GENERAL INFORMATION:

# Protocol Title:

# Short Study Title:

**Principal Investigator:**

**Coordinator:**

**Study Department:** **[ ]  Inpatient** **[ ]  Outpatient [ ]  Laboratory**

**[ ]  ED** **[ ]  Radiology [ ]  Respiratory**

**Will you require Space for this study?**

**[ ]  Research Visit Space [ ]  Storage of supplies/binders**

**[ ]  Work Space for Non-Children's Employee [ ]  Specimen Storage Space**

**Study Sponsor or Funding Source:**

Number of Visits

Number of Patients to be enrolled:

Are physician orders required for research drugs, procedures or tests? [ ]  Yes [ ]  No

Please contact Jermaine Dozier at 404-785-4592

DEPARTMENTS REQUIRED FOR RESEARCH PROCEDURES:

I. PHARMACY SERVICES NEEDED? [ ]  YES – SEE BELOW [ ]  NO – SKIP TO SECTION II

 Does Study involve Investigational Drug? – Contact Jane Chen, Investigational Pharmacist (404-785-0342)

Approved by: Date:

 Jane Chen, Research Pharmacist

1. VENIPUNCTURE or BLOOD DRAW SERVICES NEEDED?

 [ ]  YES – COMPLETE BELOW [ ]  NO – SKIP TO SECTION III

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Area(Primary Care/Specialty/ED)** | **Tests Requested** | **# of Tests Per Patient** |
|  |  |  |  |
|  |  |  |  |

To add rows: place cursor in far right box and press tab

Approved by: Date:

 Nurse Manager

III. LABORATORY SERVICES? [ ]  YES – COMPLETE BELOW [ ]  NO – SKIP TO SECTION IV

THE TEST LISTED BELOW ARE THE ONLY INHOUSE LAB TEST PROVIDED

|  |  |  |
| --- | --- | --- |
|  | **Tests Requested** | **# of Tests Per Patient** |
| Pregnancy Urine |  |  |
| Urinalysis W/ Dip Stick |  |  |
| Rapid Strep |  |  |
| Hemoglobin |  |  |
| Hemoglobin A1-C |  |  |

To add rows: place cursor in far right box and press tab

Approved by: Date:

 Starla Jones-Lab Manager

**IV. RESEARCH PROCESSING LABORATORY (SPECIMEN PROCESSING ONLY**) **(PLEASE NOTE THAT COURIER ARRANGEMENTS ARE NECESSARY)** [ ]  YES – COMPLETE BELOW [ ]  NO – SKIP TO SECTION V

**SUBMIT PROTOCOL TO labreasearchcoordinator@choa.org**

**[ ]** Processing [ ]  Storage Number of Specimens Per Patient

Processing Instructions:

Price quoted by Lab           (form must include price before approval by CHOA Research Department)

Approved by: Date:

**V. NON-INVASIVE CARDIOLOGY NEEDED?** [ ]  YES – COMPLETE BELOW [ ]  NO – SKIP TO SECTION VI **(THESE SERVICES ARE INPATIENT ONLY)**

|  |  |  |
| --- | --- | --- |
|  | **Type of Procedure** | **Number of Procedures Per Patient** |
| ECHO ONLY FOR INPATIENT |  |  |
|  |  |  |

Approved by: Date:

 Leonile Woolfork, Manager of Respiratory Care

**VI. RESPIRATORY SERVICES NEEDED?** [ ]  YES – COMPLETE BELOW [ ]  NO – SKIP TO SECTION VII

|  |  |  |
| --- | --- | --- |
|  | **Type of Procedure** | **Number of Procedures Per Patient** |
|  |  |  |
|  |  |  |

Approved by: Date:

 Leonile Woolfork, Manager of Respiratory Care

**VII. RADIOLOGY SERVICES NEEDED?** [ ]  YES – COMPLETE BELOW SECTION [ ]  NO

**THE SERVICES LISTED ARE THE ONLY RADIOLOGY SERVICES PROVIDED AT HUGHES SPALDING. ALL OTHER SERVICES PERFORMED AT GRADY**

|  |  |  |
| --- | --- | --- |
|   | **Type of Procedure** | **Number of Procedures per Patient** |
| Ultrasound |  |  |
| Fluoroscopy |  |  |
| Upper GI |  |  |
| Routine Diagnostics (Chest, Hand, Arm, etc.) Scans |  |  |

Approved by: Date:

Starla Jones, Manager of Radiology

**VIII. ED Used for Recruitment:** [ ]  YES – Get Signature [ ]  NO

Approved by: Date:

Juleen Woods, ED Nurse Manager

**IX. Clinic area Used for Recruitment:** [ ]  YES – Get Signature [ ]  NO

Approved by: Date:

Tekisha James, Practice Manager

**X. Adolescent Clinic area Used for Recruitment:** [ ]  YES – Get Signature [ ]  NO

Approved by: Date:

 Yekisha James/Tara Lynch, Clinical Operations Manager

**XI. Inpatient Used for Recruitment:** [ ]  YES – Get Signature [ ]  NO

Approved by: Date:

Shari Baker, Manager Inpatient Unit

**STUDY EQUIPMENT/SUPPLIES**

 [ ]  The sponsor will be providing any patient supplies, equipment, or devices for this study to be used inside Children’s.

 Please describe.

 [ ]  The study require Children’s purchasing any patient supplies, equipment, or devices.

 If supplies or equipment are needed whether supplied by the sponsor or being purchased a Research –Only Requisition must be completed.

 PLEASE REFER TO “PURCHASE ORDERS RESEARCH ONLY” TAB ON THE CLINICAL RESEARCH DEPARTMENT WEBSITE

 [ ]  Any equipment purchased must be inspected by clinical engineering and a copy of their approval letter sent to OSP.

Approved by: Date:

 Gary Noland, System Manager, Clinical Engineering

**IMPORTANT NOTE:**

**PROFESSIONAL FEES FOR READING/INTERPRETING:**

**Please contact the Office of Sponsored Programs for specific assistance.**

* Radiology Fees- All Radiology performed at Hughes Spalding will be sent to Emory for reading. Please contact Emory for professional fee billing.
* Cardiology Fees- Sibley Heart Center will bill professional fee directly.
* For further assistance, please contact OSP at**osp@choa.org**

**Yvette Dean Date OR Yasmin Tyler-Hill Date**

**Director Patient Care Services Campus Medical Director**

**Children’s Healthcare of Atlanta Children’s Healthcare of Atlanta**

 **Date**

**Financial Operations**

**Children’s Healthcare of Atlanta Hughes Spalding**

**Stephanie Meisner Date**

**Director of Research**

**Children’s Healthcare of Atlanta**

 **\_\_\_\_\_\_**

**Principal Investigator Date**