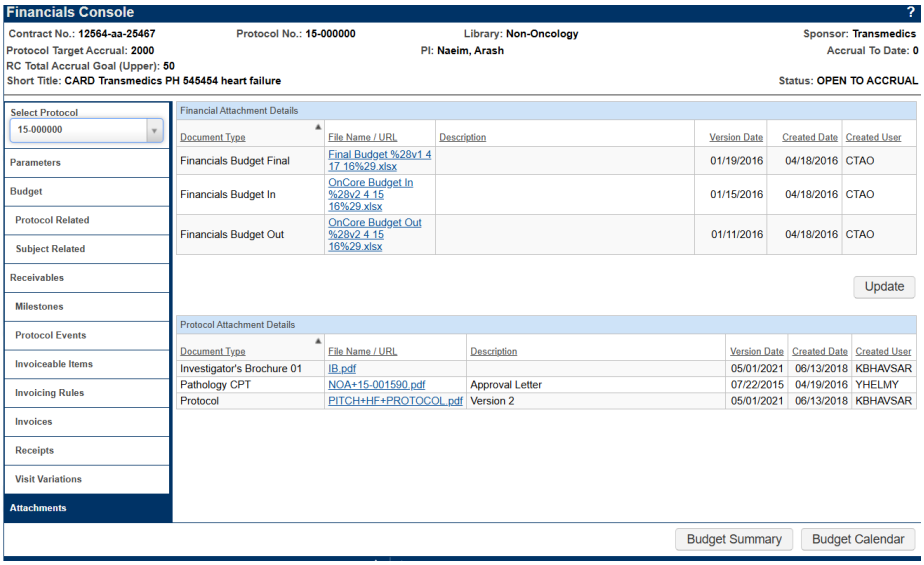
2. **Who can I contact about budget and contract related questions?**
   - Questions regarding **budget** can be directed to your Research Administrator. Your Research Administrator can be found in Oncore under **PC console** > **Main** > **Staff**.



   - Questions regarding **contracts** can be directed to the department contact with the contracts office - CTC & SR, TDG, and/or OCGA

     - Additionally, updates on status of study budgets can be found in OnCore: **Menu** > **Financials** > **Financials Console > Select Protocol** > **Attachments > Financial Attachment Details**

- Be sure to filter by **"Version Date"** which ensures the most recent document is reviewed – **"Budget In"** under **Document Type.** You will want to select the most recent budget in date that was certified



3. **Which program under the Department of Medicine can assist me in services for my research study team?**
   - If you are seeking services, such as study team staffing and/or study related services, please reach out to DOMCTP.

4. **Do coordinators handle any of the financial aspects throughout a study?**
   - Yes, CRCs may provide assistance during patient related expenses, which may include handling patient stipends and reimbursements.

5. **How do I prepare for a clinical monitoring visit?**
   - While most IMV meeting frequencies are sponsor specific, the materials required for preparation are similar. The research team will need to complete the following at minimum:
     - Receive and review the confirmation letter from the clinical monitor.
     - This letter outlines what will be reviewed during the monitoring visit.
     - Ensure all patient binders are organized and contain research related materials (i.e., PROs, Informed Consent Forms, etc.), and ensure the PI or sub-I's have signed off on any documents that require signature/confirmation of review.
     - Complete data entry in the electronic data capturing system
   - More information can be found on the CTSI Research Go website linked here.

6. **If my protocol calendar is incorrect, who do I need to contact?**
   - CRIS team, crisadmin@mednet.ucla.edu

7. **What information should I put in a study visit note in CareConnect?**
   - A study note can act as a case report form (CRF). Any new information regarding the patients' health and/or lifestyle and data regarding any other tests required for collection at the visit.
     - Make sure that at minimum each study visit is logged with the following information placed at the top*: Study Short Title, Site Number, Subject Number, and Visit Day/Week (date)*

8. **What is a protocol deviation?**
   - A protocol deviation is any departure from the procedures outlined in the approved research protocol.
     - For example, a lab that was required at Screening was not collected.

9. **What is a Note to File?**
   - A Note to File (NTF) is a documented note or memo that provides additional information or explanation about something that might not be fully captured in the standard documentation, or it clarifies a discrepancy that occurred.
   - A Note to File (NTF) template can be found through the Research Go website.
   - Remember when creating a Note to File for a study, the document must have the department letterhead and PI information, as well as any other UCLA approved language.

10. **Who is responsible for completing the Delegation Log of Authority (DOA)?**
    - Research coordinator and regulatory coordinator are both responsible. The study coordinator must provide the role of all staff and the proper coding listed on the DOA to the regulatory coordinator. The regulatory coordinator will then send the DOA for signature and return to the sponsor.

Form	Site Signature & Delegation of Responsibilities Log Protocol Number:		
Investigator Name:		Site Number:	Page of 5
Document Number:	FORM-02905 v5.0	Effective Date:	16 Jul 2022

STUDY TASKS KEY:

- Following task key should be used to assign the tasks delegated in the log.
- Numbers recorded can be consecutive numbers, or range, e.g., 1,3,5,6,7 or 1,3,5-7.
- Tasks should be aligned with the roles, expertise and training of the individuals.
- Tasks can be added, deleted or amended to cover study specific activities.

Tasks to be completed by Trained & Qualified Staff	
1. Conduct/Obtain Informed Consent (including eConsent)	23. Maintain Essential Documents- Investigator Site File
2. Obtain Medical/Medication History	24. Conduct pulmonary Function Tests (Spirometry)
3. Determine Eligibility- Inclusion/Exclusion Verification	25. Assess pulmonary Function Tests (Spirometry)
4. Subject Medical Care & Medical Assessments	26. Transmit pulmonary Function Tests (Spirometry)
5. Assess study related test results	27. Perform CT lung densitometry
6. Collect AEs	28. Assess CT lung densitometry
7. Assess AE/SAE causality	29. CT lung densitometry imaging upload
8. Receive/Assess safety notifications	30. Perform abdominal ultrasound with doppler
9. Conduct Physical Exams	31. Assess abdominal ultrasound with doppler
10. Laboratory samples collection	32. Abdominal ultrasound imaging upload
11. Laboratory samples management	33. Perform MRE
12. Liver biopsy samples collection	34. Assess MRE
13. Liver biopsy samples management	35. MRE imaging upload
14. Make (e)CRF entries, corrections and resolve queries	36. Perform VCTE
15. Sign (e)CRFs *[only to be used as succession plan for un-expected PI long term absences]*	37. Assess VCTE
16. ePROs oversight	38. Perform esophagogastroduodenoscopy
17. Use IRT	39. Assess esophagogastroduodenoscopy

11. **What is an Investigator Site File (ISF)? What should be filed in the ISF?**
    - The Investigator Site File (ISF) is the binder that contains all required information for the study, such as training logs, protocols, NTFs etc. While ISFs can be a physical binder, Florence eBinders is the digital version that can be utilized at UCLA to store these documents.
      - If your study team will utilize Florence eBinders, more information about use and training can be found here.
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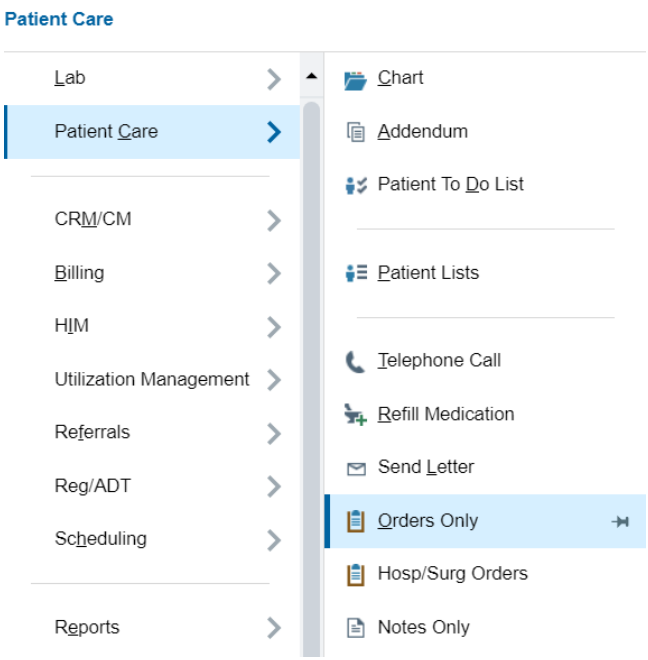
12. **What do I do if there is a PHI breach for a subject on my study?**
    - Below is the best course of action when dealing with a possible PHI breach:
        1. Notify your PI and regulatory coordinator as soon as possible
        2. Document the incident in the **Protocol Deviation or Non-compliance Report** and the **PAR Log** and send to your regulatory coordinator for review/submission to IRB
        3. Report incident to the Office of Compliance Services

13. **How do I know when to report a deviation or AE to the IRB?**
    - The principal investigator, with assistance from the clinical research coordinator, should complete the post-approval reporting (PAR) log and assess the risk and reportability. The investigator can utilize the UCLA OHRPP Decision Tree, which can be found here.

14. **What does it mean when there are "open queries" for a study? Who should answer them?**
    - Data Queries are generated for clarification or corrections to data, study documents, filing, etc.
        - Open or "active" queries mean that the CRA/Sponsor is still pending an answer or resolution to the queries.
    - The clinical research coordinator or data manager should answer the queries in the appropriate system. If the study team has a designated data manager, they may request assistance from the study coordinator or principal investigator to addresses open data queries.

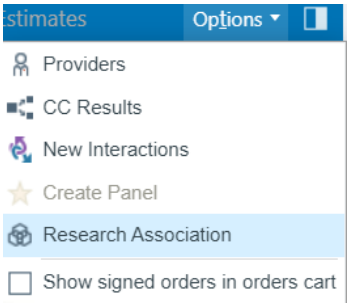
15. **How do I find approved documents that are ready to use for study purposes? (ICF, Protocol, etc.)**
    - Your regulatory coordinator can provide these documents to the study team once approved. The study team should file these documents in the ISF Binder or Florence eBinders.

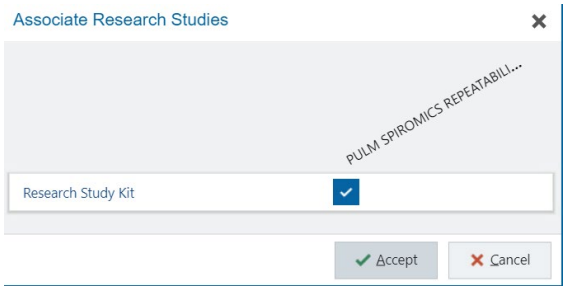
16. **How can I make sure my study visit is billed to the Sponsor and NOT to the patient's insurance?**
    - It is important to link all study related orders and encounters to the appropriate research study in CareConnect. Please follow the instructions below:
        - Log into **Care Connect** > search for the patient's chart > select **Patient Care** > **Orders Only**



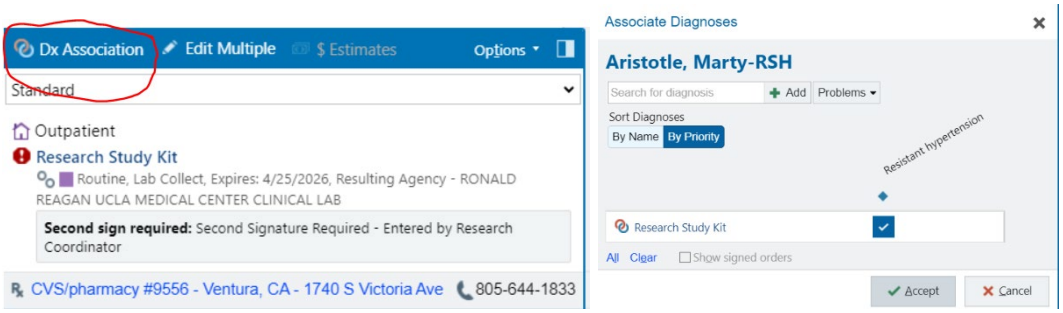
- Next, enter the orders for the research visit

- In the right-hand pop-up panel, select **"options"** > ***Research Association*** > ensure the box is checked > click **"Accept"**

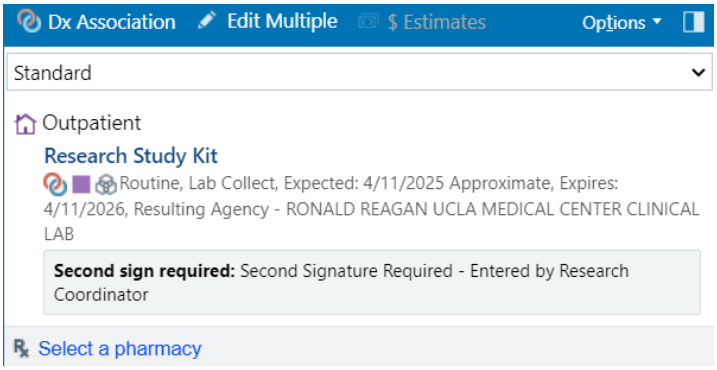




- Also ensure a Diagnosis is linked to the orders: select ***Dx Association*** > search for and select the medical diagnosis > click "**Accept**"



- Once completed, there should be icons for the Dx Association and Research Association on the order



- **NOTE**: This symbol  confirms an order or encounter is linked to research

17. **What happens if an order was sent to the physician, but it was not linked to research?**
    - If the order was sent for signature to the physician, but it was not linked to research, notify the physician and request that it be linked properly.

18. **What happens if a research encounter occurred but it was not linked to research?**
    - Be sure to notify your research administrator (RA) via email and provide the date of service, as well as emailing CRBP (uclahscrbp@mednet.ucla.edu) to ensure the charges are allocated to research and not billed to the patient's insurance.

CONTACT/RESOURCE

- UCLA DOM CTP (DOMCTP@mednet.ucla.edu) for further guidance and training, if needed.
- Research Go: ResearchGo | UCLA
- OHRPP: Contact Us | UCLA Office of the Human Research Protection Program
- UCLA Mednet Tipsheets: Knowledge Base