Office for Clinical Research

Operating Procedure

Document Type: Standard Operating Procedure (SOP)

SOP Title: Rapid Response Team

SOP Number: OCR-CRSS-SOP-1.00

Effective Date: 9-January-2020

APPROVED BY SIGNATURES:

Associate Director, Clinical Research Support Services	*Date*
Executive Director, Office for Clinical Research	*Date*

Date	Version	Description of Change	Author
9-January-2020	1.0	Initial Version	LaToya Carter
9-March-2020	1.1	Updated Version	Sherry Coleman

Table of Contents

1.0 Terminology and Acronyms

Term	Definition
CRSS	Clinical Research Support Services
EHC	Emory Healthcare
EHSO	Environmental Health and Safety Office
GCRC	Georgia CTSA Clinical Research Center
IDS	Investigational Drug Services
IRB	Institutional Review Board
OC	Office of Compliance
OCR	Office for Clinical Research
OSP	Office of Sponsored Program
OTT	Office of Technology Transfer
OoQ	Office of Quality
POC	Point of Contact
RAS	Research Administration Services
RSC	Radiation Safety Committee
SOP	Standard Operating Procedure

2.0 Document Purpose

The purpose of this SOP is to define the steps when expediting high priority studies of experimental therapeutics for pre-award approval.

3.0 Scope

This SOP applies to the process for submission of the Rapid Response Team (RRT) Service Request Form.

4.0 Responsibilities

The RRT is responsible for reviewing study submissions that meet the Qualifying Criteria for review and approval through the RRT. The RRT will faciliate the approval process concurrently to fast-track study approval within seven calendar days or based upon special protocol implementation timeline requirements.

5.0 Procedures

Step 1: Completion of RRT Request Form

The Investigator should complete the ***RRT Request Form*** and submit the proposal via the MYRESEARCHNAVIGATOR@LISTSERV.CC.EMORY.EDU listserv. The Clinical Research Navigator team will check the listserv for submissions daily. If submission is emergent, please call or text the Executive Director of the OCR at 404-877-2012 and/or by email at rginn@emory.edu.

Step 2: Submission Review

Within 24 hours of receipt (same day preferred) of the ***RRT Request Form***, the Clinical Research Navigator team will review the submission, confirm receipt of all required documents, and submit the protocol to the Associate Dean of Clinical Research or the Executive Director of the OCR for approval.

a. Documents required for submission are:
    1. RRT Request Form
    2. Protocol
    3. Inform Consent
    4. Investigator Brochure
    5. Clinical Trial Agreement (CTA)
    6. Sponsor Budget
    7. IND/IDE Approval (if applicable)
    8. IND/IDE Exemption Letter (if applicable)

The Clinical Research Navigator team will notify the Investigator the same day or within 24 hours if the study ***does not meet*** the qualifying criteria for RRT review and approval by the RRT.

Step 3: Qualifying Document Review

The Associate Dean of Clinical Research or the Executive Director of the OCR will review the submission packet to determine if the protocol meets the qualifying criteria for review. If the study meets the criteria, the RRT review will be completed by the Emory University IRB within seven calendar days; timeline contingent upon patient/subject safety or governmental directive. If applicable, external/single IRB will be notified of urgency.

If the study ***meets*** the qualifying criteria, the Clinical Research Navigator team will:

a. Notify the Investigator of approval study status via phone and email
b. Initiate deployment of the RRT
    1. Send notification email to appropriate/pertinent RRT POCs
    2. Attach approved submission form and all required documents to notification email
    3. Schedule Skype meeting with RRT POCs as necessary

Step 4: **Department Review**

Each department (if applicable) will complete departmental approval. If applicable, external/single IRB will be notified of urgency. The Clinical Research Navigator team will facilitate the pre-award approval process to completion and notify the Investigator when study approvals are completed. All POCs will be notified upon final approval.

The Associate Dean of Clinical Research and Directors of OSP and OTT should be contacted for any sponsor-related issues and/or restrictions that may affect the departmental timeline or delay departmental approval.

Appendix A: Qualifying Criteria

- High Priority: Requiring emergency approval for survival
- Public Health Emergency
- Bioterrorist Attack
- Significant outbreak of an Infectious Disease
- Other significant or Catastrophic Event
- NIH or other Federal Funded Network Study
- Centers for Disease Control and Prevention (CDC)
- IND or IDE

RAPID RESPONSE TEAM (RRT) STUDY SUBMISSION FORM

DATE OF SUBMISSION: Select date from drop-down.

CONTACT INFORMATION (please include alternates):

PI Name: Enter name	**Email:** Enter email	**Daytime #:** Enter number	**Cell/Pager #:** Enter number
CRC Name: Enter name	**Email:** Enter email	**Daytime #:** Enter number	**Cell/Pager #:** Enter number

FUNDING SOURCE: Click here to enter text.

TYPE(S) OF STUDY: ☐ DRUG ☐ BIOLOGIC/Vaccine product ☐ DEVICE ☐OTHER

IF APPLICABLE, NAME OF DRUG/DEVICE: Click here to enter text.

IRB # Click here to enter text.

IBC # Click here to enter text.

PROTOCOL TITLE: Click here to enter text.

BRIEF SUMMARY OF STUDY *(attach copies of Protocol, Informed Consent Document, research experiments and other relevant documents)***:**

JUSTIFICATION FOR RAPID RESPONSE TEAM:

For Rapid Response Team/Official Use Only

☐ Application for approval of new study **IS Approved** for Review

☐ Application for approval of new study **IS NOT Approved** for Review

Approver Comments:

APPENDIX C: POC

NAME	TITLE	OFFICE	OFFICE #	MOBILE #	EMAIL
Clinical Research Support Services (CRSS)					
Jeffery Lennox, MD	Assoc Dean, Clinical Research		[redacted]	404-384-1708	jlennox@emory.edu
Sherry Coleman	Assoc Exec Dir, Clinical Trials	5.109	[redacted]	678-849-7502	sherry.coleman@emory.edu
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Office for Clinical Research (OCR)					
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Institutional Review Board					
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Maria Davila	Assoc Director	5.212	[redacted]	404-213-1074	maria.davila@emory.edu
Julie Martin	Asst Director	5.217	[redacted]	727-244-7282	julie.t.martin
Office of Research Compliance (ORC)					
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Susan Rogers	Director	Ste. 1200	[redacted]	404 259-1503	sroger2@emory.edu
Esther Park		Ste. 1200	[redacted]		esther.sue.park@emory.edu
Clinical Research Network (CRN) *					
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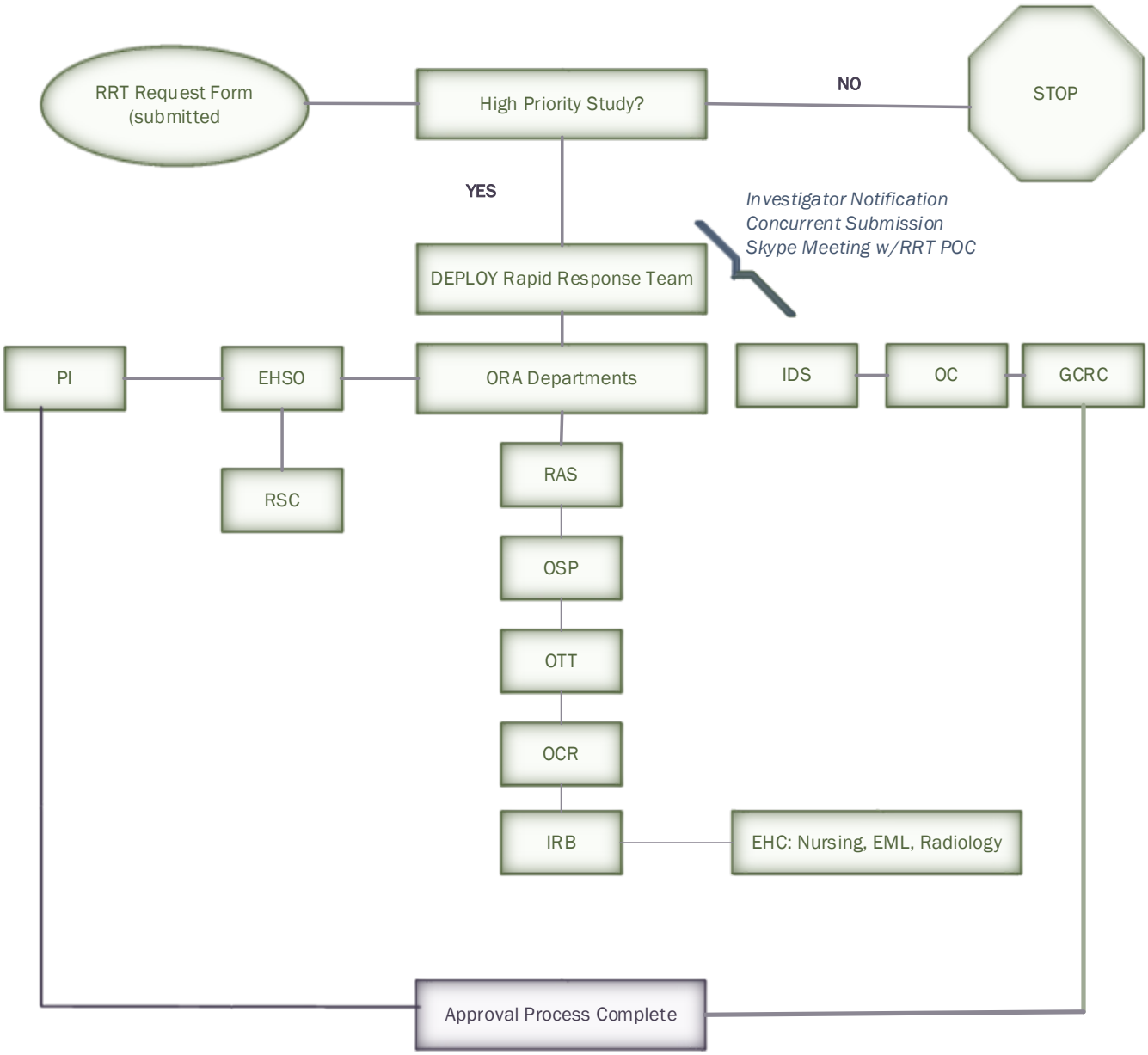
Ike Hall	Asst Director		[redacted]	404-819-4672	ike.hall@emory.edu
Jeffery Rasmituth	Director		[redacted]	404-807-6001	jeffrey.rasmituth@emory.edu

Appendix D: Flowchart



By signing below, I hereby acknowledge that I have read, comprehend and agree to comply with the attached SOP/IOP.			
Name	**Signature**	**Version**	**Date**