ATTACHMENT 14
Baseline Client Consent-Intervention Sites

Evaluation of the SAMHSA Primary and Behavioral Health Care Integration Program
Baseline Interview and Blood Draw

Description of Study
We are asking you, and approximately 1650 other men and women to participate in a research study conducted by Audrey Burnam, PhD and Deborah Scharf, PhD from the RAND Corporation. We are conducting this study with funding from the Substance Abuse and Mental Health Services Agency (SAMHSA) because we want to learn more about if locating basic medical services (primary care services) in community mental health centers improves the physical and emotional health of the people who use these services. Specifically, we want to learn more about the effect of combining physical and behavioral health care on the following conditions: high blood pressure, obesity, tobacco use, high cholesterol, diabetes, and high blood fat.

You are being asked to be in this study because you are age 18 or older, and you receive services from a community behavioral health center participating in our study. By participating you will help us understand some of the health care needs of people who receive services from your community mental health center.

Procedures
If you agree to participate, we will interview you, assess your physical health through a physical exam, and we will also draw a sample of your blood. This will take about 1 hour.

During the interview, we will ask you questions about your background, medical history, mental health, drug use, aspects of your lifestyle such as diet and exercise, what medicines you take, and about problems you may have experienced coping with life.

The physical health exam involves measuring your height, weight, blood pressure, the distance around your belly, and your exposure to tobacco smoke (we measure this from air that you will blow into a tube).

The blood draw will require up to 3 tablespoons of your blood to measure your blood sugar, blood fat, and cholesterol. We will link this information to the interview that you give us. The results of the physical health exam and blood test will be shared with you and your care team.

Risks
1. Regardless of the test results, being tested for high blood pressure, obesity, tobacco use, high cholesterol, diabetes, and high blood fat may make you nervous, and the results may make you upset.
2. Drawing blood may hurt a little and could cause a bruise or occasionally fainting, but it very rarely causes an infection.
3. If people outside the research team or your care team learn about your positive test results, you may have trouble obtaining insurance or employment.

Anticipated Benefits to Subjects
Finding out if you have health problems such as high blood pressure, diabetes, high cholesterol, tobacco use, or obesity will allow you to get referrals from your care team for treatment if you need it.

Anticipated Benefits to Society
This study will help researchers learn if including basic medical services in community behavioral health centers improves the physical and emotional health of the people who use these services.

Alternatives to Participation
You do not have to take part in this study. Whether or not you participate in the study will not affect services you normally receive.

Payment
You will receive a $20 gift card to [TARGET/WALMART/OTHER LOCAL CHAIN STORE] today for your participation in the study after you finish the interview and blood draw today.

Privacy
The information that you give us today is kept private. Only two groups of people will know about the information you provide: (1) the research team, and (2) you and your treatment team. No information about you, or information provided by you during the research, will be disclosed to others outside of these groups without your written permission, except: if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or if required by law. We will not report results of this

study with your name or report any information that identifies you. Although I will not ask you about this, if you tell me about an immediate intent to harm yourself or someone else, we may report it to the proper authorities.

Participation and Withdrawal
You do not have to participate if you do not want to. Also, if you decide to participate in the study, you can change your mind later or refuse to answer any question at any time.

If you decide not to participate, it will not affect your relationship with your community mental health center, your care providers, or your right to health care that you may be entitled to. If you decide to participate, you can refuse to answer any question, and you can end your participation at any time. Ending your participation will not affect your future care at this community mental health center or anywhere that you receive health care.

Withdrawal of Participation by the Investigator
Your study interviewer may stop you from participating in this research if things happen that warrant doing so. If you become ill during the research, you may have to drop out, even if you do not want to drop out. Your study interviewer will decide and let you know if it is not possible for you to continue.

If you must drop out at any time because your study interviewer requests it (rather than because you have decided on your own to withdraw), you will be still be paid the full $20.

Questions
If you have any questions, you can ask a member of our team, or later, you may contact the Survey Director, Judy Perlman at our toll free number ***-***-**** or Dr. Scharf or one of her colleagues at RAND, 412-683-2300 x4601.

Rights of Research Subjects
You may withdraw your consent and stop participation at any time. You are not giving up any of your legal rights by agreeing to be in this study. If you have questions regarding your rights as a research subject, or the informed consent process you may contact Carolyn Tschopik at the Office for Human Subjects Protections, 1776 Main St., Santa Monica, California 90401, (310) 393-0411.x6124.

Verbal Consent
You have been given a copy of this information form to keep.

INITIALS OF RESEARCH SUBJECT

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY INITIALING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____ _____
Initials of Date
Research Subject

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator **Date (must be the same as subject's)**