



University of California  
San Francisco

**Human Research Protection Program  
Institutional Review Board (IRB)**

**Expedited Review Approval**

Principal Investigator

Jeffrey K Lee

**Type of Submission:** Submission Correction for Initial Review Submission Packet  
**Study Title:** Yield of endoscopy in the identification of pre-malignant and malignant gastrointestinal lesions in patients with dermatomyositis

**IRB #:** 16-19908

**Reference #:** 167667

**Committee of Record:** San Francisco General Hospital Panel

**Study Risk Assignment:** Minimal

**Approval Date:** 06/22/2016

**Expiration Date:** 06/21/2019

**Regulatory Determinations Pertaining to this Approval:**

The requirement for individual Research HIPAA Authorization is waived for all subjects. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements:

(1) an adequate plan to protect the identifiers from improper use and disclosure; (2) 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 if such retention is otherwise required by law; (3) 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; (4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

A waiver or alteration of informed consent is acceptable because, as detailed in the application: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation

The waiver or alteration of informed consent applies to all subjects.

**This submission was eligible for expedited review as:**

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

**IRB Comments (if applicable):**

***All changes to a study must receive UCSF IRB approval before they are implemented.*** Follow the [modification request](#) instructions. The only exception to the requirement for prior UCSF IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these [instructions](#).

**Expiration Notice:** The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for [continuing review](#) approval has been submitted by the required time. In addition, you are required to submit a [study closeout report](#) at the completion of the project.

**Documents Reviewed and Approved with this Submission (includes all versions – final approved versions are labeled 'Approved' in the Outcome column):**

**Other Study Documents**

Study Document			
Title	Version #	Version Date	Outcome
protocol	Version 1.0	06/09/2016	Approved

For a list of [all currently approved documents](#), follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

**San Francisco Veterans Affairs Medical Center (SFVAMC):** If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The UCSF IRB [website](#) has more information.