

OUTSIDE COLLABORATOR STUDY PUBLICATIONS

To protect the scientific integrity of the AVEG and to insure that the best use of the limited resources of volunteer specimens is made, all proposals for collaborations with the AVEG by non-AVEG investigators employing AVEG volunteer specimens must undergo the following submission and approval process:

- Potential Outside Collaborators must complete and submit immunological concept sheets describing the proposed collaborative study and a signed “Responsibilities of Outside Collaborators” statement in the *Material Transfer Agreement*.
- Once the forms are submitted by the potential Outside Collaborator, DAIDS staff will verify that they are complete and the *Material Transfer Agreement* is signed. They will contact the potential collaborator to request any missing information and to confirm receipt of the forms.
- DAIDS will distribute the completed forms to the Immunology Committee for review and discussion on the next regularly scheduled Immunology Committee Conference Call (or at the next Immunology Committee Meeting). To expedite the review process, if an Immunology Committee conference call or meeting will not be occurring within two weeks of the distribution of the potential Outside Collaborator's forms, the Chair of the Immunology Committee and at least two DAIDS staff members can decide if a request has reasonable scientific merit and appropriate specimens are available. If they are in agreement, the request can move ahead in the review process before review by the full Committee. Otherwise, a conference call to specifically review the collaboration request should be scheduled. The Immunology Committee must review all requests for specimens from AVEG volunteers who have become infected with HIV-1 subsequent to enrollment in an AVEG trial and who have consented to participate in Protocol 401.
- Once the Immunology Committee and Protocol Team(s) and Executive Group, as appropriate, have approved a proposed collaboration and suggested from which protocols that specimens for the study should be derived, the Outside Collaborator's forms are sent to the appropriate Vaccine Developer(s) for review and comment.
- Once the Vaccine Developer has indicated *in writing* that they have reviewed the Outside Collaborator's request and are in agreement with the study going forward, then arrangements for distribution of the appropriate specimens can be made. If the Vaccine Developer holds the IND on a trial and they decide they are not interested in the study, unless the Protocol Chair/Team can persuade them otherwise, the potential Outside Collaborator will not be able to obtain specimens from that protocol.
- All AVEG volunteer specimens distributed to a non-AVEG investigator, whether coming from the NIAID Clinical Specimen Repository or an AVEG site, *must* be coded, include negative/positive controls (if appropriate), and be distributed in a blinded manner. DAIDS staff will provide help to AVEG site staff in choosing specimens for collaborative studies and in coding the specimens. In all instances, DAIDS *must* be provided with a list of the coded specimens distributed from an AVEG site to an Outside Collaborator.
- Outside Collaborators will be not be unblinded until the study is completed and a written report has been received for review by the AVEG. DAIDS will provide appropriate coded identifiers for any presentation or publication of the collaborative study results. Usually, one or more AVEG investigator will work with the Outside Collaborator in preparing publications from the study to assure that proper acknowledgment of the AVEG contribution to the study is made. Manuscript review will be in accordance to the AVEG Guidelines for Publications.

INSTRUCTIONS FOR SPECIMEN REQUESTS

These instructions are directed to individuals who are requesting specimens from volunteers in the clinical trials conducted by the NIAID-sponsored AIDS Vaccine Evaluation Group (AVEG).

- **SPONSORING AGENCY**

Vaccine Clinical Research Branch
Vaccine and Prevention Research Program
Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Jorge Flores, M.D.
Suzanne Gallo
Tel: 301-435-3748
Fax: 301-402-3684

Questions should be addressed to S Gallo (Tel: 301-435-3748)

- **COMPLETION OF FORMS**

Please complete both concept sheets as indicated and then sign and date the *Material Transfer Agreement*, the "Responsibilities of Outside Collaborators Form," and submit all forms and any support materials, such as publications, by mail or courier to:

Suzanne Gallo, Room 4217
Vaccine Clinical Research Branch
VPRP/DAIDS/NIAID/NIH
6700-B Rockledge Dr., MSC 7628
Bethesda, MD 20892-7628

- **REVIEW PROCESS AND DISTRIBUTION OF SPECIMENS**

Proposed collaborative experiments are reviewed by the AVEG Immunology Committee, AVEG Executive Group, appropriate Trial Protocol Teams and Vaccine Developers for scientific merit, overlap with studies already underway and availability of appropriate specimens. This review process typically requires 6-8 weeks. Once a collaborative experiment is approved, if appropriate specimens are already available, they will be distributed within a few weeks. If appropriate specimens are not yet available, the Outside Collaborator will be notified that the study is approved and the approximate time that specimens will be available. All specimens are distributed coded and blinded.

CONCEPT SHEET FOR PERFORMANCE OF COLLABORATIVE STUDIES

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Name of Investigator(s): _____

Institution: _____

Shipping Address: _____

Telephone Number: _____ Fax Number: _____

Investigator Signature: _____ Date: _____

E-mail Address: _____

SPECIMENS REQUESTED

Please specify what type of specimen (sera, cells, or whole blood), the quantity of the specimen needed, the number of volunteers from whom the specimens are required, and the timing of the specimen acquisition (pre-or post-immunization, etc.)

DISPOSITION BY AVEG/NIAID: _____ DATE OF REVIEW _____

APPROVAL _____

DISAPPROVAL _____

**SEND FORMS VIA FAX TO 301-402-3684 AND MAIL/COURIER FORMS
WITH SUPPORTIVE MATERIALS TO DAIDS [see instructions]**

CONCEPT SHEET FOR PERFORMANCE OF COLLABORATIVE STUDIES

page 2 of 2

Name of Investigator(s): _____

Institution: _____

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- *BRIEFLY DESCRIBE THE PROPOSED COLLABORATIVE STUDY, PROVIDING RELEVANT REFERENCES AND REPRINTS:*

- *BRIEFLY DETAIL THE ASSAY(S) TO BE PERFORMED WITH THE SPECIMENS:*

**SEND FORMS VIA FAX TO 301-402-3684 AND MAIL/COURIER FORMS
WITH SUPPORTIVE MATERIALS TO DAIDS [see instructions]**

MATERIAL TRANSFER AGREEMENT FOR SPECIMENS FROM AVEG CLINICAL TRIALS

RESPONSIBILITIES OF OUTSIDE COLLABORATORS

- All specimens provided by the AVEG/NIAID are to be used for research purposes only, in the Outside Collaborator's laboratory only, and only as authorized. The specimens are for *in vitro* investigational use only, not for human use. No specimens, nor provided reagents or materials derived from the specimens (e.g., T cell clones derived from AVEG volunteer Peripheral Blood Mononuclear Cells), are to be allowed to come into the possession of any other person except those individuals engaged in research under the direct supervision of the approved Outside Collaborator unless written exceptions are granted by the AVEG/NIAID. All data collected in any collaborative study involving AVEG volunteer specimens is covered by the Privacy Act.
- Specimens provided by the AVEG/NIAID are not to be used in the manufacture, marketing, or licensing of any commercial product unless written exceptions are granted by the AVEG/NIAID.
- Outside Collaborators receiving specimens from the AVEG/NIAID clinical trials must provide a timely report of the results of the testing/analysis performed, irrespective of the "positive" or "negative" nature of the findings. On occasion, the AVEG/NIAID may request a brief preliminary report in order to include the data in material prepared for the AIDS Vaccine Data and Safety Monitoring Board, the United States Food and Drug Administration, or the Vaccine Manufacturer.
- If and when sufficient data are available for publication, Outside Collaborators will be expected to adhere to the authorship guidelines of AVEG/NIAID as follows: (a) All collaborative study publications must acknowledge the AVEG, or in those instances where a considerable contribution to the study has been made by the AVEG, include AVEG investigators as co-authors; (b) Collaborative studies will not be published prior to the core manuscript without Trial Protocol Team approval; (c) All collaborative study manuscripts will be reviewed by the appropriate Protocol Chair(s)/Team(s), Vaccine Developers, and NIAID staff prior to submission; and (d) Publication numbers will be provided after the report (see above) is received at NIAID. AVEG volunteer ID numbers must not be used in any presentations or publications.
- In support of the NIAID commitment to safety in vaccine trials, an AVEG Outside Collaborator will immediately notify the NIAID of results which might be indicative of potential adverse clinical experience.

I have read the foregoing statement and agree to fulfill those responsibilities defined above.

Signature of Investigator: _____

Typed or Printed Name: _____

Institution: _____ *Date:* _____