**ACUTE CARE RESEARCH COUNCIL**

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| Standard Operating Procedure | *SOP#* | *ACRC-1* |
| *Regulatory Assistance/Consulting Access* | *SOP Effective Date* | *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:

Jackie Grupp-Phelan, MD MPH — Date: 9-13-16

Brett Kissela, MD MS — Date: 9/12/16

Christopher Lindsell, PhD — Date: 7 September 2016