

**UH Clinical Research
Services**
UH G-255 & 256
973-972-7909
973-972-5171

Scope of Research Services

This form should be used to request any hospital services related to the study that will not be provided by investigators. If any questions, please contact Arleen Wallen at 973-972-7909.

Protocol Number & Title:	
Investigator:	

IRB Number if known: Pro _____ OnCore Study Number if known: _____

Funding Proposal number in RAPSS if known: _____

- I. Briefly describe the recruitment and implementation plan (as applicable, include a description of the specific UH locations where study activities will take place, how participants will be approached and consented and by whom)

For Each UH Area: Check if yes or no as to whether these services are requested

II. Investigational Pharmacy:

<input type="checkbox"/> Yes <input type="checkbox"/> No	The investigational product will be stored in and dispensed from the UH – IDS. (If yes, the IDS pharmacist will provide a complexity assessment and proposed charges).
<input type="checkbox"/> Yes <input type="checkbox"/> No	Requesting to purchase additional materials and/or medication for use in this study. Please describe:

III. Pathology and Laboratory Medicine:

<input type="checkbox"/> Yes <input type="checkbox"/> No	Pathology Services: Description of Services Required /Special Instructions (if a separate document or laboratory manual is available, please attach):
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<input type="checkbox"/> Yes <input type="checkbox"/> No	Laboratory Services: Clinical laboratory testing will be ordered solely for research purposes. (Note: UH requires a list all clinical laboratory testing required as part of this study along with a description of whether the test is considered routine care or pure research. <u>This may be done on the Oncore</u>
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	<u>Medicare Determination Billing Grid. All Pure Research procedures should be listed on the Summary Billing Plan.)</u>
	Describe any additional laboratory services or supplies required. Please provide any available separate procedure manual received as an attachment.:

IV. Patient Care Space:

<input type="checkbox"/> Yes <input type="checkbox"/> No	List the UH locations where research activities will occur (Reference sheet is on the last page)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Location Resources: <input type="checkbox"/> Use of supplies from unit (specify type and quantity): _____ <input type="checkbox"/> Longer inpatient stay (specify hours or days): _____

V. Cath Lab or Perioperative Services:

<input type="checkbox"/> Yes <input type="checkbox"/> No	Device/Procedure Description and identify which space (Cath Lab, Main OR, Same Day Surgery, Special Procedures Unit)
Is the device FDA approved for the proposed use? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Is the device/procedure new to University Hospital? <input type="checkbox"/> Yes, never been performed here; <input type="checkbox"/> No	
Who is paying for the procedure/device? <input type="checkbox"/> Sponsor <input type="checkbox"/> Patient <input type="checkbox"/> Insurance	
Will University Hospital be responsible for purchasing the device? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes and it is a new device to University Hospital, contact Purchasing, Edwing Canaca, Supply Chain Operations at cancacaes@uhnj.org or 973-972-1255	
Will there be specimen collection during the case? <input type="checkbox"/> Yes <input type="checkbox"/> No Please list: Urine, Blood, or tissue and by whom: Specimen Type(s): _____ Collected by: _____	
Will the Specimen go to a UH Provider, NJMS Provider, or Research Team? Please specify: _____	
Specify any additional services required from the Cath Lab or Perioperative Services: _____	
Note: <u>Unless a product is normally used, storage is the PI's responsibility.</u> Sponsor representatives entering the OR will require a SYMPLR approval badge. <u>For information on contacting SYMPLR contact Scott McGowan, Supply Chain Operations at mcgowask@uhnj.org or 973-972-1246.</u>	

VI. Patient Care Personnel Responsibilities:

<input type="checkbox"/> Yes <input type="checkbox"/> No	Is this an in-patient study?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Hospital personnel will be asked to help conduct the study or to assist with various study procedures. Please describe:

VII. Radiology Services:

<input type="checkbox"/> Yes	Radiology Services: Radiology procedures will be ordered solely for research purposes. (Note: UH requires a list all radiology procedures required as part of this study along with a description of
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<input type="checkbox"/> NO	whether the test is considered routine care or pure research. <u>This may be done on the Oncore Medicare Determination Billing Grid. All pure Research procedures should be listed on the Summary Billing Plan.)</u>
	Describe any additional radiology services or supplies requested (such as uploading scans to a central reader) below. Please provide any available separate procedure manual received as an attachment.

VIII. Other Ancillary Services:

<input type="checkbox"/> Yes	List other ancillary services (cardiology, vascular, etc.) and procedures which will be ordered solely for research purposes. (Note: UH requires a list all clinical procedures required as part of this study along with a description of whether the test is considered routine care or pure research. <u>This may be done on the Oncore Medicare Determination Billing Grid. All pure research procedures should be listed on the summary billing plan.)</u> Please provide any available separate procedure manual for Ancillary Services received as an attachment.
<input type="checkbox"/> NO	

Patient Care Space(s) To Be Used

Outpatient Locations	Inpatient Care Areas
<p><u>Ambulatory Care Services</u></p> <p><input type="checkbox"/> Infectious Disease Clinic – D-level</p> <p><input type="checkbox"/> Neurology/Neurosurgery – G-level</p> <p><input type="checkbox"/> Surgical Specialties – E-level</p> <ul style="list-style-type: none"> • ENT • General Surgery • Podiatry • Urology <p><input type="checkbox"/> OB/Gyn – C-level</p> <p><input type="checkbox"/> Medical Subspecialties – F-level</p> <ul style="list-style-type: none"> • Adolescent & Pediatrics • Cardiology • Hepatology • High Risk <p><u>Cancer Center</u></p> <p><input type="checkbox"/> Hematology Clinic</p> <ul style="list-style-type: none"> • Adult Hematology • Pediatric Hematology • Primary Care <p><input type="checkbox"/> Infusion Services</p> <ul style="list-style-type: none"> • Adult • Pediatric <p><input type="checkbox"/> Oncology Clinic</p> <ul style="list-style-type: none"> • Adult Oncology • Survivorship <p><input type="checkbox"/> Surgical Oncology Clinic</p> <p><u>Doctor’s Office Complex</u></p> <p><input type="checkbox"/> Neurology - DOC 8100</p> <p><input type="checkbox"/> Ophthalmology</p> <p><input type="checkbox"/> Pediatrics</p> <p><input type="checkbox"/> PM& R</p> <ul style="list-style-type: none"> • Outpatient Therapy • Psychiatry <p><u>University Hospital</u></p> <p><input type="checkbox"/> Dental Clinic - C401</p> <p><input type="checkbox"/> Orthopedic Clinic - ACC</p> <p><input type="checkbox"/> Radiation Oncology - CC - A1120</p> <p><input type="checkbox"/> Lattimore Clinic</p>	<p><u>Critical Care Services</u></p> <p><input type="checkbox"/> E-Blue – Surgery/Trauma</p> <p><input type="checkbox"/> E-Green - SICU</p> <p><input type="checkbox"/> E-Yellow - CTICU/NICU</p> <p><input type="checkbox"/> G-Blue - Neuroscience</p> <p><input type="checkbox"/> G-Green - NICU</p> <p><input type="checkbox"/> I-Blue - Telemetry/Cardiac</p> <p><input type="checkbox"/> E-Yellow - CTICU/NICU</p> <p><input type="checkbox"/> I-Yellow 2 - CCU</p> <p><input type="checkbox"/> I-Yellow 1 - MICU</p> <p><input type="checkbox"/> I-Cardiac Cath <u>Emergency Services</u></p> <p><input type="checkbox"/> Emergency Room</p> <p><input type="checkbox"/> H-Blue - Observation</p> <p><u>Family Health Services</u></p> <p><input type="checkbox"/> G-Green - PICU/Peds</p> <p><input type="checkbox"/> F-Green - OB/GYN</p> <p><input type="checkbox"/> F-Orange - FNN</p> <p><input type="checkbox"/> F-Orange - FIN</p> <p><input type="checkbox"/> F-Orange - FICN</p> <p><input type="checkbox"/> F-Orange - L&D</p> <p><u>Medical/Surgical/Orthopedics & Liver Transplant</u></p> <p><input type="checkbox"/> H-Yellow - Medical/Oncology</p> <p><input type="checkbox"/> H-Green - Medical/Orthopedic</p> <p><input type="checkbox"/> D- Green - Medical (COVID)</p> <p><input type="checkbox"/> F-Yellow - Surgical/Liver Transplant</p> <p><input type="checkbox"/> F-BLUE - Med Surg</p> <p><u>Perioperative Services</u></p> <p><input type="checkbox"/> E-416 Recovery Room/PACU</p> <p><input type="checkbox"/> DOC 0400 - Same Day Surgery</p> <p><input type="checkbox"/> SDS - E-Yellow</p> <p><input type="checkbox"/> E-178 - Medical Special Procedures</p> <p><input type="checkbox"/> Operating Room</p> <p><u>Psychiatry Services</u></p> <p><input type="checkbox"/> G-Yellow - Psychiatry</p> <p><u>Renal Dialysis Services</u></p> <p><input type="checkbox"/> D-Green - Acute Renal</p>