UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Dr. Susan Little

RE: Project #190302
Long-Term Follow-up of Individuals Treated for Acute and Early HIV Infection

Dear Dr. Little:

The above-referenced project was reviewed and approved by one of this institution's Institutional Review Boards or through expedited process in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46), including its relevant Subparts, for federally funded/support research studies. This approval, based on the degree of risk, does not expire unless otherwise stated in this letter.

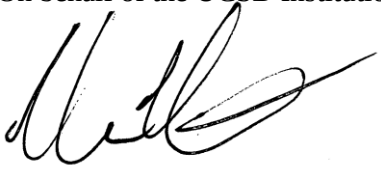
It was determined that waiver of informed consent may be granted for this project as it meets the requirements outlined in 45 CFR 46.116(d). The research is minimal risk; the waiver or alteration will not adversely affect the rights; welfare of the subjects; the research could not practicably carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

It was determined that this project presents no more than minimal risk to human subjects in that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

This study was reviewed through the expedited review procedure as authorized by 45 CFR 46.110 and falls under the following research category: (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Date of IRB review and approval: **8/21/2019**

On behalf of the UCSD Institutional Review Boards,



/jd

Kip Kantelo
Director
UCSD Human Research Protections Program
858-246-HRPP (858-246-4777); hrpp@ucsd.edu

Note: IRB approval does not constitute funding **or other institutional required approvals.** Should your studies involve other review committees such as Office of Clinical Trials Administration (OCTA), Office of Coverage Analysis Administration (OCAA), Conflict of Interest (COI), Protocol Review Monitoring Committee (PRMC), and committees under Environmental Health & Safety (EH&S) such as Institutional Biosafety Committee (IBC), Human Exposure Committee (HERC), and RSSC (Radiation Safety and Surveillance Committee), it is the researchers responsibility to ensure that all approvals are in place prior to conducting research involving human subjects or their related specimens.

UCSD HUMAN RESEARCH PROTECTIONS PROGRAM

GENERAL APPROVAL INFORMATION

The information below does not encompass all human subjects protections requirements, however, is intended to highlight those of significance to ensure awareness by researchers engaged in research involving human subjects or their related specimens and data.

Approval Letters and Consent Documents

Unless otherwise stated, approval letters will be accompanied by stamped, approved consents. Should a study be closed to accrual and no consent released as a result, this information will be documented on the approval letter. Also, any waivers will be documented in the approval letter (such as waiver of documented consent or waiver of authorization for use of PHI).

The PI must ensure approval is in place from other appropriate review boards (such as Conflict of Interest, Office of Clinical Trials Administration, Office of Coverage Analysis Administration, ESCRO Committee, etc.).

If other institutions are involved, the PI must ensure that IRB approvals (or other administrative approvals) from those sites are secured and forwarded for the study file. In addition, PI's must ensure that the clinical trial agreement, as applicable, or other funding (such as a grant) is appropriately in place prior to conducting any research activities. IRB approval does not constitute funding approval.

Duration of IRB approval

As noted in 45 CFR 46.109(f)(1) (Final Rule), unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with §46.110;
(ii) Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Amendment/revision to an IRB approved study

IRB approval is required before implementing any changes in the approved Research Plan, consent documents, recruitment materials, or other study-related documents. Amendment request approval is especially important if any changes affecting the criteria for approval are being requested (see above). If a study becomes ineligible for extended approval, such as by securing new federal funding or other changes, the PI is responsible for promptly submitting an amendment to inform the HRPP of these changes. The HRPP will issue a "new" approval letter with a shortened approval period, as appropriate. Please see Amendment Fact Sheet at http://irb.ucsd.edu/amendmodchg.pdf for submission guidance.

For Cancer Related Studies: If the study is billing or intends to bill under the Medicare National Coverage Decision (NCD) or SB37 (State) rules AND the amendment impacts the expense or billing to the study participant and/or their insurance, a revised Billing Addendum must be submitted to the Research Compliance Office. For Billing Addendum and submission instructions, please see item 27 of the IRB Biomedical Application Research Plan instructions at http://irb.ucsd.edu .

Adverse Event and Unanticipated Problems Reporting

All problems having to do with subject safety must be reported to the IRB within ten working days. All deaths, whether or not they are directly related to study procedures, must be reported. For adverse events, please utilize the form found at https://irb.ucsd.edu/UPR_biomedical.doc. For deviations and other reports, a cover letter and any supplemental information appropriate to the review should be provided. Please see IRB Guidelines for more information at http://irb.ucsd.edu.

Changes in financial Interest or Conflict of Interest (COI) disclosure

Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the Independent Review Committee via the Conflict of Interest Office. If these changes affect the conduct of the study or result in a change in the required wording of the approved consent form, then these changes must also be submitted as an amendment request.