

Petitioning investigators and their institutions seeking approval for access to DAIDS-owned VAX004 clinical trial specimens or data must complete and sign this *DAIDS Material Transfer Agreement for VAX004 Specimens* in addition to the *DAIDS Access Approval Application for VAX004 Specimens*. DAIDS purchased the samples from VaxGen's VAX004 Phase III Clinical trial through a subcontract of the NIAID contract #N01-AI-85341 with BBI Biotech.

The Recipient and Provider intend to be legally bound as of the date of the last signature hereto ("Effective Date")

Provider: *Division of Acquired Immunodeficiency Syndrome (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health*

Recipient: <insert institution name>

Provider agrees to transfer to Recipient's Investigator the following Research Material: <insert detailed description of Research Material, including the owner (i.e., NIAID or VaxGen)>

1. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Research Material will only be used for research purposes by Recipient's Investigator in his/her laboratory, for the research project described below, under suitable containment conditions.

2. This Research Material will not to be used for any commercial purposes, such as screening, production, sale, or manufacturing processes, including quality control procedures, marketing, or delivery of commercial services for which a commercialization license may be required. Exceptions to this term will only be granted if agreed to by Provider in writing. Recipient agrees to comply with all rules and regulations applicable to the Research Project and the handling of the Research Material.

3. The Research Material is of human origin and was collected by VaxGen according to 45 CFR Part 46, "Protection of Human Subjects" under **VaxGen's Federal Wide Assurance Number: FWA00001083**. The samples will be provided with codes and will not be linked to any identifiable human subjects' data. The following information will be provided with the samples: male/female, placebo/vaccine, infected/uninfected. **The local IRB affiliated with the Principal Investigator's institution will receive detailed information concerning how confidentiality will be maintained for the study.** Recipient can gain access to the proprietary VaxGen Database by successfully negotiating the terms of VaxGen's **Database License Agreement** with VaxGen. **Please contact:** Marc Gurwith, M.D., J.D., Sr. Vice Pres., Medical Affairs & Chief Medical Officer VaxGen, Inc. 1000 Marina Blvd. Brisbane, CA 94005 business phone: 650 624 2309 email: mgurwith@vaxgen.com

4. This Research Material will be used by Recipient's Investigator solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary):
<insert Research Plan>

5. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's written information about this Research Material that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from Provider to Recipient shall be identified as being CONFIDENTIAL by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given CONFIDENTIAL information to Recipient such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains.

6. This Research Material represents a significant investment on the part of Providers and is considered proprietary to Provider. Recipient therefore agrees that its Investigator will retain control over this Research Material. Recipient agrees that its Investigator will not transfer the Research Material to other people, other than employees under her or his direct supervision, without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed or two (2) years have elapsed, whichever occurs first, the Research Material will be disposed of as directed by Provider.
7. Recipient agrees that Recipient's Investigator shall acknowledge DAIDS as the source of the Research Material in any publication or abstract resulting from the use of the Research Material or findings of the Research Project. In addition, any and all data generated with the Research Material, published or not, must be made available publicly.
8. Recognizing that employees of Provider may play an important role in determining the properties and use of material and interpretation of the findings of this Research Project, the Recipient shall include appropriate individuals from the Provider in the authorship of publications resulting from the Research Project, in accordance with the generally accepted customs pertaining to authorship.
9. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.
10. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project.
11. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s).
12. No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this Agreement. Each party shall be liable for any loss, claim, damage or liability that said party incurs as a result of its activities under this Agreement, except that the parties assume liability only to the extent as provided under applicable laws and regulations.
13. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

14. This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

SIGNATURES BEGIN ON NEXT PAGE

Division of AIDS, NIAID, NIH, DHHS
CONFIDENTIAL DAIDS VAX004 Specimen Material Transfer Agreement

DAIDS VAX004 Specimen Material Transfer Agreement
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FOR RECIPIENT:

Recipient's Investigator

Signature

Printed Name and Title

Date: _____

Mailing Address for Materials:

Tel: _____ Fax: _____

Duly Authorized

Signature

Printed Name and Title

Date: _____

Mailing Address for Notices:

Tel: _____ Fax: _____

FOR PROVIDER:

Duly Authorized

Signature

Printed Name and Title

Date: _____

Mailing Address for Notices:

Tel: _____ Fax: _____

E-mail or fax completed DAIDS VAX004 Specimen Material Transfer Agreement 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 submit a DAIDS VAX004 Specimen Access Approval Application.