SCHARP
Statistical Center for HIV/AIDS Research and Prevention

STATISTICAL ANALYSIS PLAN FOR HVTN IMMUNOGENICITY

Protocol HVTN 123 (v1.0)

A phase 1 double-blind, randomized, controlled clinical trial in healthy, HIV-1-uninfected adult participants to compare the safety, tolerability and immunogenicity of CH505TF gp120 produced from stably transfected cells to CH505TF gp120 produced from transiently transfected cells

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SAP version: 1.0

Statistical Analysis Plan for Immunogenicity

Protocol: HVTN 123 (v1.0)

Document will become effective on date of last signature.

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SAP Modification History

The version history of, and modifications to, this statistical analysis plan are described below.

SAP Version	Modification
1.0	Initial version for NAb and BAMA

Table of Contents

1 OVERVIEW

The following describes the Statistical Analysis Plan (SAP) for the analysis of immunogenicity data from HVTN 123 for Protocol Team (PT) reports for immunogenicity data, and the FSR for Immunogenicity.

2 PROTOCOL SUMMARY

Title

A phase 1 double-blind, randomized, controlled clinical trial in healthy, HIV-1-uninfected adult participants to compare the safety, tolerability and immunogenicity of CH505TF gp120 produced from stably transfected cells to CH505TF gp120 produced from transiently transfected cells

Primary objective(s)

- To evaluate and compare the magnitude of binding antibody responses elicited by the CH505 TF gp120 proteins produced via transient and stable transfection methods

Study products and routes of administration

- **Stable**: CH505TF gp120 developed via upstream stable transfection of CHO-DG44 cell line, mixed with GLA-SE (glucopyranosyl lipid A in a stable emulsion [oil-in-water emulsion containing squalene])

- **Transient**: CH505TF gp120 developed via upstream transient transfection of CHO-S cell line, mixed with GLA-SE

Schema

Study arm	n	Month 0	Month 2	Month 6
Group 1	15	100 mcg CH505TF gp120 **Stable**	100 mcg CH505TF gp120 **Stable**	100 mcg CH505TF gp120 **Stable**
Group 2	15	100 mcg CH505TF gp120 **Transient**	100 mcg CH505TF gp120 **Transient**	100 mcg CH505TF gp120 **Transient**
Total	30			

Notes
GLA-SE will be admixed with all proteins. The total dose of GLA-SE will be 10 mcg at all timepoints. The total volume for protein plus adjuvant for injection is 1 mL, mixed 1:1 by volume. All injections will be administered intramuscularly (IM) by needle and syringe.

Participants

30 healthy, HIV-1–uninfected volunteers aged 18 to 50 years

Design

Multicenter, randomized, controlled, double-blind trial

Duration per participant

12 months of scheduled clinic visits (main study) followed by an Adverse Events of Special Interest (AESI) health contact at month 18

Estimated total study duration

21 months (includes enrollment, follow-up, and AESI health contact)

Investigational New Drug (IND) sponsor

DAIDS, NIAID, NIH, DHHS (Bethesda, Maryland, USA)

Study product providers

- Stable CH505TF gp120: DAIDS, NIAID, NIH, DHHS (Bethesda, Maryland, USA)
- Transient CH505TF gp120: DAIDS, NIAID, NIH, DHHS (Bethesda, Maryland, USA)
- GLA-SE adjuvant: DAIDS, NIAID, NIH, DHHS (Bethesda, Maryland, USA)

Core operations

HVTN Vaccine Leadership Group/Core Operations Center, Fred Hutchinson Cancer Research Center (Fred Hutch) (Seattle, Washington, USA)

Statistical and data management center (SDMC)

Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutch (Seattle, Washington, USA)

HIV diagnostic laboratory

University of Washington Virology Specialty Laboratory (UW-VSL) (Seattle, Washington, USA)

Endpoint assay laboratories

- Duke University Medical Center (Durham, North Carolina, USA)
- Fred Hutch/University of Washington (Seattle, Washington, USA)

Study sites

HVTN Clinical Research Sites (HVTN CRSs) to be specified in the Site Announcement Memo

Safety monitoring

HVTN 123 PSRT; HVTN SMB

3 OBJECTIVES AND ENDPOINTS

3.1 Primary objectives and endpoints

Primary objective 2:

To evaluate and compare the magnitude of binding antibody responses elicited by the CH505TF gp120 proteins produced via transient and stable transfection methods

Primary endpoint 2:

HIV-specific total IgG binding antibody responses against the homologous proteins, as assessed by BAMA at peak timepoint (2 weeks after 3rd vaccination)

3.2 Secondary objectives and endpoints

Secondary objective 1:

To evaluate and compare the breadth and kinetics of binding antibody responses elicited by the CH505TF gp120 proteins produced via transient and stable transfection methods

Secondary endpoint 1:

HIV-specific total IgG binding antibody responses against the homologous proteins and magnitude-breadth (M-B) measures against panels of cross-clade Env proteins and of cross-clade V2 proteins, as assessed by BAMA at peak timepoints (2 weeks after the 2nd and 3rd vaccinations) and late timepoints (3 and 6 months after the 3rd vaccination)

Secondary objective 2:

To evaluate and compare the IgG subclass and IgA binding antibody responses elicited by the CH505TF gp120 proteins produced via transient and stable transfection methods

Secondary endpoint 2:

HIV-specific IgG subclass and IgA binding antibody response rates and magnitudes against homologous Env and V2 proteins, as assessed by BAMA at 2 weeks after the 2nd vaccination, 2 weeks after the 3rd vaccinations, and 3 and 6 months after the 3rd vaccination

Secondary objective 3:

To evaluate the ability of the two CH505TF gp120 proteins to elicit HIV-specific neutralizing antibodies (nAbs)

Secondary endpoint 3:

Magnitude and breadth of nAb responses against a panel of viral isolates as assessed by area under the M-B curves 2 weeks after the 2nd and 3rd vaccinations

Secondary objective 4:

To evaluate the avidity of antibody responses elicited by the CH505TF gp120 proteins

Secondary endpoint 4

Avidity of Env-specific IgG antibodies at baseline and 2 weeks after the 3rd vaccination

Secondary objective 5:

To evaluate HIV-specific T-cell responses induced by the two CH505TF gp120 proteins

Secondary endpoint 5:

Response rate, magnitude, and polyfunctionality of CD4+ T-cell responses as assessed by intracellular cytokine staining (ICS) assays 2 weeks after the 2nd and 3rd vaccinations

3.3 Exploratory objectives

Exploratory objective 1:

To evaluate the ability of the two CH505TF gp120 proteins to elicit memory B cells that differentially bind wildtype CH505 gp120Env vs mutant CH505 Env IΔ371 gp120

Exploratory objective 3:

To characterize the BCR repertoire of HIV-specific B cells

Exploratory objective 4:

To further evaluate vaccine immunogenicity, additional immunogenicity assays may be performed, including on samples from other timepoints, based on the HVTN Laboratory Assay Algorithm

Exploratory objective 5:

To conduct analyses related to furthering the understanding of HIV, immunology, vaccines, and clinical trial conduct

4 COHORT DEFINITION

Analyses are modified intent-to-treat in that individuals who are randomized but not enrolled do not contribute data and hence are excluded. Because of blinding and the brief length of time between randomization and enrollment - typically no more than 4 working days - very few such individuals are expected. The primary and secondary analyses of immunogenicity data are per-protocol in that only individuals who receive the expected vaccinations within the expected visit window contribute data.

5 POTENTIAL CONFOUNDERS

No potential confounders for immunogenicity analyses.

6 RANDOMIZATION

A participant's randomization assignment will be computer-generated and provided to the HVTN CRS pharmacist through a Web-based randomization system. At each institution, the pharmacist with primary responsibility for dispensing study products is charged with maintaining security of the treatment assignments (except in emergency situations as specified in the HVTN MOP).

7 BLINDING

Participants and site staff (except for site pharmacists) will be blinded as to participant treatment arm assignments. Study product assignments are accessible to those HVTN CRS pharmacists, DAIDS protocol pharmacists and contract monitors, and SDMC staff who are required to know this information in order to ensure proper trial conduct. Any discussion of study product assignment between pharmacy staff and any other HVTN CRS staff is prohibited. The HVTN

SMB members also are unblinded to treatment assignment in order to conduct review of trial safety.

When a participant leaves the trial prior to study completion, the participant will be told he or she must wait until all participants are unblinded to learn his or her treatment assignment.

In some cases, the CRS, PSRT, or study sponsor may believe unblinding of the site PI and participant would be appropriate to facilitate the clinical management of an AE or SAE. The HVTN Unblinding MOP specifies procedures for emergency unblinding, and for early unblinding for medical reasons.

8 STATISTICAL ANALYSIS

Analyses for primary endpoints will be performed using SAS and R. All other descriptive and inferential statistical analyses will be performed using SAS, StatXact, or R statistical software.

8.1 Analysis variables

The analysis variables consist of immunogenicity for primary- and secondary-objective analyses.

8.2 Baseline comparability

Treatment arms will be compared for baseline participant characteristics using descriptive statistics (safety only)

8.3 Analyses prior to end of scheduled follow-up visits

Any analyses conducted prior to the end of the scheduled follow-up visits should not compromise the integrity of the trial in terms of participant retention or safety or immunogenicity endpoint assessments. In particular, early unblinded analyses by treatment assignment require careful consideration and should be made available on a need to know basis. Interim blinded safety and immunogenicity data should not be shared outside of the SMB, HVTN 123 PSRT, the protocol team leadership, the HVTN Executive Management Team, the study product developer, and the study sponsor and/or its designee(s) for their regulatory reporting unless approved by the protocol leadership and the HVTN leadership.

9 IMMUNOGENICITY TABLES AND FIGURES, BY ASSAY

For the statistical analysis of immunogenicity endpoints analyses will be limited to participants who received all scheduled injections per protocol. Assay results that are unreliable, from specimens collected outside of the visit window, or from HIV-infected participants postinfection are excluded. Since the exact date of HIV infection is unknown, any assay data from blood draws 4 weeks prior to an infected participant's last seronegative sample and thereafter may be excluded. If an HIV-infected participant does not have a seronegative sample postenrollment, then all data from that participant may be excluded from the analysis.

Discrete categorical assay endpoints (e.g., response rates) will be analyzed by tabulating the frequency of positive response for each assay by antigen and treatment arm at each timepoint for which an assessment is performed. Crude response rates and difference between treatment arms will be presented with their corresponding 95% CI estimates calculated using the score test method [1].

For quantitative assay data, graphical and tabular summaries of the distributions by antigen, treatment arm, and timepoint will be made. For all primary and secondary immunogenicity

endpoints, box plots and plots of estimated reverse cumulative distribution curves will be used for graphical display of all of the study arms.

Mean or median (if normality assumption severely violated) assay readouts will be compared between arms and bootstrap CIs will be estimated.

More sophisticated analyses employing repeated measures methodology (for example, linear mixed models or marginal mean models fit by generalized estimating equations) may be utilized to incorporate immune responses over several timepoints and to test for differences over time.

9.1 Intracellular Cytokine Staining

Describe the peptide pools (antigen name, number of pools, etc.) and primary time point(s) that will be included in the assay. Include broad statement about other time points that may be assayed and included in the analysis depending on results obtained from the primary time point(s).

9.1.1 List of Tables

- Response rate table by lab, T-cell subset, peptide pool, visit, day, and group/treatment arm [*check the unblinding guideline for when it's appropriate to have unblinded reports by group/treatment arm for a given time point*] for cells expressing either IL-2 and/or IFN-γ using Fisher's exact test criteria and/or MIMOSA criteria.
- Listing of positive responders for cells expressing either IL-2 and/or IFN-γ based on the criteria used for the response rate table(s). If both criteria are used, use a combined table.
- [*If marginal cytokine data available*] Response rate table by lab, T-cell subset, cytokine, peptide pool, visit, day, and group/treatment arm for cells expressing a given cytokine using Fisher's exact test criteria and/or MIMOSA criteria.
- [*If marginal cytokine data available*] Listing of positive responders for each cytokine based on the criteria used for the response rate table(s). If both criteria are used, use a combined table.
- Summary statistics (i.e., min, mean, median, max) among responders for T-cell subset, peptide pool, visit, and group/treatment arm
- Summary statistics (i.e., min, mean, median, max) among all participants (positive and negative responders) for T-cell subset, peptide pool, visit, and group/treatment arm, upon request
- Response rate and/or response magnitude comparison of treatment arms as specified in primary/secondary objectives. [*Specify the groups, time points, antigen, cytokine, endpoints, and tests used*.]
- [*State other pre-specified analyses such as COMPASS (delete if none)*]

9.1.2 List of Graphs

- Boxplots of background-adjusted IFN-γ and/or IL-2 response magnitude by T-cell subset, HIV protein, visit, and group/treatment arm using Fisher exact test and/or MIMOSA criteria. [*State layout – this depends on the comparisons of interest. The default is treatment groups side by side per protein, one T-cell subset and one visit per graph).*]

- [*If marginal cytokine data available*] Boxplots of background-adjusted marginal cytokine response magnitude by T-cell subset, HIV protein, visit, and group/treatment arm using Fisher exact test and/or MIMOSA criteria. State the default layout or other desirable layout: e.g., treatment groups side by side per protein, one T-cell subset and one visit per graph.
- [*If polyfunctional graphs requested*] Boxplots of cytokine degree by T-cell subset, HIV protein, visit, and group/treatment arm. State the default layout or other desirable layout: e.g., treatment group side by side, one T-cell subset, visit, protein per graph.
- [*If polyfunctional graphs requested*] Boxplots for each cytokine combination of a given degree by T-cell subset, HIV protein, visit, and group/treatment arm. State the default layout or other desirable layout: e.g., treatment group side by side, one T-cell subset, visit, protein per graph.
- [*State other pre-specified analyses (delete if none)*]

9.2 Neutralizing Antibody

Neutralizing antibodies against HIV-1 were measured as a function of reductions in Tat-regulated luciferase (Luc) reporter gene expression in TZM-bl cells [2, 3].

- Vaccine strains: CH505TF (Tier 2), CH505.w4.3 (Tier 1A)

Tier	Subtype	Vaccine strain	Isolate
2	C	Yes	CH505TF
1A	C	Yes	CH505.w4.3

Specimens from other time points may also be analyzed at the discretion of the HVTN Laboratory Program, which may be contingent on the results of the primary immunogenicity time point. Those time points may include visit 2 (day 0) and/or visit 9 (day 364 - 6 months post final vaccination).

Data from blood draw dates outside the allowable visit window and assay results deemed unreliable for analysis by the lab were excluded from the analysis. Post-infection samples from HIV-infected participants are excluded.

Response to a virus/isolate was considered positive if the neutralization titer was above a pre-specified cutoff. A titer was defined as the serum dilution that reduced relative luminescence units (RLUs) by 50% and 80% relative to the RLUs in virus control wells (cells + virus only) after subtraction of background RLU (cells only). The prespecified cutoff for ID50 and ID80 was 10. Tables show the response rates to each virus/isolate and corresponding 95% confidence intervals calculated by the score test method [1].

Barnard's test was used to compare response rates between treatment groups, while the Wilcoxon rank sum test was used to compare response magnitudes between treatment groups, among positive and negative responders, and among the subset of positive responders. Response

magnitude comparisons among positive responders will not be done if there are fewer than 5 responders per treatment group.

Plots of neutralizing antibody titers show both response rates and the distribution of magnitude. Positive responses are indicated by dots color-coded by treatment group, and negative responses by gray triangles. Data points for each participant are connected by a gray line. The mid-line of the box denotes the median and the ends of the box denote the 25th and 75th percentiles. The whiskers that extend from the top and bottom of the box extend to the most extreme data points that are no more than 1.5 times the interquartile range (i.e., height of the box) or if no value meets this criterion, to the data extremes.

9.2.1 List of Tables

- Response rate table by lab, cell type, virus, inhibitory dilution (ID50/ID80), visit, day, and group/treatment arm. [State positivity criteria in footnote.]
- Summary statistics (i.e., min, mean, median, max) among responders by lab, cell type, virus, inhibitory dilution (ID50/ID80), visit, day, and group/treatment arm.
- Summary statistics (i.e., min, mean, median, max) among all participants (positive and negative responders) by lab, cell type, virus, inhibitory dilution (ID50/ID80), visit, day, and group/treatment arm.
- Response rate comparison of T1 vs. T2, by visit, using Barnard's test.
- Response magnitude (ID50 & ID80 titer) comparison between T1 and T2 for vaccine strains by visit among all participants, using Wilcoxon rank sum test.
- Response magnitude (ID50 & ID80 titer) comparison between T1 and T2 for vaccine strains by visit among positive responders, using Wilcoxon rank sum test. (if there are more than 5 responders per treatment group).

9.2.2 List of Graphs

- Bar and boxplots of response rate and neutralizing antibody titers by virus, inhibitory dilution (ID50/ID80), visit day, and group/treatment arm.
- Bar and line plots (spaghetti plots) of response rate and neutralizing antibody titers by virus, inhibitory dilution (ID50/ID80), and group/treatment arm.

9.3 Binding Antibody Multiplex Assay

Serum HIV-1-specific IgG responses at a 1:50 starting dilution followed by a 5-fold serial dilution for a total of six dilution points if titrations are warranted against CH505TF gp120 (transient transfection) and CH505TF gp120 (stable transfection) or CH505TF_D8gp120/293F at visits 2 (M0, baseline) and 7 (M6.5, 2 weeks post 3rd vaccination) were measured on a Bio-Plex instrument (Bio-Rad) using a standardized custom HIV-1 Luminex assay [5, 6, 7]. The readout was background-subtracted mean fluorescence intensity (MFI), where background referred to two plate level controls (i.e., two blank wells run on each plate). Standard positive and negative controls were included in each assay to ensure specificity and for maintaining consistency and reproducibility between assays. The positive control includes purified polyclonal IgG from HIV subjects (HIVIG). The negative control was NHS (HIV-1 sero-negative human sera) and blank beads.

Several criteria were used to determine if data from an assay were acceptable and could be statistically analyzed. First, the blood draw date must have been within the allowable visit window as determined by the protocol. Post-infection samples from HIV-infected participants are excluded. Second, if the blank bead negative control exceeded 5,000 MFI, the sample was repeated. If the repeat value exceeded 5,000 MFI, the sample was excluded from analysis due to high background. The preset assay criteria for sample reporting were: coefficient of variation (CV) per duplicate values for each sample are < 20% ≥ 50 beads counted per antigen. To control for protein performance, the preset criteria include that the positive control titration in each assay must be within +/- 3 standard deviations of the mean for each antigen (tracked with a Levey-Jennings plot for high MFI and Area Under the Curve (AUC)).

Panel	Isolate	Clade
-	CH505TF gp120 (transient transfection)	C
-	CH505TF gp120 (stable transfection)	C

Samples from post-enrollment visits were declared to have positive responses if they met three conditions: (1) the MFI minus Blank values were ≥ antigen-specific cutoff at the 1:50 dilution level for IgG (based on the 95th percentile of baseline samples as calculated by SAS PROC UNIVARIATE default method, and at least 100 MFI minus Blank), (2) the MFI minus Blank values were greater than 3 times the baseline (day 0) MFI minus Blank values, and (3) the MFI values were greater than 3 times the baseline MFI values.

Net MFI (MFI minus Blank) were truncated at 22,000, the upper limit of the linear range of the assay. Additionally, samples were excluded from threshold calculation and analysis if the baseline analyte net MFI exceeded 6500. For each combination of individual and antigen the area under the titration curve (AUC) at each time point was calculated over dilutions [insert dilution factors of the titration series] using the trapezoidal integration, with base 10 log-transformation of the dilutions and with truncation at zero in the case of negative net MFI values and no ceiling (at 22,000) truncation.

Tables show positive response rates and corresponding 95% confidence intervals calculated by the Wilson score method [1], as well as summary statistics among positive responders and all participants.

Barnard's test was used to compare response rates between treatment groups, while the Wilcoxon rank sum test was used to compare response magnitudes between treatment groups, among positive and negative responders, and among the subset of positive responders. Response magnitude comparisons among positive responders will not be done if there are fewer than 5 responders per treatment group.

Net MFI responses at the 1:50 dilution level and the titers (AUC) were used to summarize the magnitude at a given time-point. These distributions are displayed graphically by treatment arm. Plots include data from responders in color and non-responders in gray, with box plots based on

data from responders superimposed on the distribution. Data points for each participant are connected by a gray line. The mid-line of the box denotes the median and the ends of the box denote the 25th and 75th percentiles. The whiskers that extend from the top and bottom of the box extend to the most extreme data points that are no more than 1.5 times the interquartile range (i.e., height of the box) or if no value meets this criterion, to the data extremes.

9.3.1 List of Tables

- Response rate table by lab, isotype, antigen, visit, day, and group/treatment arm.
- Summary statistics (i.e., min, mean, median, max) of net MFI among all participants (positive and negative responders) by lab, isotype, antigen, visit, day, and group/treatment arm.
- Summary statistics (i.e., min, mean, median, max) of net MFI among responders by lab, isotype, antigen, visit, day, and group/treatment arm.
- Summary statistics (i.e., min, mean, median, max) of AUC among all participants (positive and negative responders) by lab, isotype, antigen, visit, day, and group/treatment arm.
- Summary statistics (i.e., min, mean, median, max) of AUC among responders by lab, isotype, antigen, visit, day, and group/treatment arm.
- Response rate comparison between T1 and T2 at visits 2 (M0, baseline) and 7 (M6.5, 2 weeks post 3rd vaccination), using Barnard's test.
- Net MFI comparison between T1 and T2 at visits 2 (M0, baseline) and 7 (M6.5, 2 weeks post 3rd vaccination) among all participants, using Wilcoxon rank sum test.
- Net MFI comparison between T1 and T2 at visits 2 (M0, baseline) and 7 (M6.5, 2 weeks post 3rd vaccination) among positive responders, using Wilcoxon rank sum test. (if there are more than 5 responders per treatment group).
- AUC comparison between T1 and T2 at visits 2 (M0, baseline) and 7 (M6.5, 2 weeks post 3rd vaccination) among all participants, using Wilcoxon rank sum test.
- AUC comparison between T1 and T2 at visits 2 (M0, baseline) and 7 (M6.5, 2 weeks post 3rd vaccination) among positive responders, using Wilcoxon rank sum test. (if there are more than 5 responders per treatment group).

9.3.2 List of Graphs

- Bar and boxplots of response rate and net MFI by isotype, antigen, visit day, and group/treatment arm, with treatment groups side by side per visit, and two visits on the same page for each antigen.
- Bar and boxplots of response rate and AUC by isotype, antigen, visit day, and group/treatment arm, with treatment groups side by side per visit, and two visits on the same page for each antigen.
- Bar and line plots (spaghetti plots) of binding antibody titers by isotype, antigen, and group/treatment arm, with visits side by side per treatment group, and two treatment groups on the same page for each antigen.
- Bar and line plots (spaghetti plots) of AUC by isotype, antigen, and group/treatment arm, with visits side by side per treatment group, and two treatment groups on the same page for each antigen.

10 REFERENCES

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From: Lu, Yiwen
To: Lu, Yiwen
Subject: email approval of the HVTN 123 immuno SAP v1.0
Date: Monday, August 21, 2023 3:35:25 PM
Attachments: HVTN123_immuno_SAP_v1.0.docx

I, Yiwen Lu, SRA, approve the attached HVTN123_immuno_SAP_v1.0.docx. This email will act as a substitute for a wet signature for HVTN123_immuno_SAP_v1.0.docx.

Yiwen Lu
she/her
Statistical Research Associate
Statistical Center for HIV/AIDS Research and Prevention (SCHARP)
HIV Vaccine Trials Network (HVTN)
ylu2@scharp.org

From: Fong PhD, Youyi
To: Lu, Yiwen
Subject: Re: HVTN 123 immuno SAP v1.0 approval request
Date: Monday, August 21, 2023 8:47:53 PM

Hi Yiwen,

I, Youyi Fong, PhD, approve the attached HVTN123_immuno_SAP_v1.0.docx. This email will act as a substitute for a wet signature for HVTN123_immuno_SAP_v1.0.docx.

Thanks,
Youyi

From: Lu, Yiwen <ylu2@scharp.org>
Sent: Monday, August 21, 2023 3:54 PM
To: Fong PhD, Youyi <yfong@fredhutch.org>
Subject: HVTN 123 immuno SAP v1.0 approval request

Hi Youyi,

The HVTN 123 immuno SAP v1.0 has been completed, including analysis plans for NAb and BAMA. Please review and approve the document.

If you approve, please respond with the following statement:

I, <name>, <title>, approve the attached HVTN123_immuno_SAP_v1.0.docx. This email will act as a substitute for a wet signature for HVTN123_immuno_SAP_v1.0.docx

Thanks,

Yiwen Lu
she/her
Statistical Research Associate
Statistical Center for HIV/AIDS Research and Prevention (SCHARP)
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ylu2@scharp.org