

Human Research Protection Office

Barnes Jewish Hospital
St. Louis Children's Hospital
Washington University

IRB ID #: 201310139**To:** Surachai Amornsawadwattana

From: The Washington University in St. Louis Institutional Review Board,
WUSTL DHHS Federalwide Assurance #FWA00002284
BJH DHHS Federalwide Assurance #FWA00002281
SLCH DHHS Federalwide Assurance #FWA00002282

Re: Evaluation of Video Capsule Endoscopy in Patients with Left Ventricular Assist Devices.

Protocol Number:

Protocol Version:

Protocol Date:

Amendment Number/Date(s):

Approval Date: 08/11/15 (Expedited)

This project has been granted a full waiver of HIPAA Authorization based on the documentation provided by the researcher in the myIRB application Section IV and the assurance document signed by the Principal Investigator.

This full waiver of authorization satisfies the following criteria:

- (1) The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
 - (a) An adequate plan to protect the identifiers from improper use and disclosure
 - (b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - (c) Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
- (2) The research could not practicably be conducted without the waiver or alteration; and
- (3) The research could not practicably be conducted without access to and use of the requested information.

This approval has been electronically signed by IRB Chair or Chair Designee:

Jennifer Weinman, CIP, BA, MA

08/11/15 1300