Division of AIDS
NIAID, NIH
DHHS

Reset

DAIDS VAX004 Specimen Access Approval Application

Concept Applicant: _____ Date: _____

Institution/Address: _____

_____

Phone: _____ Fax: _____

E-mail: _____

Project Members: *Co-Investigator(s)*:

This study requests the following:

Yes	*No*	
☐	☐	Participant **PBMC** specimens
☐	☐	Participant **plasma** specimens
☐	☐	Participant **serum** specimens from *VaxGe*n (pending *VaxGen* approval)
☐	☐	Participant **semen** specimens
☐	☐	Other data collection *(may require either DAIDS alone, or DAIDS and VaxGen approval)*
☐	☐	Approval of this application is for gaining access to these DAIDS VAX004 specimens, and <u>not</u> for receiving NIH funding. If funds are not secured for this study (e.g., through a peer review grant mechanism), will the application be withdrawn?

Concept Sheet: Each application must be accompanied by a concept sheet that must include the following information:

Cover page: Investigator(s) name, title, institution, address, phone and fax numbers, e-mail address, project title, date of application, proposed project members and institution(s), target start date, and projected duration of study.

Budget: Identify source of funds to support the proposed evaluation(s).

Description of Proposed Activity: *(Must be four pages or less, single-spaced, 11 point type size.)*

Background/Rationale: The study rationale, relevant background information, implications of prior research, anticipated relationship and contribution of the proposed activity to the priorities for use of these specimens (see attached list).

Hypotheses/Study Objectives: The major study objectives.

Study Design/Methods: Outline of the study design, including, as appropriate, details regarding: 1) type, volume, and number of specimens required (e.g., number of specimens/subject); and 2) data collection/access required (e.g., VaxGen data on volunteer demographics, decoding of samples, viral sequences, etc.). Specify the sources of data to be analyzed, including VaxGen-collected data variables, or new variables to be collected. Identify whether preliminary (unaudited) VaxGen data is needed for early modeling and/or if final (audited) data will be needed to complete the analysis.

Planned Tests: Indicate planned tests (drug assays, immunologic, genetic, and virologic tests, unique and/or costly tests). A schedule is not required.

Study Population/Co-enrollment: Comment on whether this is a stand-alone study or involves the use of specimens from other protocols (specify protocols).

Statistical Issues/Sample Size Estimate and Rationale: Specify an analysis plan and include the required sample size. If appropriate, provide power calculations for primary objective(s). Provide a detailed description of outcome measures (dependent variables) to be used in answering the study objectives.

Animal Use and Human Subjects Requirements: If project involves use of animals or human subjects, include IRB/EC approval number (or pending application number) and approval date. Verify that the activity is covered under the parent study informed consent form.

E-mail or fax completed ***Application*** and ***Concept Sheet*** to:

DAIDS VAX004 Specimen Access Approval Panel

E-mail: jwarren@niaid.nih.gov
Fax: (301) 402-3684

Inquiries: Dr. Jon Warren (DAIDS/NIAID), Executive Secretary, *DAIDS VAX004 Specimen Access Approval Panel*, (301) 402-0633

Note: Petitioning investigators must also submit a *DAIDS VAX004 Specimen Material Transfer Agreement*.