DATE: December 19, 2005

RE: LETTER OF AMENDMENT #3 for PACTG 1059 A Phase I, Open-Label Study To Evaluate The Safety And Tolerability Of Recombinant HIV-1 Vaccines In HIV-1 Infected Young Adults With Control Of HIV-1 Replication And On Stable Highly Active Antiretroviral Therapy (HAART) (Version 1.0 Dated, January 31, 2005)

TO: Pediatric ACTG PIs & Study Coordinators at Sites Participating in PACTG 1059

FROM: NICHD Program Staff

THE FOLLOWING INFORMATION IS INTENDED FOR NICHD PACTG SITES ONLY, AND DOES NOT APPLY TO NIAID PACTG SITES PARTICIPATING IN PACTG 1059

THE FOLLOWING INFORMATION RELATES TO A NEW VERSION (2.0) OF THE NICHD REPOSITORY POLICY. THIS POLICY GOVERNS SPECIMEN STORAGE AT NICHD-FUNDED SITES IN SUPPORT OF THE PACTG 1059 STUDY. THIS INFORMATION MUST BE FORWARDED TO YOUR INSTITUTIONAL REVIEW BOARD (IRB)/ETHICS COMMITTEE (EC) AS SOON AS POSSIBLE FOR THEIR INFORMATION AND REVIEW. THIS MUST BE APPROVED BY YOUR IRB/EC BEFORE IMPLEMENTATION.

YOUR IRB/EC WILL BE RESPONSIBLE FOR DETERMINING THE PROCESS OF INFORMING SUBJECTS OF THE CONTENTS OF THIS LETTER OF AMENDMENT. A SAMPLE INFORMATION SHEET IS ATTACHED.

PLEASE FILE THIS LETTER AND ANY IRB/EC CORRESPONDENCE IN YOUR REGULATORY FILE AND OTHER PERTINENT FILES. YOU ARE NOT REQUIRED TO SUBMIT THESE DOCUMENTS TO THE PROTOCOL REGISTRATION OFFICE UNLESS THE CHANGES RESULT IN A CHANGE TO THE INFORMED CONSENT FOR YOUR SITE.

The purpose of this letter is to provide additional directions to NICHD sites participating in PACTG P1059 related to stored specimens. NICHD has amended its Repository Policy; it is now Version 2.0. NIAID sites should use the current language in the sample informed consent related to stored specimens.

Related to the repository storage of specimens, the consent language remains unchanged in Version 2.0. The Westat IRB oversight of the repository is removed and replaced with NICHD IRB approval and program oversight. The Version 2.0 additional NICHD template consent is attached to this LOA and will be available on the PACTG WEB site under final protocols. This information will be incorporated into the next version of the
protocol. An information sheet is attached to this LOA to inform previously-consented subjects of this change pending local IRB approval of the information sheet.

All specimens collected for repository storage are to be shipped to the NICHD-funded central repository. Specific directions can be found at https://www.nichdclinicalstudies.org/index.html

Please contact the NICHD Program with any questions about the information provided in this letter.

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The letter of amendment is available from the Member Institutions Download Final Documents and Protocol Specific Webpage area of the Pediatric ACTG website (http://pactg.s-3.com). The username is: PACTG and the password is: cure (all lower case). The filename for retrieving the document in Word is P1059loa3_d19.doc
INFORMATION SHEET

TITLE: PACTG 1059 A Phase I, Open-Label Study To Evaluate The Safety And Tolerability Of Recombinant HIV-1 Vaccines In HIV-1 Infected Young Adults With Control Of HIV-1 Replication And On Stable Highly Active Antiretroviral Therapy (HAART)

This information sheet is to tell you about a change that has been made in how the special laboratory called a specimen repository will be managed.

As part of PACTG 1059 you agreed to have some of your blood or your child’s blood stored in the repository of the National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health (NIH).

NICHD has a repository because although researchers can learn a lot from a study, as time goes by sometimes the tests that they use get improved or brand new tests are developed, and more can be learned with these better tests. When study volunteers consent, like you did, to put specimens in the repository, and also consent to have the researchers do new tests on the specimens – at some time in the future after their time in the study is ended - researchers might learn new information by being able to use the stored specimens.

We are very grateful for your trust and willingness to help researchers keep learning more from the time you gave to the study.

The change we are making is in the group of people who oversee your stored specimens to make sure that your rights and privacy are protected in any future studies.

Before, the Institutional Review Board (IRB) at Westat, a data and operations center, was responsible for reviewing each future study.

Now we have a new procedure, approved by the NICHD IRB, that will have NICHD program staff review each future study. These NICHD staff members are very knowledgeable of the rules and procedures for oversight of specimen repositories, and they will be responsible for ensuring that your rights and privacy are protected.

If you have any questions about this change, you may contact:

[Add site research staff contact information here.]

NICHD program staff and everyone working on this study thank you for all you have done to make it successful.
When your child joins this NICHD sponsored Study, you will be asked to give permission for having some specimens that the doctor or nurse will take from your child’s body saved in a repository. (A repository is a special laboratory with freezers where specimens like blood or tissue cells and body fluids that are taken from you during a study are kept. Your child’s name will not be on these specimens, only a special study number. The people who run the repository laboratory will not know your child’s name.)

**Why have a repository?**

Researchers can learn a lot from a study but as time goes by the tests that they used get better or brand new tests are developed, and more can be learned with these better or new tests. When study volunteers consent to put specimens in the repository and consent to the researchers doing new tests on the specimens at some time in the future after their time in the study is ended, researchers can learn new information by being able to use the specimens. Your child’s rights and privacy will be protected in any of these new studies.

**How will my child’s privacy be protected?**

The only record that your child participated in this NICHD sponsored study is at the clinic where it is kept separate from your child’s health records and locked away.

Your child’s specimens in the repository will not have your child’s name on them. The specimens will have a special study code. It will be the same code that is on your child’s information in the NICHD sponsored Study from your child’s interviews and examinations. Again, none of this information will have your child’s name on it.

**How would a researcher get to use the specimens in the repository?**

If a researcher wants to do a test on specimens from the NICHD sponsored repository in the future, he or she will write up the idea and it will have to be approved by a committee to make sure the research is worthwhile. If the idea is approved, then coded specimens and coded information will be given to the researcher. The researcher will not know the names, addresses, or phone numbers of the people who gave the specimens to the repository.

**Why wouldn’t I find out the results of the research using my child’s specimens?**

You will not receive the results of research done with your child’s specimens. This is because research can take a long time and must use specimens from
many people before results are known. Results from research using your child’s specimens may not be ready for many years. Often when studies are first done, it is not always clear how to use the information from the study to change the health care that people receive. So none of these study results is likely to affect your child’s care right now, but they may be helpful to people like your child in the future. Your child’s specimens can last in the freezer for many years and there is no time limit to when studies could be done in the future.

Would I ever be contacted in the future about research using my child’s specimens?

All of the studies to be done in the future on your child’s specimens in the repository will be for the particular reasons that you agreed to. Every study that is planned to use specimens from your child and others from this NICHD Study has to be reviewed to make sure that what is planned is the same kind of study that you agreed to. If it is, then the research will go ahead since you would have agreed that these particular tests could be done without anyone contacting you to get your permission in the future.

If the study to be done is not like the kind of tests you agreed could be done, then the committee will decide if you need to be contacted to give permission for the new study.

I gave my permission to testing my child’s specimens in the repository, but what if I change my mind?

People always have the right to stop participating in research. So if you decide that you do not want researchers to be able to use the specimens from your child in the repository, you can contact the clinic staff. They will tell the repository that the specimens with the study code number linked to your child’s name in the clinic should not be studied. These specimens can be removed from the repository and destroyed if you tell us to do that.

What type of research will be done with my child’s specimens?

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. If this would happen and these tests or drugs make money, there are no plans to share that money with the people who gave the specimens.

As part of this study (insert title), your child is being asked to have some (insert specimen source- blood, urine, tissue, genital fluid, saliva, etc.) taken. These specimens will go into the NICHD repository for research to be done at some time in the future so that more information can come from your child’s time in this NICHD sponsored Study.
You do not have to agree to store your child’s specimens for future tests for your child to take part in this study. Your child will not lose any benefits to which your child is entitled if you decide against storing your child’s specimens.

You will also be asked to agree that these particular tests can be done without anyone contacting you to get your permission sometime in the future. No one doing these tests would know that these specimens came from your child and no one would contact you or your doctor or nurse with the results from these tests that might happen in the future.

**TEMPLATE CONSENT FORM**

**What are the general HIV-related studies that can be done with the repository specimens?**

Researchers would like to store your child’s specimens to understand how HIV causes disease and complications, and how best to treat or prevent HIV infection and its complications. They need specimens from people who have HIV and from those who do not. Sometimes, too, the specimens can be used to learn something about new problems that people with HIV have like liver disease, diabetes, and heart disease. These general studies would not include any genetic testing (looking at your child’s DNA).

**Benefits:** There are no direct benefits to your child. Your child will be helping researchers learn more about how to help people with HIV or at risk of HIV infection.

**Risks:** The specimens would be collected as part of your child’s study visits. (Insert text about collection procedures.) Once in the repository, there are few risks. Your child’s name will not be available to the repository or to the scientists who may be doing any future test.

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**I give permission for the use of my child’s stored specimens for the purposes stated in the preceding section (general HIV-related tests).**

___________________________  ___________________________  
Parent or Legal Guardian Signature  Witness Signature  Date

**I give my assent to the use of my stored specimens for the purposes stated in the preceding section (general HIV-related tests).**

___________________________  ___________________________  
Participant Signature  Witness Signature  Date
What are the special HIV-related studies that can be done with the repository specimens?

Researchers in this study would also like to store your child’s specimens to understand how HIV causes disease and complications, and how best to treat or prevent HIV infection and its complications through looking at how each person’s genetic makeup (your child’s DNA) either protects them or puts them at greater risk. It may be that researchers use some of your child’s blood to make a “cell line”. That means the blood cells can keep dividing and give an endless supply of your child’s DNA for tests to be done in the future. This kind of information will be particularly important as scientists work toward a vaccine that could protect people from AIDS. They need specimens from people who have HIV and from those who do not.

**Benefits:** There are no direct benefits to your child. Your child will be helping researchers learn more about how to help people with HIV or at risk of HIV infection.

**Risks:** The specimens would be collected as part of your child’s study visits. (Insert text about collection procedures.) Once in the repository, there are few risks. Your child’s name will not be available to the repository or to the scientists who may be doing any future test. Since there are no plans to give participants the results of the tests performed on their stored specimens, you will not receive any information on your child’s genetic makeup.

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What if I have more questions?

If you have any questions about the repository, about storage, or the use of your child’s samples, contact [Study personnel] at (phone).

If you have questions about giving consent or your child’s rights as a research volunteer, contact the [Name of Institution] Institutional Review Board at (phone).
I refuse to have any specimen collected from my child stored in the repository.

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Why have a repository?

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How will my privacy be protected?

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