



Clinical Research Unit
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CRU Review of Ancillary Services Report

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Purpose

- To assist study teams in ensuring that CRU procedures/services are accurately accounted for in their study budget



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What is the responsibility of the study team?

- Submit a CRU Consult
 - Make sure to accurately reflect the anticipated needs of the CRU
 - identify all possible Arms/Groups that will use the CRU
 - study days/visits that will use the CRU
 - if ECGs, are they done on sponsor-provided equipment or UWHC
 - Provide a current detailed protocol
 - If CRU is expected to do sample processing, provide a lab manual



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What is the responsibility of the study team?

- Meet with CRU staff to review study needs (Consult meeting)
 - Become familiar with your study before the meeting
 - Discuss study needs
 - Confirm that procedures can be done on CRU
- Contact CRU staff (CRUProtocolTeam@uwhealth.org) in advance of the OnCore submission with specific questions.
- Submit budget in OnCore.



What is the responsibility of CRU staff?

- Consult is received by CRU nursing and administrative staff
- CRU nursing staff reviews submitted Consult and protocol for CRU needs
- CRU nursing staff schedules a Consult meeting with study staff



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What is the responsibility of CRU staff?

- CRU nursing staff meets with study team to go over study needs
 - Confirms days/visit, study-specific needs
 - Confirms who is responsible for what, are there special drug administration needs, are there special processing needs, is special training needed, etc.



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What is the responsibility of CRU staff?

- Benefit of the meeting: Discuss possible CRU procedures, which ensures that all possible CRU inpatient days / outpatient visits are accounted for

Example: A Consult requested only two visits per subject in the Consult; after Consult meeting it was determined that one of the study visits needed to be inpatient, and other visits were needed because of ECGs on sponsor equipment; ended up needing 1 inpatient day and up to 9 outpatient visits per subject.



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What is the responsibility of CRU staff?

- Administrative staff reviews ASR when submitted in OnCore



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How does CRU review an ASR?

- CRU administrative staff receives ASR from OCT (Jen Parnell)
- Days/visits on ASR are compared with Consult application and notes from meeting with nursing staff
 - Any differences are discussed with CRU nursing staff (i.e., may have discussed changes at Consult meeting)
 - If changes were not already discussed with CRU staff, study team is contacted



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How does CRU review an ASR?

- Find Study Procedures Table or find per visit outline of study days/visits (or both)
- Determine all possible CRU procedures



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How does CRU review an ASR?

- The following is considered when reviewing:
 - Is there a medication given? Is it oral or IV?
 - If IV, over what period of time is it given?
 - Are there premeds or other meds given by IV?
 - Are IV fluids needed for hydration (that aren't related to the study drug infusion) (e.g., for TLS prophylaxis)
 - Are there study-defined timepoints for vital signs?
 - If not, CRU minimums apply



How does CRU review an ASR?

- Are there research blood draws (i.e., study kits; currently does not include labs sent to UWHC Lab)
 - Identify the possible timepoints – blood draws are charged per timepoint
- Identify who is doing the sample processing, CRU or an investigator lab (e.g., 3P).



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How does CRU review an ASR?

- If CRU is doing the sample processing:
 - Identify the various research samples (e.g., PKs, PDs, biomarkers, urines, slides, etc.) – charged per tube/sample processed. (More if “double processed” or special tube handling needs to be done by CRU staff.)
 - A lab manual is usually needed for this; the protocol and Study Procedures tables usually do not provide enough detail.
 - Sample processing is charged by tube / sample / syringe processed.



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How does CRU review an ASR?

Examples of why a Lab Manual is needed:

- A Study Procedures Table in a protocol has PK samples Study Drug X and Study Drug Y as two separate lines, so it would be counted as 2 samples per timepoint. The Lab Manual was received later and indicated the samples were from the same tube.
 - Result: Accounted for too many sample processing charges.
- A Study Procedures Table and the Protocol described a PK sample for Study Drug A, but the sample involved the drawing of 2 tubes per timepoint.
 - Result: Did not account for enough sample processing charges.



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How does CRU review an ASR?

- Are ECGs, Holters or Spirometry being done on a sponsor-provided machine?
 - If so and CRU staff are performing the procedure, separate charges apply (just as they would if done by the providing department (e.g., ECG, Pulmonary))
 - For ECGs on sponsor-provided machines, for safety purposes a UWHC ECG is required
- Visit complexity
 - Based on anticipated length of visit and visit acuity



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How does CRU review an ASR?

- Compares study team's entry with protocol (and with lab manual, if available)
- CRU sends study team an email with questions or noting discrepancies, OR
- CRU confirms accuracy of ASR based on information provided by the study team.
- Study team should confirm or clarify questions / discrepancies, as CRU does not receive a revised ASR.
- If study is outpatient, CRU builds a draft billing slip.



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Other CRU charges that need to be accounted for in budget

- Proposal Review and Implementation Fee
- Amendment or Rush fees
- Are dietary services needed?
 - Meals (other than ordering off-menu) – per meal fee applies
 - Research Bionutritionist services (e.g., food record review, study-specific diet development, subject-specific diet development) – hourly fee applies
 - See Bionutritionist Fact Sheet at <https://ictr.wisc.edu/CTRCServicesScope>
- Are CRU NP services needed?
 - See NP Fact Sheet on website above



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Helpful Hints / Suggestions

- Sample Processing is usually the most difficult procedure to determine.
 - Attempt to obtain the Lab Manual from the sponsor for every study. If the sponsor refuses to provide prior to a signed contract, the sponsor should then be asked to indicate the number of samples (tubes, slides, syringes etc.) that will be needed per research sample, and which samples require immediate processing/handling (i.e., will it need to be done by CRU or can it be done by 3P).
 - If there are a number of research samples, enter each sample as a separate line item in OnCore, and use the Footnote feature to provide details.
 - Include the samples that don't require processing on the calendar, and include a footnote that those samples are not processed.



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Helpful Hints / Suggestions

- Even if a Lab Manual is provided, the estimate provided for sample processing can change when study kits are received, if the kits are different than what was described in the manual.
- Amendments could affect budget. Make sure that the sponsor allows changes. CRU cannot “write off” services because they weren’t submitted in the budget.
- Remember that if you can’t determine charges because information from the sponsor is lacking, the CRU will also not be able to do an accurate review.



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