Office of Sponsored Programs
1920 Briarcliff Road, 3rd Floor, #372
Atlanta, Georgia 30329
404.785.6958

DEPARTMENT APPROVAL FORM

GENERAL INFORMATION:

Protocol Title: _____

_____

Short Study Title: _____

Principal Investigator: _____

Coordinator: _____

Study Site: ☐ **Scottish Rite** ☐ **Egleston** ☐ **Hughes Spalding** ☐ **Emory Children's Center** ☐ **Other**
☐ **Cystic Fibrosis Center** ☐ **Marcus** ☐ **Private Practice**

Study Sponsor or Funding Source: _____

In-patient Study ☐ **Outpatient Study** ☐

# of Visits **Location of Clinic Visits**

Number of Patients to be enrolled: _____

Are physician orders required for research drugs, procedures or tests? ☐ **Yes** ☐ **No**
If yes, contact Christy Bryant, RN –Clinical Informatics Specialist to create order set in EPIC – 404-785-5062
(for all projects where inpatient enrollment will be ongoing)

DEPARTMENTS REQUIRED FOR RESEARCH PROCEDURES:

I. PHARMACY SERVICES NEEDED? ☐ YES – SEE BELOW ☐ NO – SKIP TO SECTION II
Does Study involve Investigational Drug? – Contact Jim Rhodes, Investigational Pharmacist (404-785-1281)

Approved by:_____ Date: _____
Jim Rhodes, Research Pharmacist

II. VENIPUNCTURE; EXTRA TUBES DURING ROUTINE DRAW; REQUEST FOR LEFT OVER SPECIMEN OR REFERENCE LAB
☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION III
MEET WITH GIGI DAVIS AND PROVIDE COPY OF PROTOCOL FOR REVIEW

	Tests Requested	# of Tests Per Patient

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

Approved by: _____ / _____ Date:_____
Cindy Brawley, Manager / Beverly Rogers, MD

III. CHEMISTRY AND HEMATOLOGY SERVICES NEEDED? ☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION VI
MEET WITH GIGI DAVIS AND PROVIDE COPY OF PROTOCOL FOR REVIEW

	Tests Requested	# of Tests Per Patient
Chemistry		
Hematology		

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

Approved by: _____ / _____ Date:_____
Cheri Curtis, Manager / Beverly Rogers, MD

IV. MICROBIOLOGY/ VIROLOGY SERVICES NEEDED? ☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION V
MEET WITH LAB MANAGER AND PROVIDE COPY OF PROTOCOL FOR REVIEW

	Tests Requested	# of Tests Per Patient

Approved by: _____ / _____ Date: _____
Jonelle McKey, Manager / Beverly Rogers, MD

V. HISTOLOGY/ PATHOLOGY SERVICES NEEDED? ☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION VI

MEET WITH GIGI DAVIS AND PROVIDE COPY OF PROTOCOL FOR REVIEW

	Tests Requested	# of Tests Per Patient

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

Approved by: _____ / _____ Date: _____
Carla Shoffeitt, Manager / Beverly Rogers, MD

VI. BLOOD BANK SERVICES NEEDED? ☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION VII

(i.e., transfusion products, factor storage) NOTE: All blood or blood products or factor replacement products must be stored in the Children's blood bank. Storage in unapproved refrigerators or freezers outside of blood bank is not allowed.

MEET WITH LABORATORY MANAGER AND PROVIDE COPY OF PROTOCOL FOR REVIEW

Services Needed		

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

Approved by: _____ / _____ Date: _____
Beth Polstra, Manager / Beverly Rogers, MD

VII. RESEARCH PROCESSING LABORATORY (SPECIMEN PROCESSING ONLY)

☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION VIII

SUBMIT PROTOCOL TO DIANA WORTHING-WHITE FOR PRICING

☐ Processing ☐ Storage Number of Specimens Per Patient

Processing Instructions:

Price quoted by Diane Worthington White (form must include price before approval by CHOA Research Department)

Approved by: _____ Date: _____
Diana Worthington White

VIII. NON-INVASIVE CARDIOLOGY NEEDED? ☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION IX

MEET WITH NON-INVASIVE MANAGER AND PROVIDE COPY OF PROTOCOL FOR REVIEW

	Type of Procedure	Number of Procedures Per Patient

Approved by: _____ Date: _____
Arlene Porter, Manager

IX. REHABILITATION SERVICES NEEDED? ☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION IX

MEET WITH REHAB MANAGER AND PROVIDE COPY OF PROTOCOL FOR REVIEW

	Type of Procedure	Number of Procedures Per Patient

Approved by: _____ Date: _____
Susannah Kidwell, Clinic Director of Rehabilitation Services

X. RADIOLOGY SERVICES NEEDED? ☐ YES – COMPLETE BELOW SECTION AND NEXT PAGE ☐ NO – SKIP TO SECTION X

	Type of Procedure	Number of Procedures per Patient
MRI		
CT Scan		

Ultrasound		
Interventional Radiology		
Fluoroscopy		
Diagnostic Radiology		
Nuclear Medicine		
PET/CT		

1. **PLEASE COMPLETE THE ATTACHED RADIOLOGY DEPT. RESEARCH REVIEW AND APROVAL FORM**
2. **SUBMIT THIS FORM WITH A COPY OF YOUR PROTOCOL TO:**
   MELINDA DOBBS, OPERATIONS MANAGER
   DEPT. OF RADIOLOGY
   EGLESTON CAMPUS
3. **THE RESEARCH DEPARTMENT MUST HAVE A COPY OF THE ATTACHED RADIOLOGY APPROVAL FORM PRIOR TO CHOA RESEARCH DEPARTMENT FINAL APPROVAL**

Radiology Department
Research Review and Approval Form

Protocol/Grant Title:

Principal Investigator:

Originating Department:

In the section below, please detail the involvement of the Radiology Department (i.e. staff, equipment, space) in the conduct of the above referenced study:

Site: ☐ **Scottish Rite** ☐ **Egleston**

# of subjects to be enrolled? **Length of study enrollment:**
Length of study patient follow-up:

Does this protocol involve the use of new or revised software or equipment?
☐ **Yes** ☐ **No If yes, please describe:**

_____

_____

Person responsible for staff education regarding the project: _____
Study Contact
Name:
Phone:
Fax:
Email:
Please attach a copy of the protocol and any supporting documentation (i.e. sample/proposed budget).

For Radiology Department Use Only

Radiology Review and Approval
Please sign and date once approved.

Name	Title	Signature	Date Reviewed	Comments
Jessica Huamani	Research Coordinator			
Jack Knight-Scott, PhD	MRI Physicist, ECH			
Richard Jones, PhD	MRI Physicist, SR			
Melinda C. Dobbs	Operating Manager, ECH			
Carl Saylors	Operating Manager, SR			
Kate DiStasi	Business Manager			
David Moyer	IS Administrator			
Stacey Deweese	Director, Radiology			

XI. OTHER DEPARTMENTS NEEDED?

☐ YES. COMPLETE APPROPRIATE SECTIONS BELOW. MEET WITH MANAGER OF EACH SERVICE LINE FOR APPROVAL. CONTACT THE OFFICE OF SPONSORED PROGRAMS FOR ASSISTANCE.

☐ NO – SKIP TO SECTION XI

	Type of Procedure	Number per Patient
GI Lab		
EEG/Sleep Lab		
Neuropsychology Testing		
Pulmonary Lab		
Operating Room/Minor Procedure Room		
Cath Lab		

To add lines, press TAB in the "Number per Patient" column

Approved by: _____ Date: _____

Medical Director/ Manager

XII. CONSCIOUS SEDATION SERVICES NEEDED: ☐ YES – COMPLETE BELOW ☐ NO – SKIP TO SECTION XII

☐ EGLESTON CONTACT JANA STOCKWELL AT jana.stockwell@choa.org

☐ SCOTTISH RITE CONTACT PEDIATRIC EMERGENCY MEDICAL ASSOC., DR. DAVID WERNER @ david_werner@pema-llc.com

You must make arrangements for notifying them when a patient is scheduled and for insuring that invoices are done correctly. The Research Department can not manage billing for private practices.

XIII. PEDIATRIC RESEARCH UNIT? ☐ YES ☐ NO

☐ **OUTPATIENT UNIT** ☐ **INPATIENT UNIT**

FOR COMPLETE INSTRUCTIONS ON HOW TO PROCESS YOUR PROPOSAL THROUGH CTSA RESEARCH COMMITTEE AT EMORY AND CHILDREN'S CONTACT CHRISTINE SPAINHOUR, Clinical Research Unit Manager at 404.785.0380 or email at Christine.spainhour@choa.org

Approved by: _____ Date: _____

Christine Spainhour, Manager

XIV. STUDY EQUIPMENT/SUPPLIES

☐ Will the sponsor be providing any patient supplies, equipment, or devices for this study to be used inside Children's? Please describe.

☐ Will 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:

This is a general guide only, contact the Office of Sponsored Programs for more specific assistance.

- Pathology Fees: Children's Charge.
- If procedure is done at Egleston, a professional fee is charged and billed by Emory. Most prices can be obtained through the Office of Clinical Research and all billing arrangements must be made through them.
- If procedure is done at Scottish Rite, the professional fee is charged by a private practice. Prices must be negotiated with each practice and billing arrangements must be arranged with that practice.
- Neuropsychology Fees must be negotiated with the Director of Neuropsychology (Thomas Burns).
- For further assistance, please contact OSP at **osp@choa.org**

_____ **OR** _____

Beverly Yandell or Mimi Kartsonakis **Date**
Office of Sponsored Research
Children's Healthcare of Atlanta

Kristine Rogers **Date**
Director of Research
Children's Healthcare of Atlanta