

### ACUTE CARE RESEARCH COUNCIL

Standard Operating Procedure  
Regulatory Assistance/Consulting Access

SOP#  
SOP Effective Date

ACRC-1  
15Sep2016

#### 1.0 PURPOSE

1.1 The purpose of the following standard operating procedure (SOP) is to describe the process to be followed to access *regulatory assistance/consulting* at no charge for acute care research initiatives.

#### 2.0 SCOPE

2.1 This procedure applies to all Acute Care Research Council (ACRC) member units (see attachment 4.1) that encounter a need for short term/ad hoc regulatory assistance/consulting.

#### 3.0 PROCEDURE

- 3.1 Members to email ACRC project manager (PM) with request; email to include:
- 3.1.01 Amount of effort requested, with a maximum of **10%**.
  - 3.1.02 Effective time period of requested assistance, with a maximum of **three months**.
  - 3.1.03 Reason for request (e.g., new study, FMLA, new process required)
- 3.2 PM provides request to ACRC for acceptance/rejection decision, with goal of decision notification to member in 5 business days.
- 3.3 PM transfers *accepted* requests to regulatory consultant for implementation.
- 3.4 PM communicates this resource ongoing through appropriate ACRC channels.

#### 4.0 ATTACHMENT

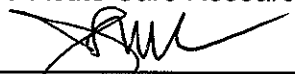
4.1 Acute Care Research Council member units

#### 5.0 REFERENCE

5.1 Acute Care Research Council – Project Charter

#### 6.0 APPROVAL

6.1 Acute Care Research Council Co-Directors:

  
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Jackie Grupp-Phelan, MD MPH

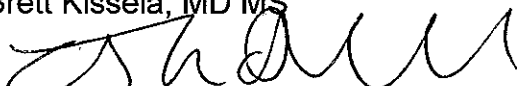
9-13-16

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Date

  
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Brett Kissela, MD MS

9/12/16

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Date

  
\_\_\_\_\_  
Christopher Lindsell, PhD

7 September 2016  
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Date