Research Study Informed Consent Document

Study Title for Participants: NCI COVID-19 in Cancer Patients Study (NCCAPS)

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: (NCICOVID) NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study (NCT04387656)

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff.

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you are receiving treatment for cancer and you have tested positive for SARS-CoV-2, the coronavirus that causes the coronavirus disease called COVID-19.

Researchers are trying to learn more about people with cancer who also have been diagnosed with COVID-19 using blood samples, medical information, copies of medical images and asking you questions about your physical and emotional well-being. If you choose to take part in this study, you can also take part in other COVID-19 research studies that may be available to you.

We will not be testing patients for the coronavirus as part of this study. We plan to test your blood for your body's response to the coronavirus. These tests will be done in large batches as part of the research and we will not give you or your doctor the results of those tests.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This purpose of this study is to collect blood samples, information, and medical images from patients who are being treated for cancer and have COVID-19. Researchers will use these blood samples, information, and medical images to answer the following questions: How does COVID-19 affect the outcomes of people undergoing cancer treatment? How does having cancer affect COVID-19?

What is the usual approach for cancer patients with COVID-19?

The usual approach is defined as the care most people get. The usual approach for cancer patients who do not have COVID-19 is to receive treatment with surgery, radiation, or drugs approved by the Food and Drug Administration (FDA), or a combination of these, from their doctor. This usual approach may be changed by your doctor because you have COVID-19.

For cancer patients who have COVID-19, the usual approach for COVID-19 is supportive care and treatment as decided by you and your doctor.

Taking part in this study will not affect the cancer treatment or approach that you receive, or the COVID-19 treatment or approach that you receive.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.

What will happen if I decide to take part in this study?

If you choose to take part in this study, researchers will collect blood samples, information such as your COVID-19 and cancer symptoms, treatments and outcomes, vaccine history, and copies of medical images such as computerized tomography (CT) scans to use for future research on COVID-19 in cancer patients.

The information may be collected from your medical records or from other sources and by asking you to answer questions about your health. The medical images will be copies of images or scans you are already having done as part of your COVID-19 care or your cancer care. The blood samples will be collected at up to 9 times when you are already having blood drawn for your regular cancer care. If you are hospitalized for COVID-19, up to 6 more blood samples will be collected when you are having blood drawn in the hospital. In adults, between 35 and 41 milliliters, or about 7 to 8.5 teaspoons, of extra blood for this study will be collected each time. In children and adolescents less than 18 years of age, no more than 16 milliliters, or about 3.25 teaspoons, will be drawn at one time for this study, and the amount may be less depending on the size of the child and other blood tests being done. See the "What exams, tests, and procedures are involved in this study?" section for more information about when the blood samples will be collected.

You will not have to make any extra trips to your doctor's office or the hospital for this study. Your blood samples, information, and medical images will be collected for this study for up to two years after your positive coronavirus test.

One of the research studies we plan to do with your blood samples is genomic or genetic sequencing. See the "What is the purpose of this study?" section for more information about these studies.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

If you choose to take part in this study, there is a risk of brief pain and maybe a bruise from collecting blood from a vein in your arm. This risk is no different than any other normal blood test. The amount of blood to be taken is not enough to cause blood loss-related problems.

Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.

In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office as part of your regular visits.
- Be asked sensitive or private questions about things you normally do not discuss.

There may be some risks that the study doctors do not yet know about.

Benefits

This study will not help you. This study may help the study doctors learn things that may help other people with cancer who develop COVID-19 in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. No additional information, medical images, or blood samples will be collected from you.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

The study doctor may also take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the Institutional Review Board (IRB) or study sponsor National Cancer Institute (NCI). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to collect blood samples, medical information, and copies of medical images from patients who are being treated for cancer and have COVID-19. We will use these samples, information, and images to answer questions about how cancer affects COVID-19 and how COVID-19 affects cancer treatment outcomes.

One of the research studies we plan to do with your blood samples is genomic or genetic sequencing. Genomic sequencing is a test that records all or part of the pieces of DNA that are in your genes, piece by piece. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families.

These sequencing studies will be done to try to find genetic traits that might mean a person with cancer has a better or worse outcome when they are infected with COVID-19. They will also look at whether there are genetic traits that might mean being infected with COVID-19 affects cancer treatment outcomes.

What are the study groups?

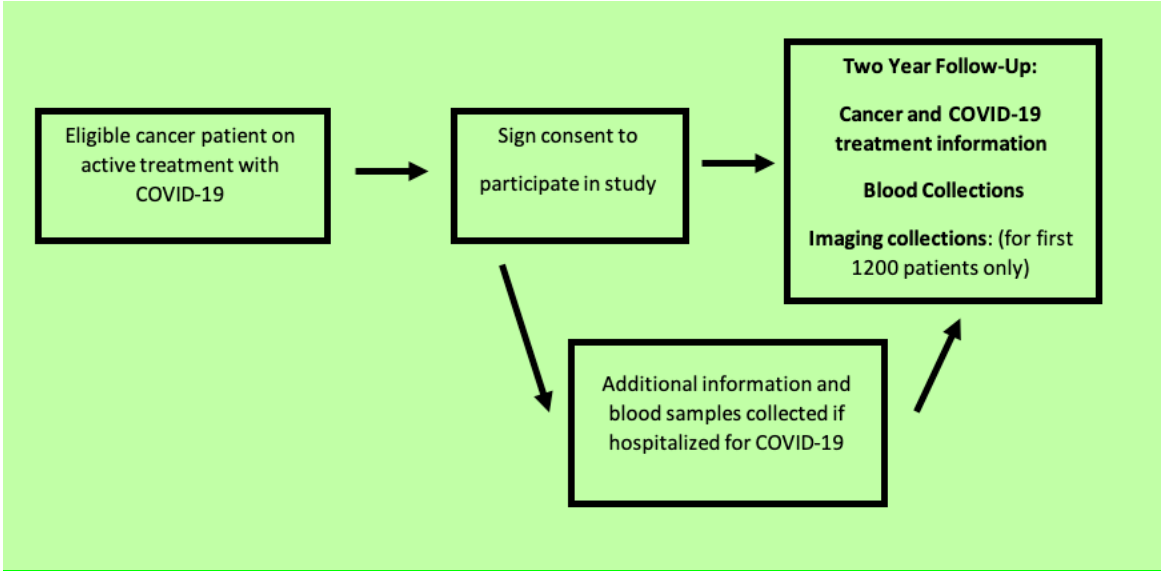
Children on cancer treatment may enroll on this study if they had a positive test for coronavirus after January 31st, 2020. Adults, ages 18 or older, on cancer treatment must have a positive test for coronavirus within 14 days of enrolling to this study. There will be about 2,000 cancer patients with a positive test for coronavirus taking part in this study.

Researchers will collect blood samples, information such as your COVID-19 and cancer treatments and outcomes, vaccine history, and copies of medical images such as computerized tomography (CT) scans to use for future research on COVID-19 in cancer patients.

The information may be collected from your medical records or from other sources and by asking you to answer questions about your health. The medical images will be copies of images or scans you are already having done as part of your COVID-19 care or your cancer care. The blood samples will be collected up to 9 times when you are already having blood drawn for your regular cancer care. If you are hospitalized for COVID-19, up to 6 more blood samples will be collected when you are having blood drawn in the hospital. Between 35 and 41 milliliters, or about 7 to 8.5 teaspoons, of extra blood for this study will be collected each time. For children and adolescents under the age of 18 who take part in the study, the amount of blood collected will be smaller, and blood will be collected less often. See the "What exams, tests, and procedures are involved in this study?" section for more information about when the blood samples will be collected.

You will not have to make any extra trips to your doctor's office or the hospital for this study. Your blood samples, information, and medical images will be collected for this study for up to two years after your positive coronavirus test. You will be followed on this study even if you are no longer being treated for cancer. If you are no longer being treated for cancer while you are still on this study, the study will collect blood samples and medical images if you have them done at follow-up visits.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



Your blood samples will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is called the Biopathology Center and is run by Nationwide Children's Hospital in Columbus, Ohio. The biobank is supported by the NCI. This is a publicly

funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you. When samples are sent to researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only. There is no limit on the length of time we will keep your samples. The samples and biobank data will be kept until the samples are used for research or destroyed.

Right now, we don't know what research may be done in the future using your blood samples. This means that:

- You will not be asked if you agree to take part in the future research studies being done with collections from this study.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.
- Some of the studies may lead to new products, such as drugs or tests for diseases.

If you decide to stop taking part in this study or after you are done taking part in the study, you can decide you no longer want your samples to be used for future research. If you decide you no longer want your samples to be used, you can call the study doctor who will let the biobank know. Then, any sample and data that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have the same exams, tests, and procedures to closely monitor your safety and health that you would have if you were not in a study.

Researchers will collect information about you at in-person visits to your doctor or over the phone. This information will include your medical history, cancer history and treatment, and COVID-19 symptoms and treatment. Researchers will collect copies of medical imaging done for your COVID-19 care and for your cancer care. If you are already having blood drawn for other testing, researchers will also collect blood samples around the following times:

Adults 18 years of age or older:

- After you have decided to take part in the study and have a positive coronavirus test
- 2 weeks after you enroll to the study
- 1 month, 2 months, and 3 months after you enroll to the study
- 6 months, 9 months, and 12 months after you enroll to the study
- 2 years after you enroll to the study

Children under the age of 18:

- After you have decided to take part in the study and have a positive coronavirus test
- 1 month, 3 months, 6 months, and 12 months after you enroll to the study
- 2 years after you enroll to the study

If you are hospitalized for COVID-19, researchers will collect additional information about your treatment in the hospital, copies of medical imaging done in the hospital, and blood samples when you are in the hospital. If it is possible to collect blood samples for this study when you are in the hospital, and you are already having blood drawn for other testing, then researchers will also collect blood samples at the following times:

Adults 18 years of age or older:

- On the day you are hospitalized.
- During your hospital stay on days 3, 7, 10, 15 and 30

Children under the age of 18:

- On the day you are hospitalized.
- During your hospital stay on day 3
- On the day you leave the hospital

All the blood samples for this study are required if you are already having blood drawn at that time. However, extra blood will not be collected for this study at any time if your doctor determines that too much blood is being collected at that time.

Right now, we don't know all the types of research that may be done using your blood samples. The planned research studies to be done with your blood samples, include:

- genomic or genetic sequencing,
- testing for signs of blood clotting, and
- studying how your immune system is responding.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your regular appointments
- If study information needs to be collected when you do not have a regular appointment, researchers will contact you.
- Tell your doctor about:
  - all medications and supplements you are taking
  - any doctors' visits or hospital stays outside of this study

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care for your cancer and for your COVID-19, just as you would if you were getting the usual care for your cancer and not taking part in this study. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study.
- your insurance co-pays and deductibles.

You will not need to pay for research blood collection, storage, or testing.

You will not have to make any extra trips to your doctor's office or the hospital for this study. The blood collections for this study will only be done at times when you are already having blood collected as part of your regular care.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. Contact information for your study doctor is listed on the consent cover page.

The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

No funds have been set aside to compensate you in the event of injury.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. There is no limit on the length of time we will keep your information and images in the study database.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- Montana Cancer Consortium
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network, NCI Community Oncology Research Program, NCI Experimental Therapeutics Clinical Trials Network, and the groups these programs work with to conduct research, including the Imaging and Radiation Oncology Core (IROC).

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact information for your study doctor is listed on the consent cover page.

For questions about your rights while in this study, call the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

Optional studies that you can choose to take part in (adult patients 18 years or older)

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies hope the results will help other people in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say "no" to any or all of these studies. There is no penalty for saying "no." You and your insurance company will not be billed for these optional studies. If you sign up for, but cannot complete any of these studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

Optional quality of life study for patients 18 years or older

If you are an English, Spanish, French, Chinese or Arabic speaker and choose to take part in this study, you will be asked to fill out forms with questions about your physical and emotional well-being. Researchers will use this information to learn more about how treatment for cancer and COVID-19 affects people.

Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues of other concerns, please talk with your doctor or nurse right away.

You will be asked to complete these forms 5 times throughout your participation in this study as follows:

- 1 month and 3 months after you enroll to the study
- 6 months and 12 months after you enroll to the study
- 2 years after you enroll to the study

The forms will take about 10 minutes to complete using paper forms and then returned to the study team. Alternatively, you may complete the forms remotely over the phone, by providing the information directly to a study team member. The forms will ask you about things like fatigue, sleep quality, pain, memory and focus, and your physical, mental, and social health. You don't have to answer any question that makes you feel uncomfortable. If you are hospitalized, you will not be asked to complete any forms that are due during that time.

Please circle your answer: I choose to take part in the patient-reported quality of life study and will fill out these forms:

YES NO

Optional sample collections for known laboratory studies and/or storage for possible future studies

Researchers are trying to learn more about COVID-19 in cancer patients using blood samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies

You may participate in this optional research blood collection if you receive a vaccine for COVID-19. If you choose to take part in this optional study, when you are scheduled to receive a vaccine, contact the study doctor to let them know. Contact information for your study doctor is listed on the consent cover page. They will work with you to schedule the optional research blood collections. Researchers will collect blood samples at up to three timepoints. These blood samples will be used to learn more about how cancer treatment affect the body's response to COVID-19 vaccines. Researchers plan to check levels of antibodies to SARS-CoV-2, the virus that causes COVID-19, before and after vaccination.

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. About 2 tablespoons of blood will be collected from a vein in your arm at three timepoints:
    - Anytime in the 4 weeks prior to your receiving the first dose of vaccine
    - Within 1 week after you receive the second dose of vaccine, if the vaccine is given in 2 doses.
    - 3-6 weeks after you receive your final dose of vaccine

    If you receive a vaccine that only requires one dose, you will only be asked to provide a blood sample at 2 timepoints.
2. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.

3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part. The blood tests are being done for research and the results will not be given to you or your doctor.
The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, Dr. Larissa Korde, at 301-284-9224 or NCCAPS@mail.nih.gov, who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, Dr. Larissa Korde, at 301-284-9224 or NCCAPS@mail.nih.gov.

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for known future studies:

I agree that my samples and related health information may be used for the laboratory (*study or studies*) described above.

YES NO

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to learn about results from this study.

YES NO

Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

Contact for Future Research

Please circle your answer below to show if you would or would not like to be contacted for future research:

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study.

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)

(Required for initial consent only)