

**Appendix L1: Consent Form for Cases
Adult Patients and Minors Who Provide
Consent for Their Own Treatment**

THIS STUDY AND ITS PURPOSE

You are being asked to take part in a research study that is being conducted by RTI International. This study is funded by the Health Resources and Services Administration (HRSA) to test a text-messaging intervention program to help improve the health and wellbeing of young people with HIV. About 500 young people with HIV will be asked to take part in this study.

DO I HAVE TO JOIN THIS STUDY?

Being in this study is completely voluntary. You can refuse to answer any questions. You can stop at any time. Your decision to take part in this study will not affect your access to any services or benefits.

WHAT WE'RE ASKING OF YOU

To take part in this 9-month study, you must agree to participate in the text messaging intervention. Being in the intervention means the following:

- The study coordinator will access your medical records four times during the study to verify your HIV status (when you enroll) and record your CD4 count and viral load, appointment attendance, and the medications you are taking to treat HIV.
- You will complete four surveys on a computer. The surveys will ask you about your background; use of computers and cell phones; how you take your HIV meds; support you get from friends and family; how people with HIV are treated by others; what you know, think or believe about HIV; how you manage your HIV; your sexual behaviors; your smoking and substance use; your satisfaction with your health care; and your opinions about the text messages (at the end of the study).
- You will receive 1-4 text messages a day for 9 months. The text messages will remind you to take your HIV medication, go to medical appointments, avoid unsafe sex and substance abuse, and promote healthy behavior. At the end of the study, we will de-activate your phone number in the text-messaging system and stop sending you text messages.
- You may be asked to complete a telephone interview about your experiences in the project.

RISKS OF PARTICIPATION

There is a small risk that completing the surveys may make you feel uncomfortable or upset. You may also feel anxious or uncomfortable with the text messages sent to you. If this happens, contact the onsite study coordinator, NAME, at [xxx-xxx-xxxx]. He/she will meet with you to find out if you need additional counseling, and if necessary, refer you to social worker or other mental health provider at the clinic. However, this study will not pay for the cost of these services.

Your HIV status may become known through your participation in this study. For example, if you allow someone else to read your text messages, he/she may learn that you are HIV positive. To reduce this risk, make sure to read your text messages in private. We will also ask you to create a unique personal identification number (PIN) which you must enter in order to see messages that may disclose your HIV status. You will not have to enter the PIN to retrieve all messages,

just the ones that mention HIV or HIV-related topics. Do NOT share your PIN with others. If you are worried that someone knows your PIN, you may change it at any time by 1) contacting the onsite study coordinator, NAME, at [xxx-xxx-xxxx] or 2) by replying to any message received from the study with the word “STOP” or “QUIT” in the body of the message.

We also strongly suggest that you

- not share your phone with others,
- password protect your phone,
- delete the study text messages after reading them,
- notify your cell phone carrier to terminate service to your phone should you lose it, and
- only use a personal cell phone and not one that that is provided to you by an employer.

It is possible that your family or friends might find out that you are in this study. For example, if your parents/guardians pay your cell phone bill (or have access to your cell phone account), they might notice that you are getting more text messages than usual. Even though they can't read your messages unless they have your phone, they might ask you about your increased usage. Also, your parents/guardians could put monitoring software on your phone. If this software is on your phone, someone with access to the software could read your text messages.

BENEFITS OF PARTICIPATION

You may benefit directly from this study if the text messages help you to do a better job of taking care of your health. You might also help other people with HIV by the knowledge gained from this study.

COSTS OF PARTICIPATION

Taking part in the study will not cost you anything if you have an unlimited text-messaging plan. If you pay for each text message you receive on your phone, your wireless carrier will charge you the standard rate for each text message we send to you as part of this study, which could range from 1-4 messages per day. We estimate this cost to be between \$0.90 and \$3.60 per month. You will be responsible for these charges. You will not receive any medications or medical treatments as part of this study. We cannot promise that the risks we told you about or other unknown problems will not occur.

COMPENSATION

You will be given \$25 when you enroll in the study and complete the first survey and then \$25 for completing each additional survey at 3-, 6-, and 9-months (up to \$100 total). If you participate in an in-depth interview, you will receive an additional \$25.

RESPECT FOR YOUR PRIVACY

Any personal information (e.g., your name and telephone number) will be kept in locked file cabinets or on a password protected computer. When you enroll, we will assign you a special ID number that you will use to enter your answers to the surveys. All of your answers will be recorded under the ID number and not your name or anything else that can identify you. All forms with a study ID number will also be kept in locked file cabinets. All documents will be destroyed at the end of the study.

Anyone who is working with any of the information you give us has to sign an agreement with RTI International to protect the privacy of the people in the study.

Data will be kept private to the extent allowed by law. ~~Your personal information will be kept private as permitted by law.~~ This means that if you tell us that you are about to hurt yourself or someone else, or you are involved in the neglect and/or abuse of a child, then we must report that information to the appropriate authorities.

TERMINATING PARTICIPATION

There are two ways that you can stop taking part in this study:

1. Contact the onsite study coordinator, NAME, by phone (NUMBER) or email (EMAIL ADDRESS). She/he will start the process to stop sending you text messages.
2. Reply to any message received from the study with the word "STOP" or "QUIT" in the body of the message.

WHO TO CONTACT WITH QUESTIONS

The investigator in charge of this study at RTI International is Dr. Jennifer Uhrig. You may call Dr. Uhrig toll-free at 1-866-784-1958, extension 2-3311. You can call Dr. Uhrig if you have any problems or questions related to this study.

If you have any questions about your rights as a research subject, you may ask RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

STATEMENT OF CONSENT FOR THE INTERVENTION STUDY

Signing the line below indicates that we have described the study procedures to you, asked you to take part, and given you the chance to ask questions. You do not give up any rights by signing this consent form. We can give you an unsigned copy of this form if you would like.

Do you have any questions?

By putting my signature on the line below, I am agreeing to take part in the intervention study.

Date

Signature of Individual

STATEMENT OF CONSENT TO BE CONTACTED FOR AN INTERVIEW

You may be asked to participate in a telephone interview during the course of the 9-month text messaging intervention. Participation in these interviews is completely voluntary and will not impact your participation in the text messaging intervention. If you decide to participate, your interview will be audio-recorded with your permission, and we will also take notes. The audio recording and notes will only name your study ID number. Interview notes will be stored on a secured computer.

Do you have any questions?

By putting my signature on the line below, I am agreeing to be contacted should I be selected for an interview.

Date

Signature of Individual