Update and Proposed Additions to the VACS Tissue Bank

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Our Objectives

- To demonstrate that we can enroll antiretroviral naïve participants into the VACS
- To demonstrate that we can collect serial blood specimens on VACS participants at multiple site
- VACS current has store blood specimens on 1525 HIV infected and 843 uninfected Veterans
**Target Population**

- All subjects newly enrolled in the main VACS observational study and naïve to ART are eligible to participate in the DNA and/or blood banking protocols.

- Subjects will be enrolled from ALL VA Medical Centers currently participating in VACS.

- We propose to enroll 700 subjects:
  - 350 HIV infected and 350 site matched uninfected controls.
  - Ideally 50% of those enrolled over 60 will be ≥65 years of age.
  - Due to small numbers, we only enroll men in this substudy.
Components and Time Line

Blood samples (plasma, serum, and cells) and AUDIT will be collected at the following time points:
- Time zero (prior to ART initiation)
- 30 days
- 90 days
- 6 months
- 2 years

DNA will be collected once ideally at baseline

CD4 and CD8 will be assessed in both HIV infected and controls at baseline and at the 2 year visit

Importantly uninfected Veterans will be sampled at the same time points

We selected the majority of the blood draws to be within 6 months to monitor the immediate effects of ART on inflammation
Blood Samples

- If subject participates in both studies, 
  ~ 58 mls of blood will be collected (Visit 1)
- Subsequent serial blood draws (at Visits 2-5). Each draw will be (~40 mls of blood)
- DNA sample will be collected only once and ideally at Visit 1.
- No processing will be done on site
All samples will be shipped, processed and stored at MAVERIC.

MAVERIC Tissue Core Laboratory (TCL)
The TCL will serve as the central repository for blood specimens. The TCL will be responsible for tracking, processing and storing blood, cells, serum, and plasma specimens.

MAVERIC Genetic Tissue Core Laboratory (GTCL)
The GTCL will serve as the central repository for DNA specimens for this study. The GTCL will be responsible for extracting and storing the DNA specimens.
Aliquots

Once a specimen arrives at the GTCL, it will be assigned a GTCL barcode number. The GTCL will prepare the following aliquots for the DNA Bank:

- 4 vials of EDTA plasma (2 per 9 ml EDTA)
- 2 vials of buffy coat (1 per 9 ml EDTA) vs. direct extraction

Once a specimen arrives at the TCL, it will be assigned a TCL barcode number. The TCL will prepare the following aliquots for blood banking:

- 2 vials of serum (2 per 9.5 ml SST)
- 6 vials of EDTA plasma (2 per 9 ml EDTA)
- 4-6 vials of PBMC (5 x 10^6 per ml)
- 2 vials of RBC
Compensation

A participant will receive $20 after a blood specimen is collected and the AUDIT survey is completed at each time point.

If a blood collection is unsuccessful or a blood specimen is unusable for any reason, subject will be invited to donate another specimen.

No more than 2 attempts will be made to obtain a successful sample at each time point.

If subject decides at some point during the study not to continue with the study, compensation will only be paid for those samples that have already been donated.
Summary

At three VACS sites we will

– Enroll 700 ART naïve participants
– Collect a DNA specimen
– Collect 5 blood specimens (before ART initiation and 4 time points post ART initiation)
– Collect AUDIT data at all 5 time points
– All blood processing and storage will be at MAVERIC
Acknowledgements

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