

**INFORMED CONSENT FORM
FOR OPTIONAL USE OF EXTRA SAMPLES**

Sponsor / Study Title: National Institute of Allergy and Infectious Diseases /
“Adaptive Platform Treatment Trial for Outpatients with
COVID-19 (Adapt Out COVID)”

Protocol Number: ACTIV-2/A5401

Principal Investigator: [REDACTED]
(Study Doctor)

Telephone: [REDACTED]
[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]

Everything in the main study consent form you signed and dated before still applies to your participation unless otherwise noted in this form.

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns “you” and “your” should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant’s representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

When samples are no longer needed for this study, the ACTG may want to use them in other studies and share them with other researchers. These samples are called “extra samples.” The ACTG will only allow your extra samples to be used in other studies if you agree to this. If you have any questions, please ask.

Identifiers will be removed from your samples and from any private information that has been collected about you. This means that no one looking at the labels or at other information will be able to know that the samples or information came from you.

Extra samples are stored in a secure central place called a repository. Your samples will be stored in the ACTG repository located in the United States.

There is no limit on how long your extra samples will be stored.

When a researcher wants to use your samples and information, the research plan must be approved by the ACTG. Also, the researcher’s institutional review board (IRB) will review the plan. IRBs protect the rights and well-being of people in research. If the research plan is approved, the ACTG will send your samples to the researcher’s location. This means that

[REDACTED]

researchers who are not part of the protocol team may use your samples without asking you again for your consent.

You will not be paid for your samples. Also, a researcher may make a new scientific discovery or product based on the use of your samples. If this happens, there is no plan to share any money with you.

You may withdraw your consent for research on your extra samples at any time and the specimens will be discarded.

Please choose the response that matches what you want by putting your initials in the space provided. Please ask the study staff any questions that you have before you indicate your selection.

Research without Human Genetic Testing

If you agree, your extra samples may be stored (as described above) and used for ACTG-approved research that does not include human genetic testing.

_____ (initials) I understand and I agree to this storage and possible use of my samples.

OR

_____ (initials) I understand but I do not agree to this storage and possible use of my samples.



SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below and date it.

Participant's Name (print)

Participant's Signature and Date

Participant's Legally Authorized Representative
(As appropriate) Signature and Date

Legally Authorized Representative (print)

Study Staff Conducting
Discussion (print)

Study Staff's Signature and Date Consent

Witness's Name (print)

Witness's Signature and Date (As appropriate)

