

Initial Review: Notification of IRB Exemption Protocol #: 2015P002706/BWH

Date: January 11, 2016

To: Richard D Urman, MD
BWH
Anesthesia

From: Partners Human Research Committee
116 Huntington Avenue, Suite 1002
Boston, MA 02116

Title of Protocol: Preventable Adverse Outcomes after Surgery: Intraoperative and Postoperative Variables Affecting Adverse Outcomes, Readmission and Reoperation Rates after Major Surgery (using ACS-NSQIP database)

IRB Review Type: Expedited

IRB Review Date: 1/11/2016

IRB Review Action: Exempt

The IRB has determined that this project meets the criteria for exemption 45 CFR 46.101(b) (4) Research involving the collection or study of EXISTING data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. EXISTING means that the data, documents, records, pathological specimens, or diagnostic specimens already exist at the time the research is proposed and are not prospectively collected.

Continuing review is not required.

As Principal Investigator, you are responsible for the following:

1. Ensuring that this project is conducted in compliance with the exemption determination.
2. Ensuring that all study staff have completed the required human research education requirements through the Collaborative Institutional Training Initiative (CITI).
3. Submission of significant proposed changes to this project to ensure that the project continues to meet the criteria for exemption.

Questions related to this project may be directed to Fred Syllien, FSYLLIEN@PARTNERS.ORG, 617-424-4124.