



Research – Ordering Research Labs



Introduction

With the transition to Connect Care, research staff will enter orders for clinical care and services associated with Research into the Clinical Information System.

Research lab testing follows a few different workflows, each of which will have a slightly different process:

- Standard of Care Labs: for when your specimen will be resulted by AHS and the results should file to the patient's chart.
- Blinded Lab Ordering: for when your specimen will be resulted by AHS but the results should not file to the patient's chart.
- Send-out Labs (Research Kit): for when your specimens will be sent to a sponsor or outside lab to be resulting

The following sections explain these processes briefly.

Standard of Care Labs

Scenario: Ordering labs that will be resulted by an AHS lab and the results will file to the patient's record. When your study specifies lab test to be completed that will be processed and resulted by an AHS lab, you should use existing standard of care lab orders in Connect Care. This will ensure that the results file to the patient's chart and will route to the appropriate clinicians.

When placing these orders, study team members and PIs should use the Research Association activity to associate the orders to patient's study enrollment.

If you need to provide specific instructions to the lab related to the processing or resulting of these tests, you have two options:

- Send a paper instructions sheet to the lab along with the specimen. This likely mirrors current state for most studies.
- Enter the instructions into the Comments field on the order. You can copy/paste this information from another document, or can create your own SmartPhrase to quickly pull the information into the order.

All charges related to these standard of care labs will go to Research Billing Review for the study team to confirm whether the study or the patient's coverage should be responsible for payment.

Blinded Lab Ordering

Scenario: Ordering research labs where the results should be blinded from the patient, study team, or both.

When your study specifies that labs resulted by AHS should be blinded, you will place these orders on paper outside of Connect Care. We choose to not enter these orders in order to prevent the possibility of a result filing to the patient's chart.



This paper order process will be in place for both double-blind and single-blind studies. For double-blind, we need to ensure that clinicians do not see patient results. For single-blind we will keep these out of the system to ensure that results are not released to the patient via MyAHS Connect or other patient portals.

You should submit paper orders for these tests in the same way that you do today; your paperwork should include your study name and identifiers. When the lab receives these specimens they will enter the order and attach it to the research study account in Connect Care to support downstream billing. The results will not file back to the patient record, but will be stored in a way that allows the study team to receive that information later.

Send-out Labs (Research Kit)

Scenario: Ordering research labs that will be sent to a sponsor or outside lab to be resultated.

Many studies collect specimens and then send them to a sponsor or outside lab to be resultated. These results may or may not be sent back to the study team at a later time. You should use this order both for when there is an actual kit provided by the study sponsor, and also when collecting specimens using AHS-provided tubes.

For these tests, study teams should enter an order for a Research Kit. This is a generic order that will help facilitate specimen collection, as this order will be available in the patient's chart for nurses and phlebotomists to document collection. The order also helps ensure that the patient record reflects that we collected labs.

When entering the Research Kit order, include information about expected date, priority, and the other typical orders items. You will also be asked whether there is a kit provided for the order, and whether there are any processing instructions. You can enter instructions onto the order; this is especially important if you do not have a study kit and you need specific tubes collected. You can also include any lab processing instructions.

Remember to associate the order to your study using Research Association.

After the order is signed and released, it will be available for collection. Nurses and/or phlebotomists should document the collection in Connect Care, just as they would any standard of care order. Upon collection, all specimens will need to go to the lab to be received – this is true even if the study team is sending out the specimen without lab assistance or processing. This is required to ensure that the lab orders are not cancelled by the system.

For studies when the lab is helping to process and ship the specimens, they will continue to help with those steps as they have in the past. Study teams can include instructions on the order as comments, or send as paper instructions if that is your current process. Lab staff will be able to enter service codes for the various levels of processing that they perform.

If your study sponsor or outside labs send results back to the study team, you can add them to the patient's chart in Connect Care. See the relevant document for more details of how to add those results.





Pharmacokinetics (PKs)

Scenario: Collecting multiple specimens at specific time points for research purposes.

For studies collecting pharmacokinetic labs, you should follow the process above for Send-out Labs (Research Kit). You only need to enter a single order for the series of draws; you do not need an order for each draw time point. Include information in the instructions for the number of draws, for reference in the chart if needed later.

This will only create 1 collection task within the chart. Nurses or phlebotomists should complete this as part of the first collection in the PK sequence.

