

**INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY**

Sponsor / Study Title: Pfizer, Inc / “LOW-INTERVENTIONAL RANDOMIZED STUDY TO EVALUATE THE FEASIBILITY AND ACCEPTABILITY TO ADULT PARTICIPANTS OF 2 DIGITAL CLINICAL ASSISTANTS PERFORMING STUDY SPECIFIC TASKS”

Protocol Number: C5591001

Principal Investigator: Mona Shahbazi, MS, APRN

Telephone 24-Hours 203-401-0300

Address: New Haven Clinical Research Unit
One Howe St.
New Haven, CT 06511

INTRODUCTION

You are here today as a possible participant in a research study sponsored by Pfizer Inc. Taking part in this study is voluntary (your choice). The study staff will be available to answer questions before, during, and after the study.

The sponsoring company (the company paying for this study), Pfizer Inc, employs the study investigator conducting this study.

If you are not completely honest about your health history, you may be harmed by being in this study.

PURPOSE OF THE STUDY

You will not receive any study drug, or any medicines during this study.

The purposes of this study are:

- To check the feasibility (practical or workable) of a digital clinical assistant versus standard procedures in the administration of a mock (fake)-informed consent process, to answer the question “does it work?”
 - Digital clinical assistants (digital people) are autonomously (independent) animated virtual people whose interactions are driven by artificial intelligence (AI). AI technologies enable digital people to simulate (imitate) human behavior. Digital clinical assistants will appear on a computer screen and will interact with you by seeing and hearing them and speaking to you.
 - The mock-informed consent is from an actual Pfizer study in progress at another clinical site outside the United States.
- To check the feasibility of a digital clinical assistant in the instruction and confirmation of self-collected vital signs, again, to answer the question “does it work?”

- To check the acceptability of digital clinical assistants in the administration of a mock-informed consent process and in the instruction and confirmation of self-collected vital signs, to answer the question, “how do people think and feel about interacting with digital clinical assistants?”

ABOUT THE STUDY

Number of Study Participants

There will be about 10 people taking part in this study.

Length of Study for Participants

You will be in this study for one day, lasting about 3 - 4 hours.

This study involves:

- 1 in-person visit to the New Haven Clinical Research Unit (CRU)

Study Procedures and Activities

Two groups of participants are planned.

GROUP	NUMBER OF PARTICIPANTS	STUDY ACTIVITY
1	5	Mock-consent and vital signs self-collection with Digital Clinical Assistants
2	5	Mock-consent with CRU staff and vital signs self-collection with Digital Clinical Assistant

Before any study procedures begin, you will be asked to read, sign, and date this consent document.

Screening

Once you have signed the informed consent document (ICD) to participate in this study, administered under standard CRU procedures, you will be provided a unique ID number (SSID). You and the CRU staff will use this number to identify your data. You will then begin screening activities. The purpose of the screening is to find out if you meet all of the requirements to take part in the study. Procedures that will be completed during the study (including screening activities) are described below. If you do not meet the requirements, you will not be able to take part in the study. The study investigator or study staff will explain why.

If you do meet the screening requirements, you will be randomly assigned, like the flip of a coin, to one of the study groups.

Both you and the study staff will know your assigned group.

As part of the screening visit, you must complete all of the items listed below:

- Give your race, age, gender, ethnicity and educational level
- Vital signs (blood pressure, pulse, and pulse oximetry [measures the amount of oxygen in the blood] will be measured by CRU staff using the same equipment you will use for self-collection)
- You will be asked “How do you feel?”

Study Visit

Mock-Consent Process

Following screening and randomization, a mock ICD will be administered with either the assistance of a digital assistant, named Mia (Group 1), or the CRU staff (Group 2, standard eConsent procedure). Mia (Group 1) or the CRU staff (Group 2) will each do the following:

- Provide instructions for completing the mock-informed consent process
- Summarize the mock-ICD section-by-section and allow you time to read it
- Solicit and answer questions (Mia will generate responses using AI) that you may have on the mock consent
- Determine if you wish to provide mock-consent by asking you to answer “yes” or “no” to each of the mock-consent statements
- Instruct you how to provide your consent to participate in the mock study (Mia will ask you to provide a fingerprint; CRU staff will ask for an electronic signature)
- Confirm that you have provided mock-consent

If you are in Group 1, you will sign the mock-ICD by using a fingerprint. If you are in Group 2, you will sign the mock-ICD with an electronic signature.

Both groups will then complete a mock-ICD comprehension questionnaire to determine your level of understanding of the mock-ICD. The questionnaire will be presented to you on a tablet and will include 10 multiple choice questions.

Vital Signs Self-Collection

After you complete the mock-ICD comprehension questionnaire, a digital clinical assistant, named Phillip, will instruct both groups on how to collect certain limited vital signs (i.e., your pulse oximetry, pulse, and blood pressure) using a standard CRU pulse oximeter and then using a wearable blood pressure monitor. Phillip will verify that these vital signs have been collected into an electronic database for each type of equipment. Phillip will be able to be paused or to repeat instructions. However, Phillip will not be able to answer any questions you may have.

You will then complete a participant acceptability survey on a tablet that will be handed to you. Participants in Group 1 will be asked about their interactions with Mia and Phillip (rating 21 statements on a scale from 1 to 7 and answering 8 open-ended questions). Participants in Group 2 will be asked about their interactions with Phillip (rating 10 statements on a scale from 1 to 7 and answering 4 open-ended questions). This will be the final study procedure. You will be dismissed from the CRU at that time.

During the study, you may request to pause or discontinue interaction with digital clinical assistants. If the digital clinical assistant is unable to answer a relevant study related question, they will refer the question to the CRU staff who will be present with you during the study. If you need help from the CRU

staff in order to complete a task (e.g., answering a question about the mock-ICD, understanding how to provide your fingerprint, understanding how to self-collect vital signs) you will exit the digital clinical assistant application.

Text transcripts of your interactions with digital clinical assistants will be saved at the CRU. Personally identifiable information disclosed by you during these interactions (that may be retained in the text transcripts, for example, your name or participant ID) will be handled as detailed in the Confidentiality Section located later in this ICD. The text transcripts will be shared with the sponsor after your personally identifiable information has been removed.

We may add procedures at any time during the study to check on your health status.

You will be provided a participant ID, sometimes referred to as SSID. This will be used by CRU staff, by you when you are engaging with the digital assistants and self-collecting vital signs, and by the sponsor to ensure accurate and reliable data collection.

Possible Risks and Discomforts

Taking part in this study has some risks. The study procedure(s) may make you feel unwell or uncomfortable or could harm you.

It is important that you report all side effects that you have as soon as they occur. This is regardless of whether or not you believe they are caused by the study devices or your participation in this study.

If you are not honest about any side effects that you have during the study, you may be harmed by staying in the study. There may be risks that are currently unforeseeable.

Interactions with Digital Clinical Assistants

The use of AI and interacting with clinical digital assistants, including the questions and responses may make you uncomfortable. Otherwise, there are no other expected risks to you.

Standard CRU Pulse Oximeter and Wearable Blood Pressure Monitor

There are no expected risks to you from the standard CRU pulse oximeter or the wearable blood pressure monitor you will use to measure the limited vital signs of pulse oximetry, pulse, and blood pressure. Some people are slightly uncomfortable as a blood pressure cuff inflates.

PARTICIPANT RESPONSIBILITIES AND RIGHTS

Participant Responsibilities

- You must be willing and able to comply with the study procedures.
- You must not have any significant medical or psychiatric conditions that would limit your ability to complete the study tasks and use the standard CRU pulse oximeter or wearable blood pressure monitor as determined by the study investigator as a result of your medical history.
- Please let us know if you or a relative are a staff member of Pfizer or PCRU. If so, you may not take part in this study if you or your relative are supervised by the study investigator or are directly involved with the study.
- If you are taking any Pfizer product as part of your routine care and you or your partner become pregnant while you are participating in this study, tell your study Investigator or study staff

immediately. The study staff will ask to collect information about the pregnancy, its outcome, and the health of the child after birth.

Activity Restrictions

- You will need to stay in the CRU for about 4 hours.

Possible Benefits of the Study

This study is for research purposes only. There will be no direct benefit to you from taking part. However, information learned from this study may benefit other people in the future.

Alternatives to Participating in this Study

This study is for research purposes only. Your alternative is to not take part in the study.

Confidentiality

This section describes how we will collect, use, and share your personal information.

What personal information may be collected about me during this study?

The study staff will collect information about you. This information may include:

- **Information that directly identifies you** such as your name, address, telephone number, date of birth, and Social Security Number
- **Personal information** such as your medical history, data from this study (including study results from tests and procedures), demographics (for example, age and gender) and other sensitive information that is needed for this study such as race, ethnicity, sexuality, substance abuse disorders, mental health disorders, diagnoses, treatment, and status
- **Data captured from electronic devices**
 - Body measurements and calculations related to human characteristics, such as facial images, voice and fingerprints, all “Biometric Data” will be collected from electronic devices. The following information, including Biometric Data, will be collected as part of your interaction with the digital clinical assistants:
 - Your image will be collected using the computer’s camera. Your image will then be processed and converted from pixels to diametric data relating to the outline of your facial features, such as your eye, forehead, etc. This means that the images will be used to generate data that cannot directly identify you and then discarded after the session.
 - Your voice and surrounding audio will be collected using the computer’s microphone. Your voice and audio data will be encrypted and input to a speech to text system and then discarded after the session.
 - eConsent tablet will be used to complete the consent process for this study, and for the mock-consent process
 - This information may include:
 - The number of times you scroll between pages or click to hyperlinked items
 - Your electronic signature

- Verified Clinical Trials (VCT) registration: The following personal information will be collected as part of the VCT registration/ fingerprint scanning:
 - The scan of your fingerprint is translated into a unique series of numbers that cannot be used to reproduce your fingerprint image (Identity Token). This Identity Token is further encrypted and stored, but your fingerprint image is not stored.
 - Study Identifying Data, including study name (protocol name), study sponsor (the company on whose behalf the study is conducted), name of the institution that is the study site, location of the study site, your single subject identifier (SSID) which is the number assigned to you for the purpose of the study, study specific dates, such as the date when you registered for the study and participated in the study.
- CRU pulse oximeter: This will record your pulse oximetry (the oxygen level in your blood) and your pulse.
- Wearable blood pressure monitor: This will record your blood pressure and your pulse.
- Study questionnaires: These will record your responses to the required study questionnaires.

Mobile applications and other digital tools used in this study may have their own privacy policies. Those policies provide additional information about the data processing activities performed.

Who will use my personal information, how will they use it, and where will it be stored?

Any personal information collected during this study will be stored by the study staff at the CRU. The study staff must keep your personal information confidential.

Your personal information will be accessed by:

- The study investigator and other CRU study staff members
- Pfizer and its representatives (including its affiliated companies)
- People or organizations providing services for, or collaborating with, Pfizer
- Government or regulatory authorities (including the U.S. Food and Drug Administration (FDA) and authorities in other countries)
- Advarra Institutional Review Board (IRB), the IRB that reviewed this study and any other committees responsible for overseeing the research
- Certain third parties engaged by Pfizer to conduct this study (as described in greater detail in section “**What happens to my personal information that is sent outside the CRU?**”)

The individuals and groups listed above will use your personal information to:

- Determine if you are eligible for this study
- Conduct this study
 - Your image is being processed to make your conversation with digital clinical assistants seem more realistic by assigning an emotion to your facial features that the digital clinical assistant can react to (for example, happy, sad, confused).
 - A text transcript of your conversation with the digital clinical assistants will be used by the sponsor to understand how the digital clinical assistant performed in answering your questions and providing instructions to you.
- Comply with Legal or Regulatory Requirements
- Verify that the study is conducted correctly and that study data are accurate
- Answer questions from IRB(s) or government or regulatory agencies

- Contact you during and after the study (if necessary)
- Follow-up on your health status, including using publicly available sources (for example, public databases or the internet) should the study staff be unable to contact you using information held on file
- Protect your vital interests such as providing information to an emergency department of a hospital if you are being treated
- Publish the results of studies

We will only use such information in keeping with this informed consent and applicable law. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

Are there any circumstances by which my personal information may leave the CRU?

Under certain circumstances, information that identifies you by name may leave the CRU study site in connection with the study and be sent to the Sponsor or a vendor contracted by the Sponsor, in order to:

- support the use of digital tools (e.g. electronic consent, interactions with the digital clinical assistants, mobile applications (apps), and certain wearables) in the study
- provide you with reimbursement, as allowed by the study, for your time, effort and certain expenses related to your participation

The people and/or organizations contracted by the Sponsor to provide these services must keep your personal information private, and they will not share with the Sponsor any information that can directly identify you.

What happens to my identifiable personal information that is sent outside the CRU?

Before the study staff transfers your identifiable personal information outside the CRU, the study staff will:

- Replace your name with a unique code
- Remove information that directly identifies you

This is called "**Coded Information.**" The link between the code and your personal information will be kept confidential by the CRU study staff.

Your Coded Information will be used by the following:

- Pfizer and its representatives (including its affiliated companies)
- People and/or organizations providing services to or collaborating with Pfizer
- Any organization that obtains all or part of Pfizer's business or the rights to the product under study
- Other researchers
- Advarra IRB
- Government or regulatory authorities

The above parties may use your Coded Information for the following purposes:

- **Conducting the study**, including:
 - Examining your response to devices
 - Understanding the study and the study results and learning more about the use of digital clinical assistants
 - Assessing the safety of the devices
- **Complying with legal and regulatory duties** such as:
 - Ensuring the study is conducted according to good clinical practice
 - Making required disclosures to IRB(s), or government or regulatory authorities
 - Sharing study data with other researchers not affiliated with the study staff or Pfizer. This includes through publication on the internet or other ways. However, information that could directly identify you will not be made available to other researchers
- **Publishing summaries of the study results:**
 - In medical journals
 - On the internet
 - At educational meetings of other researchers

You will not be directly identified in any publication or report of the study, but some journal representatives may need access to your Coded Information to verify the study results and ensure the research meets the journal's quality standards. Also, journals may require that other information from the study that does not directly identify you be made available to other researchers for further research projects.

- **Improving the quality, design, and safety** of this study and other research studies.

Data captured from digital tools or electronic devices sent outside the CRU will be handled as described in this Section, and below in the “How will my Biometric Data be Handled?” Section:

- Raw image and audio data collected from your interactions with the digital clinical assistants using the computer’s camera and microphone will not be stored or saved.
 - The raw image data will be used to generate summaries of data that cannot directly identify you. These summaries are retained by the third party that creates the digital clinical assistant experience. These summaries are coded and associated with a session ID and User ID specific to you, apart from your SSID within the study.
 - A text transcript of your conversation with the digital clinical assistants’ (in other words, a text version of what you say and what the digital clinical assistant says) will be retained by the sponsor after any personally identifiable information is removed (for example, your name). This will be used by the sponsor to understand how the digital clinical assistant performed in answering your questions and providing instructions to you.
- CRU pulse oximeter: The data will be linked to your SSID and will be transferred to the Sponsor.
- Wearable blood pressure monitor: This data will be linked to your SSID and will be uploaded to a mobile app and an internet portal. It will then be transferred to the Sponsor.
- Study questionnaires: These will record your responses to statements and questions on a tablet. This data will be linked to your SSID and will be transferred to the Sponsor.

How will my Biometric Data be Handled?

As you interact with digital clinical assistants, **your image** will be collected from the provisioned laptop’s camera, processed and converted from pixels to data detailing the outline of your eyes, forehead, etc. This means that the images will be used to generate data that cannot directly identify you and will then be discarded after the session.

Your **voice or audio data** will be collected from the laptop's microphone, encrypted and input to a speech to text system. The raw audio data will then be discarded after the session. As you interact with the digital clinical assistants, your voice is being processed to inform the digital clinical assistants when you are speaking and what you are saying. A text transcript of your conversation with the digital clinical assistants (in other words, a text version of what you say and what the digital clinical assistant says) will be retained by the Sponsor after any personally identifiable information (for example, your name) is removed.

Processing of your image and voice takes place within a secured firewalled database network in the US. Once your session ends with the digital clinical assistant, their memory of your interaction will also be discarded.

CRU pulse oximeter: This will record your pulse oximetry (the oxygen level in your blood) by shining a light on your fingertip to determine the amount of oxygen in your blood cells. It will also record your pulse.

Wearable blood pressure monitor: This will record your blood pressure by an inflatable cuff around your wrist and a pressure monitor. It will also record your pulse.

Identity Token: The scan of your fingerprint is translated into a unique series of numbers that cannot be used to reproduce your fingerprint image (Identity Token). This Identity Token is further encrypted and stored, but your fingerprint image is not stored.

How long will my information be used? The CRU site will retain your information indefinitely.

Can my Coded Information and Biometric Data, if collected as part of the study, be used for other research?

Yes. Pfizer may use your Coded Information and Biometric Data, if collected as part of the study, to support and advance other scientific research projects, including improving the quality, design, and safety of other research studies, research supporting public health aims, and developing medicines, vaccines, diagnostic products and tools. As described above, a third party engaged by the study sponsor retains coded summaries of your facial features that cannot be used to directly identify you. These coded summaries may be used to improve digital clinical assistant experiences in the future.

At this time, we do not know the specific details of these future research projects; however, your Coded Information and Biometric Data, if collected as part of the study, could be used in combination with data from other sources, not related to you or this study. Reasonable safeguards will be used to protect your Coded Information and biometric data used in any future research and may include:

- Limiting access to individuals bound by duties of confidentiality
- Taking steps to minimize the risk that you could be re-identified
- Obtaining approval of institutional review boards

Furthermore, if your Coded Information and biometric data, if collected as part of the study, has identifiers removed such that they can no longer be readily identified with you, they may be used for future research purposes.

Study-Related Injuries

You will also receive a card with information about this study. This information includes:

- The name or number of the study
- The CRU 24-hour phone number

You should keep this card with you in case you have a medical emergency. You can give this card to any healthcare provider if they need more information about the research study to provide the best treatment for you.

If you experience a research injury, the CRU will arrange for medical treatment at no cost to you. Pfizer will cover the costs of this treatment. A research injury is any physical injury or illness caused by being in this study. There are no plans to offer you payment for such things as:

- Lost wages
- Expenses other than medical care
- Pain and suffering

To help avoid injury, it is very important to follow all study directions. You can get more information about medical treatment for research injuries from the study investigator or study staff.

You must call the study investigator immediately if you experience a research injury. The number is listed on the first page of this consent document. A 24-hour answering service is available.

If you are treated for a research injury that is paid for by Pfizer, Pfizer or its representative will collect your:

- Medicare Health Insurance Claim Number or
- Social Security Number

This is to determine your Medicare status. If you are a Medicare beneficiary, Pfizer will report the payment and information about the study you are in to the Centers for Medicare & Medicaid Services (CMS). This is in keeping with CMS reporting requirements. Pfizer will not use this information for any other purpose.

Legal Rights

You will not lose any of your legal rights by signing and dating this consent document.

Whom To Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Study Investigator's or study site's decision to withdraw you from participation;

- Results of tests and/or procedures;

Please contact the Study Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00075293.

Payment for Taking Part in the Study

The amount of payment is based on a number of things, including the length of the study.

You may be eligible for a travel and accommodations payment:

- \$0.20/mile per one-way trip to or from the CRU based on your home address
- For participants traveling long distances, a 1-night hotel stipend (\$150.00) for the night prior to your visit(s), if needed

All payments will be in U.S. dollars. Compensation may be provided on a loadable debit card or by paper check. Pfizer New Haven CRU reserves the right to determine method of payment.

U.S. Citizens: Payments may be considered taxable income. If you receive \$600.00 or more in taxable payments within a calendar year, your earnings will be reported to the Internal Revenue Service (IRS), and you may receive a tax form (1099). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 24% and receive a tax form (1099). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

Non-U.S. Citizens: Payments may be considered taxable income. Your earnings will be reported to the Internal Revenue Service (IRS) and you may receive a tax form (1042-S). Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS and vendors working on behalf of Pfizer for tax purposes. If you do not provide your SSN or TIN, you may have taxes deducted from your payment at a rate of 30% and receive a tax form (1042-S). If you prefer to not receive payment for this study, you may alert your study site. In some countries, compensation may not be allowed due to immigration status.

The payment for completing the entire study is listed below. Please be aware that:

- If you do not follow instructions (including those listed in the New Haven CRU House Rules), if you miss certain activities relating to this study, your payment may be reduced. You will be paid a prorated amount based on the extent of your participation if:
 - You are not able to complete the study
 - You choose to leave the study
 - You are withdrawn from the study early by the study investigator for non-safety-related issues
 - The study is stopped early
- A final payment will be provided to you within 2 weeks of finishing the study
- Pfizer may use information resulting from the study to develop products or processes. Pfizer may make a profit from these. There are no plans to pay you or provide you with any products developed from this research. Pfizer will own all products or processes that are developed using information from the study

Study participants will be paid (\$250.00) for their participation.

Additional payments are made if we ask you to return to the CRU or to outside medical providers for additional tests (\$250.00 per visit). During times that you need to stay in the CRU, you will not be paid more for repeat or added tests.

If you have any questions regarding your compensation for participation, please contact the study staff.

Costs for Study Participants

The study-related procedures and study visits will be provided at no cost to you.

Your Decision to be in the Study

Taking part in this study is voluntary. You cannot be forced to be in this study. You may leave the study at any time without penalty or loss of any benefits. Your future medical care will not be affected. If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your or your family member's performance appraisal or employment at this clinical research center. You may refuse to participate, or you may withdraw from the study at any time without penalty or anyone blaming you.

The study investigator, Pfizer Inc, or the FDA may take you out of the study without your permission at any time for the following reasons:

- You do not follow the instructions of the study investigator
- We find out you should not be in the study
- The study is stopped
- The study becomes harmful to your health
- You do not follow the New Haven CRU House Rules

The data collected to the point of your withdrawal remains part of the study database and may not be removed.

New Findings

If there is new information about the safety of the study or changes in the study activities and procedures, we will tell you in a timely manner. You can then decide if you still want to be in the study.

AGREEMENT TO BE IN THE STUDY

PIMS # _____

This consent document contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent document, ask one of the study staff.

By checking each of the following, you are agreeing that the statements below are true: Please

Check

A.	This consent document is written in a language I understand	
B.	I understand the information in this consent document	
C.	I have been given enough time to ask questions and talk about the study	
D.	All of my questions have been answered completely	
E.	I have received enough information about the study	
F.	I agree that I was not pressured by the study investigator or the study staff to be in this study	
G.	I know that I can leave the study at any time without giving a reason and without affecting my health care	
H.	I know that my health records from this study may be reviewed by Pfizer Inc and by government officials	

**IF YOU DID NOT CHECK THE BOX NEXT TO ANY OF THE ABOVE QUESTIONS
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN AND DATE THIS CONSENT DOCUMENT**

- You will get a copy of this signed and dated ICD for your records
- You agree to participate in this study
- It is your responsibility to tell the study investigator about all changes in your physical or mental health during the study

Printed Name of Adult Study Participant (Name as appears on U.S./State Government-Issued ID)

Signature of Adult Study Participant

Date

Printed Name or Initials of Person Explaining Informed Consent

Signature of Person Explaining Informed Consent

Date