University of California
San Francisco

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

# Full Committee Approval

**Principal Investigator**
Rachael Callcut, MD

**Co-Principal Investigator**
Lucy Kornblith, MD

**Type of Submission:** Continuing Review Submission Form
**Study Title:** Activation of Coagulation & Inflammation in Trauma (ACIT)

**IRB #:** 10-04417
**Reference #:** 218388
**Reviewing Committee:** San Francisco General Hospital Panel
**Study Risk Assignment:** Minimal

**Approval Date:** 04/19/2018 **Expiration Date:** 04/18/2019

**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.

A waiver of the requirement to obtain a signed consent form is acceptable for this study because, as detailed in the application, the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
The waiver applies to some subjects, as detailed in the application.

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 some subjects, as detailed in the application.

The plans for obtaining informed consent from legally authorized representatives are acceptable and are consistent with California law and UC guidance.

***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:**

## Consent Documents

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|---|---|---|---|
| Study Consent Form | | | |
| Title | Version # | Version Date | Outcome |
| ACIT Surrogate no ICU consent form Version 3.19.18 | Version 1.15 | 04/10/2018 | Approved |
| ACIT Surrogate ICU consent form Version 3.19.18 | Version 1.14 | 04/10/2018 | Approved |
| Consent Healthy Volunteer | Version 1.5 | 03/19/2018 | Approved |
| ACIT Subject no ICU consent form Version 3.19.18 | Version 1.20 | 04/10/2018 | Approved |
| Telephone Consent Subject Only 3.19.18 | Version 1.14 | 04/10/2018 | Approved |
| ACIT Subject ICU consent form Version 10.16.17 | Version 1.26 | 04/10/2018 | 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 IRB website has more information.

Please note: At UCSF, this study is using data already collecting under an ongoing study investigating blood coagulation in trauma patients (not exclusively HIV+ patients). As such, we are not posting our full IRB protocol submission, as much of it does not pertain to this study. Please reach out to the Study Coordinator, Amanda Conroy at Amanda.Conroy@ucsf.edu, for questions relating to IRB Submission. Thank you!