UTILIZING CRC CLINICAL SERVICES



University of Nebraska Medical Center



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REQUESTING SERVICES

PROCESS

All clinical service requests must go through the process outlined below to be considered.

- Request services via the CRC <u>Study Intake Form</u>.
 - a. If not originally requested on Study Intake Form, please complete <u>Teams</u> <u>Intake Survey</u>.
- 2. CRC Clinical Trials Analyst (CTA) receives the initial intake request.
- Requests for clinical services are sent to the Clinical Intake Team by CTA.
- 4. The Clinical Intake Team reviews the request for clinical services at a Clinical Intake Meeting and provides recommendations to leadership.
- 5. The CRC Leadership Team reviews the study.
- 6. The CRC Clinical Intake Team will reach out to the study contact to coordinate a meeting between CRC clinical staff and the study team to discuss workflows if the request is deemed feasible.



 Occur every other Friday afternoon to discuss all request received in the previous two weeks.

Considerations and Concerns

- Patient safety
- Requested services
- Timing and frequency of visits
- Number of expected subjects
- Expected start-up timeline
- CRC staff members required

Clinic Tours

Reach out to Serena Gaines
 (serena.gaines@unmc.edu) to
 find a time for clinic tour. Once a
 time has been agreed on, please
 send a calendar invite to
 <u>crcclinic@unmc.edu</u>,
 <u>serena.gaines@unmc.edu</u>, and
 <u>crcresearchassistants@unmc.edu</u>.

PREPARING FOR YOUR APPOINTMENT

EPIC ONE CHART

See Appendix A research order information.

Research encounters and orders must be linked to research prior to the scheduled appointment. View One Chart tip sheets in Service Now via search bar.

Non-CRC staff should not document in the CRC Clinic encounter. If documentation needs to occur in EPIC, a separate encounter needs to be created. All orders must be placed prior to research subjects being seen in clinic. These may be placed under the CRC Clinic appointment. A tip sheet can be found in Appendix B for creating research encounters and Appendix C and D for CRC ECG orders.

SCHEDULING AN APPOINTMENT

Appointments should be scheduled a minimum of three days prior to the appointment date. This ensures staff and dry ice (if applicable) will be available. CRC Scheduling Instructions can be found in Appendix E. Additional tips can be found in Appendix F.

GENERAL

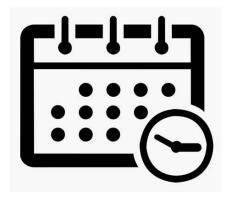
Coordinators should create source documents for the CRC staff on which to write relevant information from the CRC clinic portion of the visit, such as draw times, vitals readings, or notes. CRC staff will return the document to the coordinator upon the coordinator's request.

Coordinators are expected to bring all materials including kits, shippers, requisition forms, source documents, and other relevant materials to the CRC on the day of the visit. The CRC does not store these materials for outside departments as CRC storage is used for the CRC supplies.

DURING AND AFTER YOUR APPOINTMENT

DURING APPOINTMENT

- Coordinators and subjects are expected to check in at the front desk.
- If a coordinator or subject is going to be late to an appointment, please call 402-559-7685 as soon as possible.
- Only CRC staff will perform clinical services (e.g., phlebotomy) in CRC CRU space unless other prior arrangements have been made and approved by CRC leadership.
 - Coordinators must complete the applicable CRC Competency Checklist prior to the subject's first appointment if performing clinical services.
- Coordinator must be available during the appointment for any questions or emergencies that may arise.



AFTER APPOINTMENT

- CRC CRAs will keep electronic copies of shipping documents and send them to coordinator on request.
- Coordinator should clean up any space and equipment used after each subject. This includes throwing away the exam table paper, putting pillowcases in the laundry returning all furniture and materials back to where they were found, and wiping down all touchable surfaces (including vital signs equipment and pillows) and the exam table with the gray-top alcohol wipes found in each room. Additionally, coordinators are responsible for terminal cleaning if a participant is infected and considered contagious in any way.
 - Please let a CRC staff member know if supplies are running low in the room.
- Coordinators and subjects are expected to check out at the front desk.

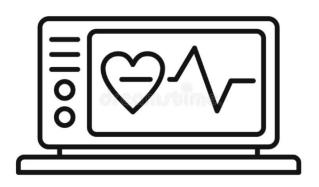
ADDITIONAL INFORMATION

CLINIC EQUIPMENT

- Annual calibration records for all CRC clinic equipment can be found in <u>Sodexo</u>.
 Navigate to Device Info -> Advanced Search -> Department Name + Contains -> Clinical Research Center.
- Temperature logs for CRC refrigerator and -20 C freezer, and the certificate of conformance for the -80 C freezer can be requested by emailing CRCResearchAssistants@unmc.edu.

OTHER

- Space is available for non-CRC staff and coordinators to sit or work on paperwork in Clinic Room 8. Please only utilize this space while you have research subjects in clinic.
- Clinical Research Center Standard Operating Procedures can be found <u>here</u>. CO31, CO33, and CO50 should be reviewed.
- When emailing the Research Assistants, please always use the <u>CRCResearchAssistants@unmc.edu</u> email, not individual emails. This will ensure your email is reviewed in a timely manner.
- When emailing the CRC Research Nurses, please always use the <u>CRCResearchNurses@unmc.edu</u> email, not individual emails. This will ensure your email is reviewed in a timely manner.



REVIEW CONFIRMATION

BY SIGNING...

- I acknowledge that I have received a copy of the Utilizing CRC Clinical Services packet, which describes valuable information about using CRC clinical services.
- I confirm that I have reviewed the Utilizing CRC Clinical Services packet and will abide by the rules, SOPs, and policies of the department when using CRC services.

	PRINT	SIGN	DATE
Coordinator			

Appendix A - How to Place Research Orders for the CRC in EPIC/OneChart

Associate your subject with the study:

- 1. In EPIC, click on "Pt Research Enrollment" along the top of the screen. If it is not there, click the wrench icon in the top right corner to add this option to the toolbar.
- 2. Type the patient's name/MRN and click "Accept" once you have selected the correct patient using two patient identifiers.
- 3. In the box that reads "Add study", type the IRB number and the study should show up. Click "Add".
- 4. Fill in the participant details and click "Accept". A research icon should appear to the right of the patient's name, indicating that they are involved in a research study.
 - a. Note: You may need to select "Screening" as the current status prior to the screening visit to associate screening visit orders with research and see the research icon.
- 5. The patient has now been associated with the study and orders can now be placed.

Place study-specific orders prior to the appointment:

- 1. Click on the "EPIC" dropdown menu in the top left corner of your screen and select "Encounter".
 - a. If that option is not there, click "Modify this Menu" under the "EPIC" dropdown menu and add the "Encounter" option, then retry.
- 2. Type in the subject's name/MRN and click accept.
- 3. Select "New". For encounter type, click "Orders Only". Change the provider to the PI and select the appropriate department. Click "Accept.
- 4. In the bottom left corner of the screen, click "ADD ORDER", then type the name of the order and hit enter
 - a. Note: Central labs should be ordered as "Collection for blood- research only" and/or "collection for non-blood- research only". Local labs can be ordered as normal; just make sure they are linked to research. ECGs done in the CRC should be ordered as "ECG-Only for CRC, IMAGI, UHC".
- 5. A list of options should appear. Be sure to select the appropriate option. If ordering multiple items, hit "Select and Stay", and the order will move to the right-hand column. Once all orders have been entered, click "Accept".
- 6. A new pop-up should appear asking for more details. Select "Future" as the status and choose the expected date for the order to be completed. For indication, always select "Other" and type "Research". Add the study information and your contact information under "Comments".
 - a. Note: ECGs are always to be read by "Academic Physician". Always leave "Auto Release Standard" as selected, and don't adjust the "Class" option unless necessary. When the information has been filled in, click "Accept". Do this for all orders placed.
- 7. Next, Select "Dx Association". Type in the diagnosis number "Z00.6" (research) and select the most appropriate description.
- 8. Click the diamond beneath the diagnosis and check the boxes next to all the orders placed. Click "Accept".
- 9. Now click on the triangle next to "Options" and click "Research Association". A box will pop up with the name of the study and the orders placed. Check the box next to each order associated with this specific study. If the study name is not there, then you need to first associate the patient with the study (see above). Click "Accept."

How to Place Research Orders for the CRC in EPIC/OneChart

10. Now select "SIGN ORDERS" or "PEND", depending on your abilities within EPIC. Make sure that the PI reviews and signs the orders prior to the appointment.

Helpful Hints:

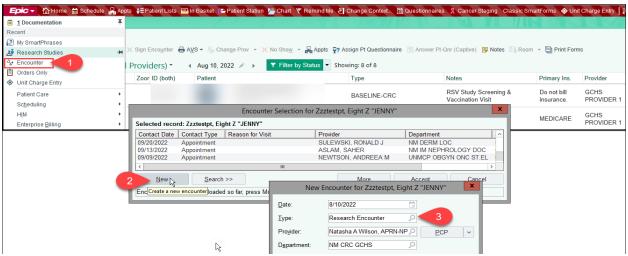
- If you are ever unable to find an option in a toolbar, type the name of the desired option into the search bar underneath the patient's name. DO NOT hit enter. Instead, select the option that appears under "Jump To", and it will take you to that page.
- Practice enrolling patients in research studies and placing orders in "Test Patient" charts in EPIC.
 Below is a list of test patients that can be used for practice:

ZZZTESTPT,EIGHT Z	00989998
ZZZTESTPT,FIVE B	00989995
ZZZTESTPT,FOUR M	00989994
ZZZTESTPT,NINE A	00989999
ZZZTESTPT,ONE J IV	00989991
ZZZTESTPT,SEVEN Y	00989997
ZZZTESTPT,SIX ANN	00989996
ZZZTESTPT,THREE L	00989993
ZZZTESTPT,TWO D	00989992
ZZZTESTPT,ZERO S	00989990

- Once you have placed a specific order multiple times, it should show up with a lightbulb next to it when you search for that order. This makes it easier to know which to select if there are multiple options in EPIC for one specific order.
- For more tip sheets and EPIC resources, go to https://updates.nebraskamed.com/onechart/ and look under "Training" for your specific needs. You can also type "Research" into the search bar.
- You can email OneChartResearch@nebraskamed.com with any questions or requests.

Appendix B - How to Create a Research Encounter in EPIC/OneChart

- 1. Click on the "EPIC" dropdown menu in the top left corner of your screen and select "Encounter".
 - a. If that option is not there, click "Modify this Menu" under the "EPIC" dropdown menu and add the "Encounter" option, then retry.
- 2. Type in the subject's name/MRN and click accept. Then select "New". For the type of encounter, click "Research Encounter". Change the provider to the PI and select the appropriate department. Click "Accept.
- 3. Now you may document any study visit assessments, vital signs, and notes within this encounter. You may also order study procedures or medications and mark study drugs as administered within the MAR tab.



- 4. Prior to signing the visit or ordering any study interventions, add a research diagnosis. In the bottom left toolbar, click "Add Diagnosis" and type in "Z00.6". These are all research diagnoses-you may select the most appropriate description for the diagnosis.
- 5. Once all documentation for the visit has been completed within the encounter, you may hit "Sign Encounter". EPIC will not let you sign off if there is anything left incomplete (i.e., no diagnosis code entered).
- 6. If you must add something into the encounter later, you may double click on the patient's EPIC encounter and select the "Addend Encounter" option.

How to Create a Research Encounter in EPIC/OneChart

Helpful Hints:

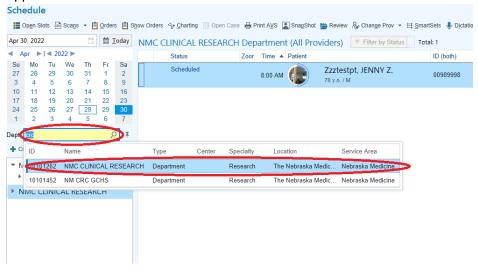
• Practice enrolling patients in research studies and creating research encounters in "Test Patient" charts in EPIC. Below is a list of test patients that can be used for practice:

ZZZTESTPT,EIGHT Z	00989998
ZZZTESTPT,FIVE B	00989995
ZZZTESTPT,FOUR M	00989994
ZZZTESTPT,NINE A	00989999
ZZZTESTPT,ONE J IV	00989991
ZZZTESTPT,SEVEN Y	00989997
ZZZTESTPT,SIX ANN	00989996
ZZZTESTPT,THREE L	00989993
ZZZTESTPT,TWO D	00989992
ZZZTESTPT,ZERO S	00989990

- For more tip sheets and EPIC resources, go to https://updates.nebraskamed.com/onechart/ and look under "Training" for your specific needs. You can also type "Research" into the search bar.
- You can email OneChartResearch@nebraskamed.com with any questions or requests.

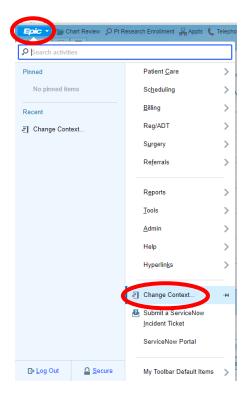
Appendix C - CRC ECG Orders for Local Machine

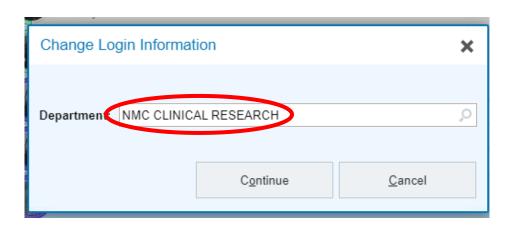
- 1. Once you have received confirmation from the CRC Clinic that your appointment has been scheduled, open EPIC.
- 2. Change department to "NMC Clinical Research Center" and select the date of your upcoming appointment.



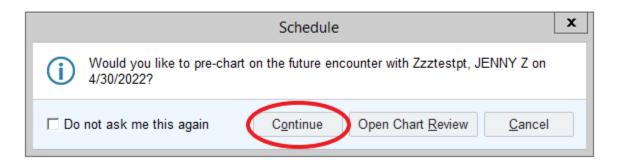
OR

You can also change the context in EPIC to NMC Clinical Research by clicking on the EPIC dropdown menu in the top left, clicking "Change Context," then searching "NMC Clinical Research" in the search bar. Click Continue.

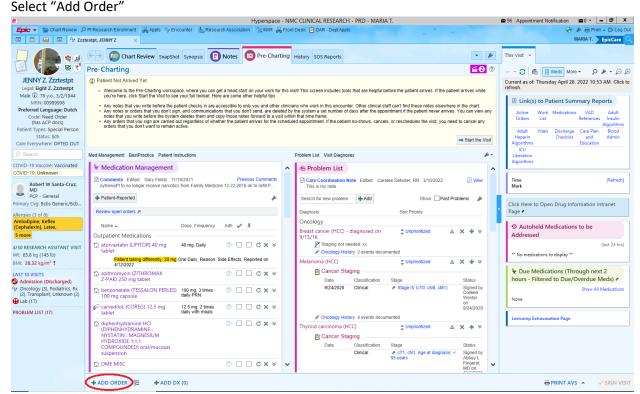




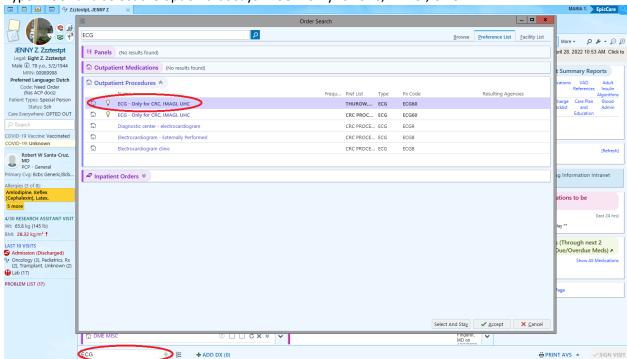
Double click on your participant's name and select "Continue" when prompted.



4. Select "Add Order"



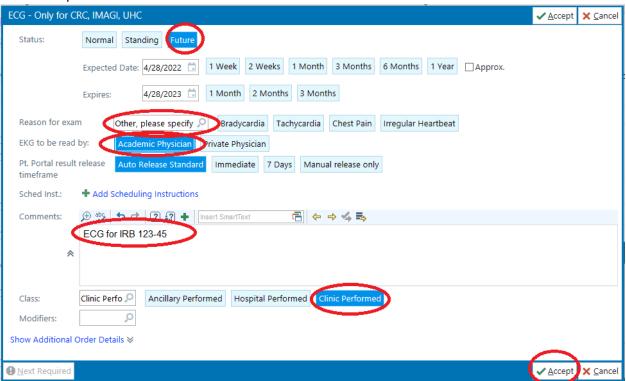
5. Type "ECG" and select the option that says "ECG – Only for CRC, IMAGI, UHC"



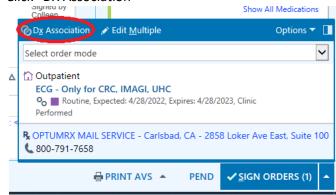
6. Change the:

- a. Status of the order to "Future"
- **b.** Reason for exam to "Other" (include IRB number in comment section)
- c. EKG to be ready by to "Academic Physician"
- **d.** Class to "Clinic Performed"

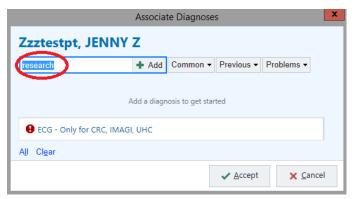
Click "Accept" when finished



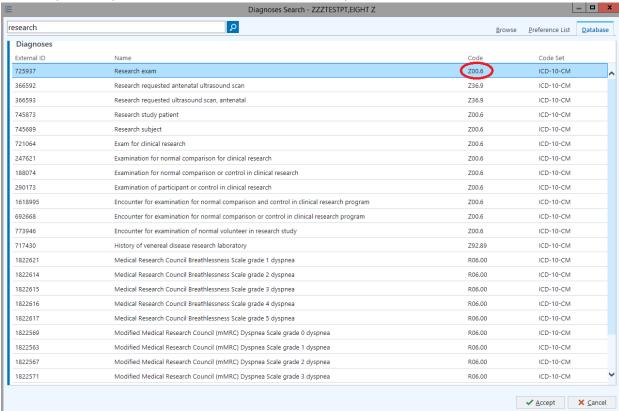
7. Click "DX Association"



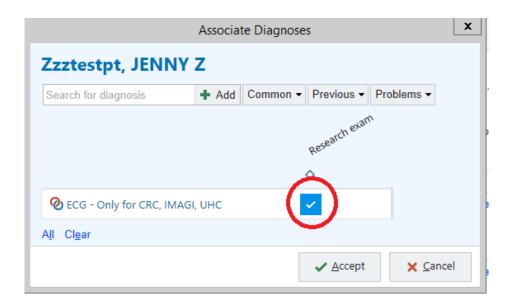
8. Type "Research"



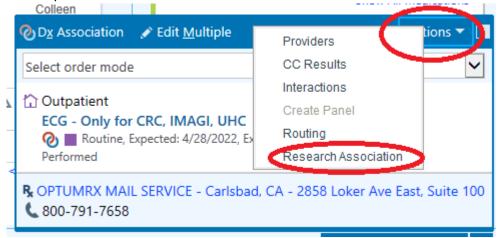
9. Select any of the options with code "Z00.6" and click accept



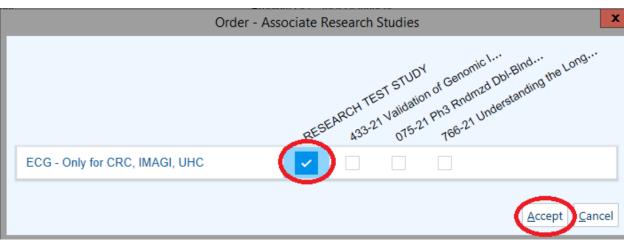
10. Associate the ECG order with the research diagnosis you selected in the previous step and click accept.



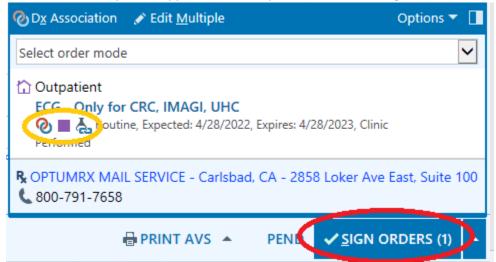
11. Click "Options" and select "Research Association"



12. Select the correct research study and click accept.



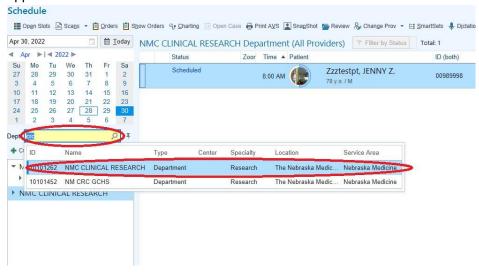
13. Ensure that all 3 symbols appear (circled in yellow) and select "sign orders"



- **14.** Complete the order information by filling in the "order mode" and "ordering provider" sections and click accept when completed.
- **15.** These steps must be completed for <u>each</u> ECG that the CRC is performing (ie if you need a triplicate ECG there must be three orders in epic)
- **16.** The day before the first appointment occurs, email the "CRC Research Assistants" or call 402-552-2285 to ensure that the orders were placed correctly. Please reach out if you have any issues.

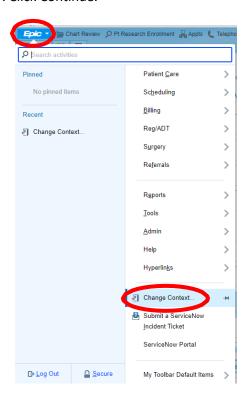
Appendix D - CRC ECG Orders for Sponsor Provided Machines

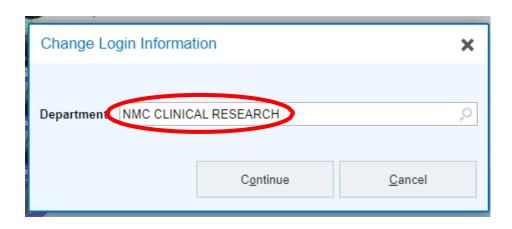
- 1. Once you have received confirmation from the CRC Clinic that your appointment has been scheduled, open EPIC.
- 2. Change department to "NMC Clinical Research Center" and select the date of your upcoming appointment.



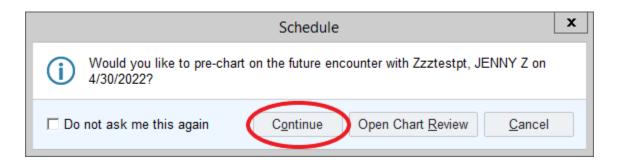
OR

You can also change the context in EPIC to NMC Clinical Research by clicking on the EPIC dropdown menu in the top left, clicking "Change Context," then searching "NMC Clinical Research" in the search bar. Click Continue.

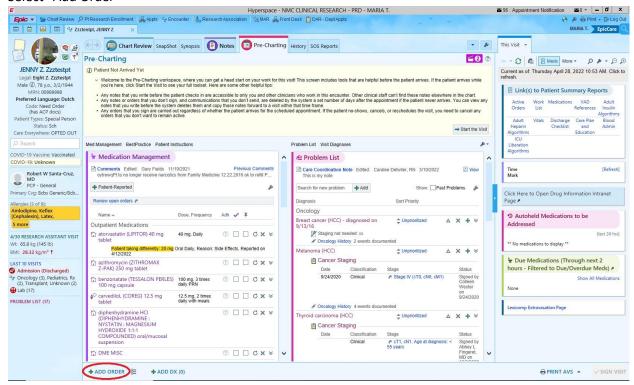




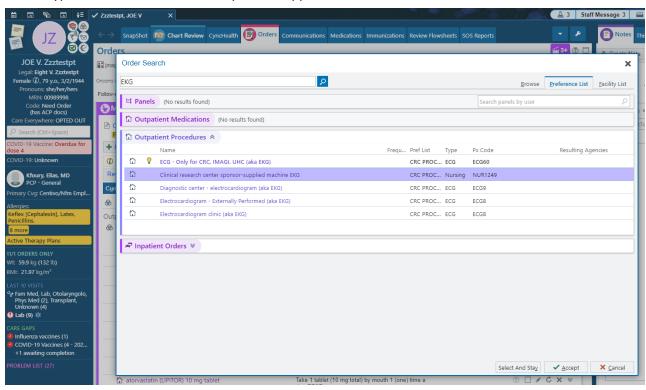
3. Double click on your participant's name and select "Continue" when prompted.



4. Select "Add Order"



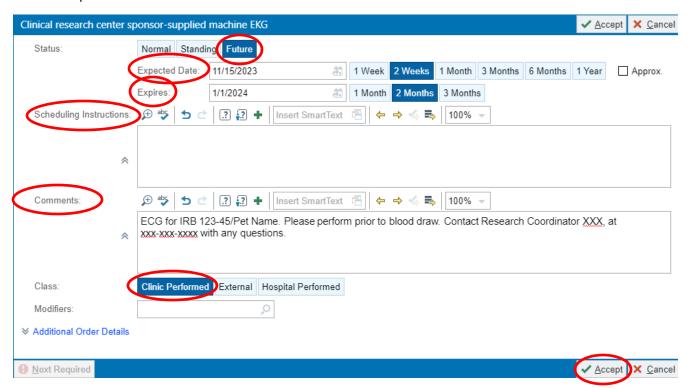
5. Type "Clinical research center sponsor-supplied machine EKG"



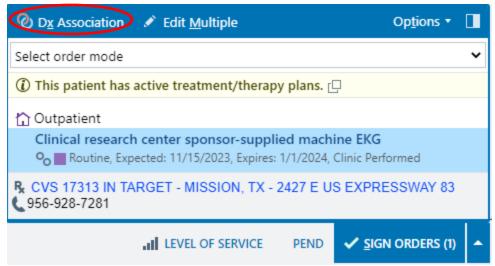
Change the:

- a. Status of the order to "Future"
- **b.** Update the Expected Date and Expiration as appropriate
- c. Add Scheduling Instructions and Comments as appropriate
- **d.** Class to "Clinic Performed"

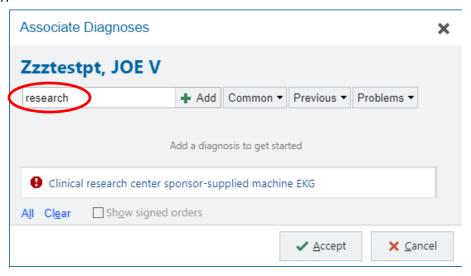
Click "Accept" when finished



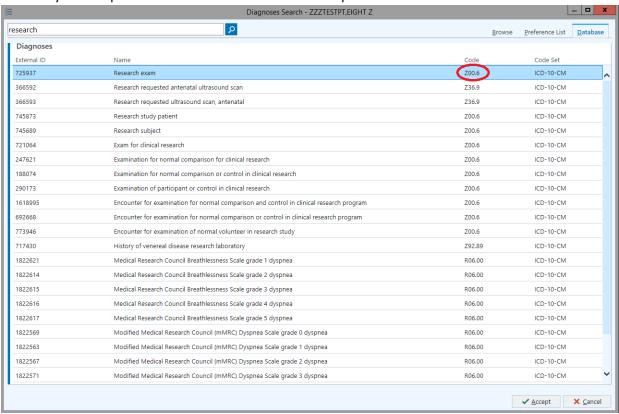
6. Click "DX Association"



7. Type "Research"



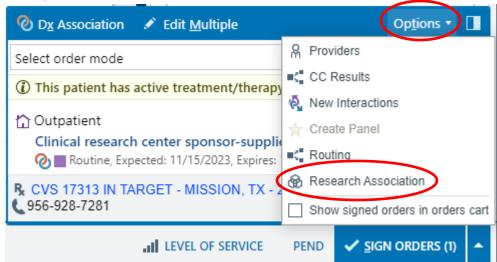
8. Select any of the options with code "Z00.6" and click accept



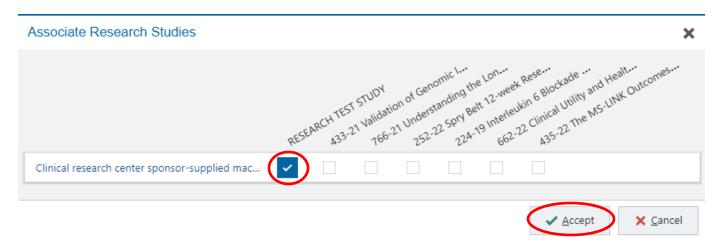
9. Associate the ECG order with the research diagnosis you selected in the previous step and click accept.



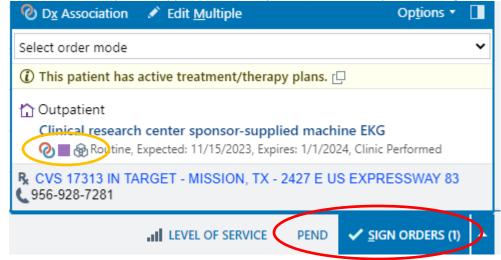
10. Click "Options" and select "Research Association"



11. Select the correct research study and click accept.



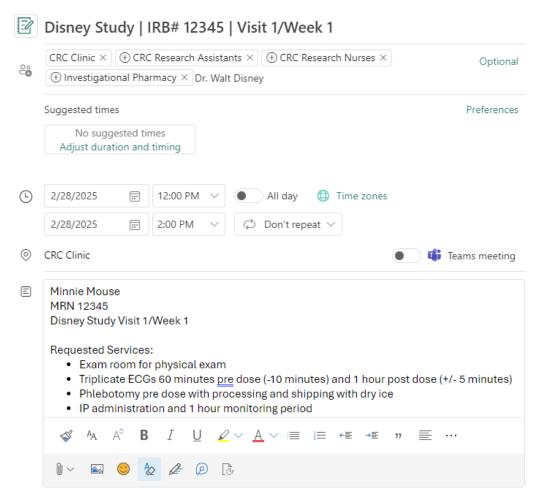
12. Ensure that all 3 symbols appear (circled in yellow) and select "pend" or "sign orders" as appropriate



- **13.** Complete the order information by filling in the "order mode" and "ordering provider" sections and click accept when completed.
- **14.** These steps must be completed for <u>each</u> ECG that the CRC is performing (ie if you need a triplicate ECG there must be three orders in epic)
- **15.** The day before the first appointment occurs, email the "CRC Research Assistants" or call 402-552-2285 to ensure that the orders were placed correctly. Please reach out if you have any issues.

Appendix E - How to Schedule with the CRC

- 1. Create a new appointment within Microsoft Office Calendar for the desired date*.
- 2. Select "Invite Attendees" and add CRCclinic@unmc.edu along with any other invitees.
- 3. Enter the pet name of the study, the IRB #, and the visit description in "Title".
- 4. Enter the correct start and end times for the appointment.
- 5. Select CRC, or other location if previously discussed, for "Location".
- 6. In the body of the email, please type the name of the subject and their MRN, visit #/week # (if applicable), services requested, time points (if applicable), and if dry ice is required.



- 7. Send the invitation.
- 8. The CRC Clinic administrators will accept the invitation if the appointment time works, or they will send a follow-up email if more details are needed or if the appointment will need to be rescheduled.
- 9. The CRC Clinic administrators will then enter the subject's appointment information in EPIC into the NMC Clinical Research Department's schedule.
 - a. Please DO NOT edit or change this appointment.
- 10. If you have any questions, feel free to call the office at 402-559-7685.

^{*}Whenever possible, please try to schedule appointments at least 2 weeks in advance.

Thank you for using the Clinical Research Center to assist with your studies. Please see the helpful hints below to promote efficient workflow during subject visits.

Scheduling:

- When scheduling appointments in Outlook, please indicate whether the coordinator will be present at the appointment (required at Screening). If the coordinator will not be present, please provide a phone number at which they can be reached during the visit.
- Please include all other pertinent CRC staff members in the invite. The CRC RA email address is CRCResearchAssistants@unmc.edu. If RN services are required, please also include CRCResearchNurses@unmc.edu in the invitation.

• Documentation:

 If requesting vital sign documentation, please provide source documents and clarify if charting in EPIC is required as well.

• Labs:

- Please clarify how labs will be drawn (i.e., port- already accessed or needing accessed, PICC line, PIV, phlebotomy).
- Please specify each specific timepoint which requires a blood draw and identify where this will occur.
- Please indicate how any study-specific tubes will be provided to the CRC prior to the appointment. If drawing local labs, the CRC can provide their own tubes.
- Please ensure that lab orders are placed in EPIC prior to the appointment time.
- Please clarify what should be done with lab tubes after the visit. (i.e., take to local lab for processing, study coordinator will pick up, process and ship to central lab)

• ECGs:

- Please have the ECG order placed in EPIC prior to each visit. If triplicate ECGs are requested, three separate orders must be placed.
- For ECGs done in the Treatment Center, please ensure that the Treatment Center RN knows to call the RAs to communicate the specific study timepoints.