UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

PATIENT VERBAL CONSENT FOR VIRTUAL APPOINTMENT

READING OF VERBAL CONSENT FORM

I am now going to get started and read you the verbal consent form.

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

You are invited to join the study with study title, Improving diabetes outcomes and health disparities through a patient activation intervention addressing unmet resource needs

The study is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

The Principal Investigator is:
Minal R. Patel, Ph.D., M.P.H
Associate Professor in the Department of Health Behavior & Health Education at the University of Michigan School of Public Health

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information I am reading. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to give verbal consent before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to dedicate time to study activities. This may require you to change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for diabetes. This research will see if a resource designed to help people with diabetes better manage their disease works as it is supposed to. Your health-related information, responses to survey questions, blood pressure readings, and HbA1c readings will be collected for this research study.

This study involves a process called randomization. This means that the resource you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate

groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include breach of privacy and discomfort or bruising at the site of the fingerstick. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by helping patients be more consistent with their diabetes treatment. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 12 months.

You can decide not to be in this study. Alternatives to joining this study include standard of care you already receive from your health care providers.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The purpose of this study is to see if an online program designed to help people with diabetes better manage their disease works as it is supposed to.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

In order to be in this study, you must:

- Be 18-75 years of age
- Be diagnosed with type 1 or type 2 diabetes with prescribed anti-hyperglycemic medication
- Have a most recent hemoglobin A1c(HbA1c) level within the past 6 months of greater than or equal to 7.5% for individuals ages 18-70 years and greater than 8.0% for individuals between 70-75 years in age
- Indicate resource considerations for diabetes management
- Have access to a telephone that can receive and send text messages

3.2 How many people are expected to take part in this study?

We expect 600 adults with diabetes to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

To join this study, you will be placed into one of two different groups for this study. You will not know which group you are assigned to and your placement into the group will be determined by chance, like the flip of a coin. Both study groups will complete three virtual appointments by phone. All three appointments will last about an hour and a half. In these appointments, you will complete a survey and give blood pressure and HbA1c readings using at-home testing supplies provided to you by the study team. Trained study staff will provide instruction by phone to complete a fingerstick blood test and blood pressure readings. Written instructions will also be provided with the testing supplies you receive. At each appointment, you will share your results of your blood pressure and HbA1C readings to the study team member completing your virtual appointment. You will also be given information on what the readings mean and what you can do if your readings are outside of the ideal range. You will measure your blood pressure twice and if it is above 180/120 for both readings, or only the second reading, we will terminate the interview for your own safety and encourage you to go to the nearest Urgent Care.

You will also be asked to use one of two different programs to help you manage your diabetes. You will be asked to engage with a program resource during your initial appointment for up to 20 minutes. You will also have the opportunity to use the program on your own time, after your first appointment. These programs are to help you better manage your diabetes. One program is a website and one program is a University resource program. If you are assigned to the group that uses the website, you can access it via internet access or through a phone or other mobile device. If you do not have access to the internet or a computer, the study team will provide you with a list of computer/internet access locations.

As part of this study, you will also receive regular contact from the study team over the course of the study. All people enrolled in this study will receive 3-5 text messages each week. You will be asked to read these text messages and respond to one of them. Depending on the group you are assigned to, you may also be asked to complete one automated phone call per week. Finally, all people in the study will get calls to schedule your study appointments and remind you of when they occur. You must have access to a telephone that can receive and send text messages in order to participate in the study.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you are available by phone during the time of your scheduled virtual appointment, engage with the study components, and report any adverse reactions you may have during the study.

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data. We would also like your permission to keep some of your study data and medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your study data and medical information for future research.

If you give us your permission, we will use your study data and medical information for future research. Even if you give us permission now to keep some of your study data and medical information, you can

change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your study data, we may not be able to take the information out of our research.

We may share your study data and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your study data and medical information with other researchers, we will not be able to get it back.

Potential risk of future research includes breach of participant privacy and confidentiality of information and identification. The researchers will minimize this risk by securing all study files with passwords stored on password protected and secure drives and in locked cabinets and offices. Access to information will be on an "as needed" basis. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your study data. Allowing us to do future research on your study data and medical information will not benefit you directly.

With appropriate permissions, your collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

4.2 How much of my time will be needed to take part in this study?
Throughout the study each person will complete 3 virtual appointments by phone over a period of 12 months. All three appointments will take about an hour and a half. In addition to your study appointments, you will also be asked to read and respond to text messages, use one of two programs, and you may be asked to answer a weekly phone call depending on the group you are assigned to. The total amount of time over the course of the study is estimated to be about 12 hours, plus any time you spend on the program information provided to you.

4.3 When will my participation in the study be over?
Most participants will finish their participation in the study after completing the 3 virtual appointments. The appointments will be spread out over a period of 12 months.

We may ask a small number of study participants to answer additional questions about their experience in this study.

May we contact you again in the future to ask you about your experience in this study?

☐ Yes ☐ No

4.4 What will happen with my information used in this study?
Your collected information may be shared with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private

information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Your identifiable private information that can be used to identify you will be securely stored in locked drawers and password protected computers in locked offices. All private information will be stripped of identifiers before being used for research purposes. Results from both the HbA1C test and blood pressure readings will be coded before being used for research. This is so that your readings are not tied back to you.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- Breach of participant privacy and confidentiality of information and identification
- The blood draw from the HbA1c rapid test can cause discomfort or bruising at the site of the stick
- Although not common, swelling and bleeding from the area where the HbA1C blood draw occurs could happen
- Rarely, fainting and local infection may occur

The researchers will try to minimize these risks by:

- All study activities will take place in private rooms. All data collected will be coded so that no identifying information is linked with your data.
- Only the Data Manager and Project Manager will have access to the code that links data with your identifiable information. All other research staff, including the data collection staff and the investigators will only have access to information on an 'as needed' basis.
- All databases with your information will be password protected and stored on a secured, encrypted University of Michigan drive.
- When data must be shared for study purposes it will be shared through HIPAA-compliant technology and servers hosted by the University of Michigan information technology services.
- Text messages will be sent and received through a text-messaging server called Twilio. The messages will be automatically removed so that identifiable information such as phone numbers are not stored on the server.
- Some virtual study appointments may be conducted with a HIPAA-compliant tele-meeting program used at the University of Michigan. The virtual study appointments will be audio only; no audit content of the call will be saved.
- When logbooks or paper records must be kept, they will be kept locked in file cabinets in a locked room. Only research staff will have access to this room. All consent forms will be stored in the same manner.
- All data with your identifiable information will be destroyed as soon as it is no longer needed for study purposes.
- All research staff will be trained on conducting HbA1C tests in line with university and federal guidelines including Biosafety Training for Laboratory Personnel in order to provide further

instruction and support.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently participating in another diabetes study, you are not eligible to participate in this study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. We hope that this research will lead to better ways for doctors to provide care for non-medical diabetes issues. We also hope that it will help patients be more consistent with their diabetes treatment.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Answering our surveys, taking the fingerstick blood tests and blood pressure readings are voluntary. You don't have to answer them or take the tests if you don't want to. You can skip any questions in the surveys that you don't want to answer for any reason and you don't have to tell us why. Choosing not to participate in this study won't affect the medical care you might receive at the University of Michigan Health System.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the

study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There are no dangers involved if you decide to leave the study at any time.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list.

All costs and billing associated with this study are paid for by the study sponsor. There will be no cost to you to be in the study other than your standard phone billing for the study appointments.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will receive a $25 MasterCard gift card upon completing your first appointment (the first appointment includes: a survey, blood pressure readings, a fingerstick blood test/HbA1c assessment, and engagement with or use of a program resource that will take up to 20 minutes). You will receive a $35 MasterCard gift card for completing the second appointment approximately 6-months after the first and you will receive a final $35 MasterCard gift card for completing the third and final appointment approximately 12-months after the first appointment. The second and third appointments include a survey, blood pressure readings, and a fingerstick/HbA1c assessment. You will also receive small token gift(s) during your study participation. If you decide to leave the study before it is finished, you will not receive the gift cards for appointments you did not complete.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information I am about to read describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect your information?

In order to keep your information confidential, the study team has put several protections in place. All recruitment and data collection activities will take place in private rooms to help protect your privacy. Survey data, your HbA1C, and blood pressure readings will all be entered into a survey management system, Qualtrics. This data will be password protected and only key study staff will have the ability to download the data.

All data collected will be coded so that information that could identify you is not linked with your data. All databases storing your information will be password protected and stored on a secure server maintained by the University of Michigan. Any paper records of your information, including consent forms, will be stored in locked file cabinets in locked offices. Paper copies of your information will be destroyed as soon as possible.

When reporting data from the study, information will only be provided as group statistics and no individuals will be recognizable from the data.

When data must be shared for study purposes, it will be shared through HIPAA-compliant technology and servers hosted by the University of Michigan information technology services. No information will be uploaded into your medical record unless you request it. Text messages will be sent and received through a text-messaging server called Twilio. The messages will be automatically removed so that identifiable information such as phone numbers are not stored on the server. Some virtual study appointments may be conducted with a HIPAA-compliant tele-meeting program used at the University of Michigan. The virtual study appointments will be audio only; no audio content of the call will be saved.

Besides the information about this study, the following information is specific to unspecified future use of your identifiable data. We would also like your permission to keep some of your medical information collected in this study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in this study even if you decide not to let us keep your information for future research.

If you give us your permission, we may use your data for future research. Even if you give us permission now to keep some of your medical information, you can change your mind later and ask us to destroy it.

We may share your medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your medical information with other researchers, we will not be able to get it back.

Allowing us to do future research with your medical information will not benefit you directly.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Diabetes and Digestive and Kidney Disease which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse or intention to harm yourself or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Health plan/health insurance records

- Billing information
- Demographic information
- Personal identifiers
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at

http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Minal R. Patel **Mailing Address:** 1415 Washington Heights Ann Arbor, MI 48109 **Telephone:** 734-763-0087 **Email:** minalrp@umich.edu	**Study Coordinator:** Katherine Worthington **Mailing Address:** 1415 Washington Heights Ann Arbor, MI 48109 **Telephone:** 734-647-3515 **Email:** worthk@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your verbal consent in the next section means you understand you will receive copies of the following documents at your first in-person study appointment:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- A study timeline
- A blood pressure handout
- An HbA1c handout
- A handout with information for accessing a study resource

12. AGREEMENT TO PARTICIPATE/CONSENT

12.1 Verbal Consent

You have heard all of the information provided in this consent form. I will ask if you agree to participate in the study described.

Consent to Participate in the Research Study **Sig-A**

By saying "yes" you are agreeing to the following statement:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Do you agree to participant in the study described?

_____ Yes, I agree participate in the study described.

_____ No, I do not agree to participate in the study described.

Participant Legal Name: _____

Date Verbal Consent Obtained (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

We are also asking for your Consent to Collect Data for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. You understand that it is your choice whether or not to allow future use of your specimens. You understand that if your ability to consent or assent for yourself changes, either your or your legal representative may be asked to re-consent prior to your continued participation in this study.

Do you agree to let the study team keep specimens for future research?

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Participant Legal Name: _____

Date Verbal Consent Obtained (mm/dd/yy): _____

For documentation purposes please provide me with your contact information, which I will write on this form. We will also use this information to mail you your at-home testing supplies for your first virtual appointment:

First name: _____ Last name:_____

Street Address:_____ Apt. number: _____

City: _____ State: _____ Zip Code: _____

Home phone: (__)_____ Cell phone: (__)_____ Other phone: (__)_____

Email Address: _____

You will receive a copy of this consent form in the mail shortly for your personal records.

Thank you for going through that information with me. Now we will schedule your first study appointment.

Principal Investigator or Designee **Sig-G**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____