

## Research Details Outside the Meriter IRB Purview

### Meriter IRB Scope of Authority

Meriter IRB approval means that you have met regulatory requirements to perform human subject research at UnityPoint Health - Meriter.

Meriter IRB approval does not represent approval or imply support from other UnityPoint Health – Meriter work areas necessary for the conduct of your research. See table below.

1	<p><b>Research that involves a lab test/result</b></p> <ul style="list-style-type: none"> <li>• Will research incur a lab charge? Who will pay for the charge?</li> <li>• Even when a specimen is sent to an outside laboratory, the Meriter lab may generate a charge to perform the labor of collecting the specimen and/or sending the specimen to the outside lab. Confirm that Meriter Lab can accommodate your research need.</li> <li>• Have you coordinated the lab workflows with your research workflow? For example, collecting what is left of a specimen after a test is done or collecting infant cord blood once the blood bank is ready to discard it.</li> </ul>	Meriter Laboratory (Amy Job)
2	<p><b>Research that involves an imaging test/result</b></p> <ul style="list-style-type: none"> <li>• Will research incur a medical imaging charge? How will this charge be handled?</li> <li>• Have you coordinated the medical imaging workflows with your research workflow?</li> <li>• Use of PACS data/images for research requires Meriter “permission” per contractual agreement between UW and Meriter.</li> </ul>	Meriter Medical Imaging (Holly Grundahl)
3	<p><b>Research that involves pharmaceuticals</b></p> <ul style="list-style-type: none"> <li>• Meriter does not have a research pharmacist. We are aware that UW has a separate service to support research that involves pharmaceuticals.</li> <li>• Have you coordinated research workflows with Meriter and/or UW pharmacy workflows?</li> <li>• There have been multiple protocol violations because a study drug wasn’t available at the time of administration. Careful planning can prevent this.</li> </ul>	Meriter Hospital Pharmacy (Tammy Adler)
4	<p><b>Research that involves medical supplies, forms, and equipment</b></p> <ul style="list-style-type: none"> <li>• Study teams will use their own supplies and, in most cases, their own equipment.</li> <li>• Have you arranged for storage at Meriter for supplies and equipment?</li> <li>• Have you arranged for replenishing supplies as they are used up?</li> </ul>	Unit Staff SPD (Shipping, Processing, and Delivery)  (Kyle Walker)

	<ul style="list-style-type: none"> <li>• Have you coordinated research workflows with Meriter unit staff or Meriter SPD?</li> <li>• If research involves the use of UnityPoint Health supplies or equipment, will there be a charge? If so, how will this charge be handled?</li> </ul>	
<p>5</p>	<p><b>Billing for Research Procedures</b> (e.g., blood draw, specimen collection and test, medical supplies used, etc.)</p> <ul style="list-style-type: none"> <li>• Are there research procedures that are paid for with research funds?</li> <li>• How will you ensure that the patient/subject doesn't receive a bill for something that research pays for?</li> <li>• How will you ensure that Medicare/commercial insurer doesn't get billed for research?</li> <li>• Do you have a way to code the research procedure that facilitates billing the correct party?</li> <li>• Do you have the billing information needed to create a specific Research account in Epic for billing purposes?</li> <li>• Who is responsible for reconciling the research specific charges/accounts?</li> <li>• Who is the contact that will need to be billed for the research accounts?</li> <li>• What is the timeframe for the research as there may be time limits related to billing the research account?</li> </ul>	<p>Revenue Cycle (Ryan Klein)</p>
<p>6</p>	<p><b>Research Documentation in Epic</b></p> <ul style="list-style-type: none"> <li>• UnityPoint Health Epic does not have the research module. Do you have an alternate plan for Epic documentation for research purposes?</li> <li>• How will research-related procedures be ordered or processed?</li> <li>• Will research related lab tests, radiology study be included in standard of care documentation? Often research tests are not included in standard of care documentation. How will you make sure research tests are excluded from Epic?</li> </ul>	

*The names in the far-right column are accurate as of this writing.*