University of California
San Francisco

Human Research Protection Program
Institutional Review Board (IRB)

Expedited Review Approval
No Continuing Review

Principal Investigator
Andrew Auerbach

Type of Submission: Submission Correction for Initial Review Submission Packet
Study Title: Improving pain control and mobility through a multidimensional QI program

IRB #: 19-28287
Reference #: 255392
Committee of Record: San Francisco General Hospital Panel
Study Risk Assignment: Minimal

Approval Date: 08/29/2019

Regulatory Determinations Pertaining to this Approval:

Individual Research HIPAA Authorization is required of all subjects. Use the Permission to Use Personal Health Information for Research form.

A waiver of HIPAA Authorization and consent is acceptable for the recruitment procedures to identify potential subjects. The recruitment procedures involve routine review of medical or other records, do not adversely affect the rights and welfare of the individuals, and pose 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, or a health or research justification for retaining the identifiers was provided or 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 study recruitment could not practicably be conducted without access to and use of the requested information. Study participants will sign a consent form prior to participation in the study.

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)
Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Expedited Review Category 5: Identifiability of the final data set
Identifiable data set with direct identifiers

IRB Comments:

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 46.108(a)(3)(iii), 21 CFR 56.108(a)). In such cases, report the actions taken by following these instructions.

Expiration Notice: As a study qualifying for expedited review under the revised Common Rule, this study will not expire. You will not be required to submit continuing review reports to the IRB. However, this study remains under the oversight of the IRB and it may request periodic updates on the status of the study. You are still required to submit modifications, adverse events and protocol violations.

In addition, you are required to submit a study closeout report at the completion of the project.

Documents Reviewed and Approved with this Submission:

Consent Documents

Study Consent Form			
Title	Version #	Version Date	Outcome
CONSENT	Version 1.3	06/24/2019	Approved

Other Study Documents

Study Document			
Title	Version #	Version Date	Outcome
PostdischargePatientQuestionna	Version 1.1	06/24/2019	Approved
PredischargePatientQuestionnai	Version 1.1	06/24/2019	Approved
STEADI-OPIOIDS Patient Contact Letter	Version 1.2	06/24/2019	Approved
Letter from Kay	Version 1.0	08/02/2019	Approved
STEADI-OPIOIDS Patient followup letter	Version 1.0	06/24/2019	Approved
STEADI - HIPAA research form	Version 1.0	06/24/2019	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.