



September 6, 2018

RE: 10-779: REGISTRY: Acute Pancreatitis Registry

Your response dated 9/6/2018 to the prior review of your renewal application on 8/28/2018 is acceptable. Your study is now fully **approved for the period 9/7/2018 to 9/6/2019.**

You are approved to continue this research with the use of Continuing Renewal Application 8/21/18 and Data Collection Sheets.

The stamp-approved Data Collection Sheets are available on-line under the Stamped Documents tab.

A waiver of Informed Consent and waiver of HIPAA authorization is approved to allow access to PHI by the research team however, sharing or releasing identifiable data to anyone other than the study team is not permitted without additional IRB approval.

Any changes or amendments require IRB review and approval prior to implementation. Unanticipated problems including adverse events and deviations are to be reported in accordance with IRB Policy 60: Adverse Events and IRB Policy 70: Unanticipated Problems.

This study may not continue beyond the approved expiration date. Submit a renewal application up to 30 days prior to expiration to allow sufficient time for IRB review or a completion report for closure.

Sincerely,

A handwritten signature in black ink that reads "Bridget Howard".

Bridget Howard, Esq., CIP
Executive Director, IRB and Human Research Protections

BH/sls

Expiration Date: 9/6/2019

A signed copy of this letter is available online under the Correspondence tab

