Parkland Health & Hospital System
Department of Pathology
Research Support

The Road to Successful Request for Pathology Research Services

Kim Coston, MT(AMT)
Pathology Research & Client Services Coordinator
Research Approval Initiation

- Study is submitted to IRB for approval
- Parkland patients involved - Clinical Research Department (CRD)
- If Pathology services are requested, the study is forwarded to the Pathology Department
- Kim Coston, MT(AMT)
  Research and Client Coordinator
  - 214-590-5480
  - KACOST@parknet.pmh.org
Pathology Research Coordinator

- FT Medical Technologist
- Liaison between the CRD team, research staff and the lab
- Advanced knowledge of specimen processing, lab workflows, test analysis and regulatory requirements
Pathology Site Approval Process

1. Review

2. Implementation

3. Support Activities
Pathology Research Review Process

Lab services requested:

- Does the request match what is in the research Protocol and the Coverage Analysis?
- Does PHHS Pathology perform the test as requested?
- Does PHHS Pathology have the resources to participate in the research?
- Is the request in accordance with lab regulatory requirements?
Pathology Research Review Process (cont’d)

- Lab Manager Review
  - Approves participation
  - Reasons not to participate
    - Resources not available or adequate for the life of the study
    - Specimen for analysis has not been validated
    - Special handling (requiring interruption of normal processes or unsafe practice)
    - Participation requires IT alteration or build of new reporting structure

- Lab Director Approval
Pathology Research Implementation

- Special Account is established in EPIC to enable semi-automated billing of the research client

- Special Study “client” is built in the lab computer systems
  - Streamlines specimen processing
  - Allows for research results to be entered into the lab computer system (LIS) and reports printed
Pathology Research Implementation (cont’d)

- Special Studies Requisition is generated if a specimen is to be submitted to the lab
  - Lists only those lab tests specifically contracted for by the research study
  - Can not be used for other studies
  - Must accompany every research specimen to be analyzed by PHHS Pathology labs
  - May include special instructions/reminders for the research coordinator, patient care staff and the lab
# Special Studies Requisition Form

<table>
<thead>
<tr>
<th>Mall Code:</th>
<th>Participating ID:</th>
<th>Last Name:</th>
<th>First Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5121 Harry Hines Blvd.</td>
<td>(CRP)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dallas, TX 75235</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>Race:</td>
<td>Sex:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Black</td>
<td>White</td>
<td>Asian American</td>
</tr>
<tr>
<td></td>
<td>Hispanic</td>
<td>Non-Hispanic</td>
<td>Unknown</td>
</tr>
<tr>
<td>Client:</td>
<td>Ethnicity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RN:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CN:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigator:</td>
<td>Coordinator:</td>
<td>Study begins date:</td>
<td>Study end date:</td>
</tr>
</tbody>
</table>

## TEST REQUESTED

- White - Laboratory
- Yellow - Cost, Reimbursement
- Pink - Principal Investigator/Co-Principal Investigator

Distribution: White - Laboratory

Yellow - Cost, Reimbursement

Pink - Principal Investigator/Co-Principal Investigator
Pathology Research Services

- Phlebotomy services
- Routine test analysis
- Unstained and stained tissue slides; tissue specimens if available
- Microorganism culture, identification and isolates
- Lab computer database search
Pathology Research Services (cont’d)

Phlebotomy Services

- Specific request for a Pathology Department phlebotomist to collect the research specimen
- Special Studies Requisition or the Phlebotomy requisition is to accompany the patient to the Outpatient Phlebotomy area or the Heme / Onc Clinic lab area.
- Special Studies Requisition should be given to the phlebotomist at the nurses station if an inpatient.
- A fee is charged to the study if blood is collected for research only.
Heme/Onc LABORATORY VISIT

Study Title:  
IRB #:  
Client #:  
Principal Investigator:  

**EXTRA blood collection for research study.**  
No charge for blood collection if being done with standard lab draw

**Date & Time** of visit:  
Medical Record Number:  
Patient’s name:  
Date of birth:  

**Attention Study Coordinator:**  
1. This form & tubes to be collected should be given to the phlebotomist in the Heme/Onc lab.  
2. Demographic patient label is to be placed on tubes for phlebotomist.  
3. Research specimen will be given back to the Research Coordinator.

**Attention Heme/Onc Phlebotomist:**  
1. This patient is here to have extra blood collected.  
2. **Phlebotomist check one:**  
   - Extra blood collected with other lab draws  
   - OR Research only  
3. Give Research tubes to the Research Coordinator.  
4. If Research only, place copy of this form in Linda Sidden’s box.  
5. File original form.  

(Contact Kim Coston, Pathology Research Office, 214.590.5480 for questions)
Pathology Research Services (cont’d)

Laboratory Services Website

http://Parklandlab.com/

- Resource for lab tests performed at PHHS Pathology
- Test name and alias
- Specimen collection container
- Special handling instructions
- Reference range and Critical values
Pathology Research Services (cont’d)

- Anatomic Pathology Tissue and Slides
  - Tissue specimen and slides used for initial diagnoses are kept for ten years
  - Blocks used to report the initial diagnoses can be ‘checked out’ and must be returned to the lab
  - Tissue and slides can be released only with a signed patient consent
  - Tissues are released only if there is sufficient redundant specimen available
Tissue requests for research

- For slides, blocks and fresh tissue requests, contact KimberlyCoston@phhs.org
- Research Coordinator will be notified by lab when requested item is ready for pickup
- Must provide copy of signed patient consent to release tissue specimen
## Anatomic Pathology Fresh Tissue Request

| Date of Request: | ____________ |
| Requesting Personnel: | ______________ | Contact Phone/Beeper: | ______________ |
| Principal Investigator: | | Legacy IRB #: | ______ |
| eIRB #: | ____________ | Study Title: | ______________ |
| Medical Record Number: | | Patient’s Name: | ______________ | Date of Birth: | ____________ |

**Attention Requestor:**

1. Individual requesting specimens must be listed as a member on the study team before any tissue is released.

**Attention Anatomic Pathology Dept.:**

Date Service Completed: mm/dd/yy

Completed by: ____________

Initials only

(>Kimberly Coston, Pathology Research Office, 214.590.5480 for questions)
Microbiology Service

- Fees are based on a negative culture result
- Additional fees are billed for organism identification and/or susceptibility testing
- Fees are assessed for long-term storage of isolates and shipping of isolates to referral or sponsor labs
- Important to involve the Pathology Research Coordinator at study planning stage
- Project Summary must be reviewed for appropriate tests to help establish a reasonable budget
Pathology Research Services (cont’d)

Laboratory Database Search

- Specifics of the data requested must be discussed to determine feasibility
- Limitations to data retrieval from lab computer system
- Fees are based on time required to perform the search, complexity of the search and if IT outsourcing is required
Pathology Research Support Services

Research test results

- Chart reports mailed next business day via interoffice mail
- Same day results can be given via telephone:
  Kim Coston
  214-590-5480

- Provide the study patient’s name, date of birth and requisition number found under the barcode on the Special Studies Requisition
Pathology Research Support Services (cont’d)

- Invoice reconciliation assistance
- Pathology accreditation certificates
- Meet with study monitors
- Assist with pricing for budgeting purposes
Pathology Mission Statement

- We, as members of the Department of Pathology, are dedicated to contributing to the Parkland Mission of patient care, medical education and research.
- We will participate in this mission by providing timely, accurate, clinically relevant, state-of-the-art laboratory technology.
- We are committed to continuous improvement of our services and to meeting and exceeding the expectations of those we serve.
PHHS Pathology Department Team

- Kyle Molberg, MD
  Medical Director

- Debbie Perrault, MT(ASCP)
  Department Director

- Linda Siddens, MT(ASCP)
  Phlebotomy Services & Research Manager

- Kim Coston, MT(AMT)
  Research & Client Services Coordinator