



Monday Morning Practice Pearls #81

What happens if a “Research Tissue Procurement Request” CRIS order is not entered and released?

If a research team is procuring tissue for research, whether it’s in the OR, clinic, interventional radiology, or in any other location, a member of the research team must enter a “Research Tissue Procurement Request” order in CRIS for the patient before the procedure.

This order must have the correct date of the procedure, protocol, and anticipated list of tissues.

The Tissue Procurement & Processing Facility will not release any research tissue to investigators or their teams that does not have a current, accurate, and active order which supports the collection of the tissue.

If the order is entered on hold, the research team **must** release the order before the tissue is collected.

Why is this specific order needed?

Per MAS Policy M01-2, the purpose of the “Research Tissue Procurement Request” CRIS order is to provide documentation of the transfer of human biologic materials from the point of acquisition to a location other than a CLIA certified laboratory. This documentation reduces the chance that human biologic material is procured for an investigator without IRB approval, or that human biologic material is acquired only for research when a diagnostic specimen also is necessary.

The screenshot shows a web-based form for entering a "Research Tissue Procurement Request" order. The form includes the following fields and sections:

- Order:** Research Tissue Procurement Request
- Requested By:** Ross, Douglas
- Template Name:** (empty)
- Order ID:** 002BBD086
- Messages:** Orders should be entered BEFORE 6:00 a.m. the day of the surgery. For all same day orders entered after 6:00 a.m., you must call 301-496-5646 and notify Operating Room front desk staff to ensure the order is acknowledged. Research materials will not be released unless form is complete and signed (MAS M01-2 policy).
- Allocate Order to Protocol:** 16-CC-9950
- Collection Date:** (calendar icon)
- Procurement Location:** (dropdown menu with "Clear" button)
- Location Selection:** Bedside Clinic IR/Special Procedures OR Procedure Suite
- Name of Principal Investigator:** (text field)
- IRB Certification:** I certify that the specified IRB approval covers both the protocol and patient-executed consent, and that the research proposed is specified within the approved protocol and consent.
- Research Specimen Certification:** (text field)
- Specimen Use:** If Specimen will be divided between research investigator & Path Lab for diagnostic tests and/or used for transplant purposes please select "Research/Dx/Transplant"
- Specimens Will Be Used For:** (dropdown menu)
- SPECIMEN STORAGE SITE 1:** (text field)
- Anticipated Research Sample 1:** (dropdown menu)
- Anatomic Site of Specimen 1:** (dropdown menu)
- Lab Name:** (text field)
- Institute:** (dropdown menu)
- Enter name and number of the person to be contacted for specimen pick-up:** (text field)
- Pick-Up Person's Name:** (text field)
- Pick-up Person's Contact Info:** (text field)

Individuals performing procedures to remove human biologic materials for research (other than blood, which has its own CRIS order) are required to document this procedure in the medical record via the Research Tissue Procurement Request CRIS order. The NIH 2803-1 form may also be used, especially during downtime procedures.

In addition, procedure notes should mention that research tissue has been procured, including the protocol number, for source documentation purposes.

So who can enter this order? And who can release this order?

Only members of the research team can enter and release this order in CRIS. This may include:

- Physicians (MD/DO)
- Advanced Practice Providers (Nurse Practitioner/Physician Assistant)
- Nurse Clinical Research Coordinators (if part of a protocol order set)

Orders must be entered AND released BEFORE 6:00 a.m. the day of the procedure. The research team member who releases the order does not have to be the same person who enters the order.

What if there is a last minute change, cancellation, or the procedure is rescheduled?

If there are any same day changes to a procedure, including cancellations, the research team must notify the department directly AND update the order in CRIS. If the procedure is rescheduled, the CRIS order must be updated prior to the procedure. Otherwise, research materials will not be released.

Resources

- [MAS Policy M01-2 Procurement and Use of Human Biological Materials for Research](#)
- [NIH 2803-1 Form](#)