

**RUSH UNIVERSITY MEDICAL CENTER
DEPARTMENT OF PATHOLOGY and RUSH MEDICAL LABORATORIES (RML)**

**PRICING FOR RESEARCH STUDIES
POLICIES REGARDING RESEARCH STUDY PROTOCOLS**

1. The investigator must complete Parts I, III and IV of the Department of Pathology/RML "**Research Project Request.**" form. Send this completed document with the laboratory portion of the research protocol to the Department of Pathology/RML Administrative Office, Room 409 Rawson at least two weeks prior to the start of the study. Do not send the entire protocol. These documents can be faxed to 312-563-3697 if the laboratory portion is 5 pages or less.
2. Submission of the Department of Pathology/RML Research Project Request form is not a substitute for review and approval by the Office of Research Administration (ORA) or the Human Investigation Committee (HIC).
3. Research pricing will be established for only those test procedures **listed in Part III of the Research Project Request form.** Check the appropriate boxes or list additional tests under "OTHER" for only the tests the protocol requires that will be paid for by the research fund. Research pricing will be established for only the tests listed in Part III. Any other tests ordered on study participants will be **routinely charged and billed at list price to the appropriate payor.** Tests for routine patient management and assessment should be ordered on the appropriate Outpatient requisition or via POE to insure these tests are billed to the correct payor and not the research fund.
4. The investigator is responsible for notifying in writing the Department of Pathology/RML of any substantial changes in the research protocol which affect specimen collection, handling and results reporting.
5. The investigator must obtain HIC approval for any test procedures added after a study is underway. The investigator must file an amendment for the protocol with the HIC. After HIC approval is granted, an amended request for discount pricing must be submitted to the Department of Pathology/RML Administrative Office.
6. Each study must have its own unique requisition form prepared by the Department of Pathology/RML which includes specific information for collecting, ordering and processing. Specimens for research studies should not be sent to the laboratory without this requisition.

Restrictions regarding the use of a study requisitions are in place to avoid inappropriate billing to the patient, insurance or Medicare. Billing inappropriately for research testing could have serious reimbursement and compliance implications for RUMC.

- A. The laboratory will not collect, process, store or test any research specimens without an a research study requisition. Researchers must not send samples to the laboratory without an appropriate requisition form.
- B. Specimens will be collected per laboratory protocol unless otherwise specified on the research requisition.
- C. It is strongly suggested that once a RUMC medical record is established for a patient, this number is used as the as the patient identification number with the research requisition as well. Using the RUMC medical record will allow the research test results to be available via R-Chart.
- D. Only the tests approved to be billed to the research fund will appear on the research requisition. The tests will be listed by test name and LIS ordering mnemonic.

- E. If the laboratory draws blood specimens as part of the study, a blood collection order [VENI] must appear on the requisition form. Please see items #7 and #8 below. If the laboratory is expected to process and store specimens only (no testing), a processing and storage order [STORE TEST] must appear on the requisition.
 - F. A [STORE TEST] consists of spinning and storing the specimen for retrieval by research team members. Instructions on the requisition must include length of time sample needs to be centrifuged and temperature requirements. Storage instructions on the requisition must include amount of sample required and final storage location (e.g. refrigerator and/or freezer number). The laboratory will not aliquot specimens for research studies.
7. The phlebotomy staff will not respond to verbal requests to collect blood for research studies. Phlebotomists will draw inpatient research studies only if: (a) a study requisition is placed on the phlebotomy clipboard before the beginning of a sweep, or (b) a study requisition is given to the phlebotomist during the sweep as an add-on, and the phlebotomist already has orders to draw the patient. Phlebotomists will draw inpatient research studies only at regular blood draw sweep times. Sweep times are: 05:00, 10:00, 15:00 and 20:00.
 8. Outpatients who are part of a research study can be drawn in Suite 104 Professional Building if they present a study requisition form.
 9. All research samples will be processed in the 4 Jelke laboratory.
 10. Non-laboratory personnel may not use laboratory equipment to process specimens. This is contrary to accreditation and safety regulations.
 11. The laboratory will not prepare blood smears as part of a research study protocol.
 12. The laboratory cannot perform serum drug levels on research specimens where results are likely to be more than ten times higher than the upper reportable range of the test. The researcher should call Dr. Robert Webster (2-4012) to discuss this.
 13. The laboratory cannot perform special courier pickups for research studies. Pickups must coincide with regular hospital and/or Professional Building courier rounds.
 14. The laboratory does not provide dry ice for research personnel to use in shipping research specimens. Dry ice purchased by the laboratory is for laboratory use only. Regular deliveries of dry ice to any location at the Medical Center may be arranged by calling Megan McNichols, Medical Center Purchasing at ext. 2-5409.
 15. The laboratory will not ship research study samples to off-site laboratories or other locations. The laboratory will process and store specimens, but researchers must obtain them from the laboratory and perform any need aliquoting and shipping themselves. Due to space limitations, the Department of Pathology/RML is unable to allow storage of these special shipping supplies. The storage of these supplies is also the responsibility of the researcher.

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RESEARCH PROJECT REQUEST

INSTRUCTIONS: The Investigator must complete Section I (General Information) and Section III (Pricing) and return the completed form, with a copy of the title page and laboratory portion of the research protocol, to the Department of Pathology/RML Administration, Room 409 Rawson. Inquires, phone 2-4942.

(PLEASE ALLOW TEN WORKING DAYS FOR PROCESSING)

I. GENERAL INFORMATION:

Principal Investigator : _____

Department: _____ Extension: _____ Suite #: _____

Project Coordinator: _____ Extension: _____ Suite #: _____

Title of Research Project: _____

Fund Number: _____ Cost Center: _____

Anticipated Starting Date: _____ Length of Project: _____

ORA/HIC Approval: Received Pending ORA # _____

II. RML CHECKLIST (For RML Office Use Only)

Protocol submitted to RML Administration _____ (DATE)

Reviewed by RML Associate Director and distributed to appropriate RML Divisions _____ (DATE)

Notification to Client _____ (DATE)

Notification to Client Services _____ (DATE)

Fund Number Verification _____ (DATE)

LIS CLIENT NO.: _____

III. PRICING - RML LABORATORY PROCEDURES

CHECK THE TEST(S) NEEDED FOR THE RESEARCH STUDY.

<u>TEST NAME</u>	<u>PRICE</u>	<u>COMPONENTS</u>	<u>NUMBER FREQUENCY</u>
Chemistry Panels			
<input type="checkbox"/> BASIC METABOLIC PANEL [BMP]	\$ 14.75	Na, K, Cl, CO2, BUN, Creatinine, Glucose, Calcium, Anion Gap	
<input type="checkbox"/> COMPREHENSIVE METABOLIC PANEL [CMP]	\$ 18.50	Na, K, Cl, CO2, BUN, Creatinine, Glucose, Protein, Albumin, Calcium, Tbili, AP, SGOT, SGPT, Anion Gap	
<input type="checkbox"/> ELECTROLYTE PANEL [EP]	\$ 12.25	Na, K, Cl, CO2, Anion Gap	
<input type="checkbox"/> HEPATIC FUNCTION PANEL [HFP]	\$ 14.25	Protein, Albumin, Dbili, Tbili, AP, SGOT, SGPT	
<input type="checkbox"/> LIPID PANEL [LIPID PANEL]	\$ 23.50	Cholesterol, HDL, Triglycerides, Calculated LDL	
<input type="checkbox"/> RENAL FUNCTION PANEL [RFP]	\$ 15.25	Na, K, Cl, CO2, BUN, Creatinine, Glucose, Albumin, Calcium, Phosphorus, Anion Gap	
	If ordered individually		
Individual Automated Chemistry Tests			
<input type="checkbox"/> ALANINE AMINO TRANSFERASAE (ALT) [SGPT]	\$ 9.25		
<input type="checkbox"/> ALBUMIN	\$ 8.75		
<input type="checkbox"/> ALKALINE PHOSPHATE [AP]	\$ 9.00		
<input type="checkbox"/> AMYLASE	\$ 11.25		
<input type="checkbox"/> ASPARATE AMINO TANSFERASE (AST) [SGOT]	\$ 9.00		
<input type="checkbox"/> BILIRUBIN, DIRECT [DBILI]	\$ 8.75		
<input type="checkbox"/> BILIRUBIN, TOTAL [TBILI]	\$ 8.75		
<input type="checkbox"/> CK	\$ 11.38		
<input type="checkbox"/> CALCIUM	\$ 9.00		
<input type="checkbox"/> CARBON DIOXIDE [CO2]	\$ 8.50		
<input type="checkbox"/> CHLORIDE	\$ 8.00		
<input type="checkbox"/> CHOLESTEROL	\$ 7.50		
<input type="checkbox"/> CREATININE	\$ 9.00		
<input type="checkbox"/> GLUCOSE	\$ 6.75		
<input type="checkbox"/> LDH	\$ 10.50		
<input type="checkbox"/> LIPASE	\$ 12.00		
<input type="checkbox"/> PHOSPHORUS [PO4]	\$ 8.25		
<input type="checkbox"/> POTASSIUM [K]	\$ 8.00		
<input type="checkbox"/> TRIGLYCERIDE	\$ 10.00		
<input type="checkbox"/> TOTAL PROTEIN	\$ 6.50		
<input type="checkbox"/> SODIUM [NA]	\$ 8.50		
<input type="checkbox"/> UREA NITROGEN [BUN]	\$ 8.25		
<input type="checkbox"/> URIC ACID	\$ 8.00		
<input type="checkbox"/> ACTIVATED PTT [APTT]	\$ 11.25		
<input type="checkbox"/> AEROBIC CULTURE	\$ 7.50		
<input type="checkbox"/> ANA TITER	\$ 19.50		
<input type="checkbox"/> ANAEROBIC CULTURE	\$ 7.50		
<input type="checkbox"/> BLOOD CULTURE	\$ 18.00		
<input type="checkbox"/> C DIFFICILE TOXIN	\$ 21.00		
<input type="checkbox"/> CAMPYLOBACTER ANTIGEN DETECTION	\$ 21.00		
<input type="checkbox"/> CBC WITH DIFFERENTIAL	\$ 13.50		
<input type="checkbox"/> CD4/CD8	\$ 82.00		
<input type="checkbox"/> FERRITIN	\$ 23.75		
<input type="checkbox"/> FUNGUS CULTURE	\$ 13.50		

<u>TEST NAME</u>	<u>PRICE</u>	<u>COMPONENTS</u>	<u>NUMBER FREQUENCY</u>
<input type="checkbox"/> GRAM STAIN	\$ 7.50		
<input type="checkbox"/> HEPATITIS B SURFACE ANITGEN [HBSAG]	\$ 18.75		
<input type="checkbox"/> HCV GENOTYPING	\$ 61.30		
<input type="checkbox"/> HCV RNA PCR QUANTITATION	\$ 74.81		
<input type="checkbox"/> HEMOGLOBIN A1C	\$ 31.50		
<input type="checkbox"/> HIV ANTIBODY	\$ 15.50		
<input type="checkbox"/> HIV DNA BY PCR	\$ 148.61		
<input type="checkbox"/> HIV WESTERN BLOT	\$ 27.00		
<input type="checkbox"/> IRON	\$ 11.25		
<input type="checkbox"/> OCCULT BLOOD, STOOL	\$ 5.75		
<input type="checkbox"/> PAP SMEAR	\$ 35.50		
<input type="checkbox"/> PATHOGEN SEROTYPING	\$ 9.04		
<input type="checkbox"/> PROCESSING FEE*	\$ 15.00		
<input type="checkbox"/> PROTHROMBIN TIME [PT]	\$ 6.75	INR included	
<input type="checkbox"/> ROUTINE STOOL CULTURE	\$ 16.48	Salmonella, Shigella, Campylobacter, Aeromonas, Plesiomonas	
<input type="checkbox"/> SERUM PREGNANCY TEST [QUANT HCG]	\$ 26.25		
<input type="checkbox"/> SPECIAL STOOL CULTURE	\$ 16.50		
<input type="checkbox"/> T3	\$ 12.00		
<input type="checkbox"/> T4	\$ 12.00		
<input type="checkbox"/> TOTAL IRON BINDING CAPACITY [TIBC]	\$ 15.26		
<input type="checkbox"/> TSH	\$ 29.25		
<input type="checkbox"/> TU/T4	\$ 22.25		
<input type="checkbox"/> URINALYSIS	\$ 3.93		
<input type="checkbox"/> URINALYSIS WITH MICROSCOPY	\$ 5.54		
<input type="checkbox"/> URINE PREGNANCY TEST	\$ 11.05		
<input type="checkbox"/> VENIPUNCTURE	\$ 3.75		
<input type="checkbox"/> OTHER TESTS			

* The processing fee is for centrifuging and/or storage shipping of specimens for testing performed outside of RML. If special handling beyond that is required, please include a written procedure. The processing fee may vary depending on the extent of special handling required.

NOTE: Where appropriate, please specify the type of specimen, i.e., blood, urine, serum. For Microbiology procedures specify source.

NUMBER OF PATIENTS INVOLVED IN STUDY

Inpatients _____ Outpatients _____ Animal (specify) _____

IV. SPECIAL REQUIREMENTS

A. SPECIMEN COLLECTION

B. SPECIMEN HANDLING

C. RESULTS REPORTING
