ID: UMCC 2020.041	**Cannabidiol (CBD) for Treatment of Aromatase Inhibitor-Associated Arthralgias**	**NCT04754399**

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
Phase 2 Trial of Cannabidiol (CBD) for Treatment of Aromatase Inhibitor-Associated Arthralgias (UMCC 2020.041)

Company or agency supporting the study:
This is an investigator-initiated trial lead by Dr. N. Lynn Henry at the University of Michigan.

Conquer Cancer – Rising Tide Foundation for Clinical Cancer Research is also supporting this study.

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator:
N. Lynn Henry, MD, PhD Department of Internal Medicine, University of Michigan

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. 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 sign this form 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 travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, 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 is a Phase II study, which means the goal is to test the safety and effectiveness of the investigational study intervention, in other words - does it help prevent side effects from your cancer therapy, and do the benefits outweigh the risks and side effects. This is usually done by comparing the outcomes of subjects in the study to those of people who previously received standard treatment.

You are being asked to take part in this study because you are taking an anti-hormone treatment called an aromatase inhibitor for treatment of breast cancer, and you are now having bothersome joint pain or stiffness.

This research is testing whether treatment with a study intervention called cannabidiol, or CBD, will improve joint pain and stiffness. In the research we will collect health-related information including questionnaires and four blood samples to better understand whether this study intervention improves symptoms and is safe to take.

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 additional symptoms from taking CBD, such as elevated liver enzymes and decreased appetite. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by decreasing symptoms that you experience when taking an aromatase inhibitor medicine. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 15 weeks.

You can decide not to be in this study. Alternatives to joining this study include continuing to take the aromatase inhibitor medicine while not participating in a clinical trial to treat your joint pain, or participating in a different clinical trial to try to improve your joint pain.

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:

Aromatase inhibitor medications have been approved by the U.S Food and Drug Administration (FDA) for treatment of hormone receptor positive breast cancer. This treatment has been shown to be very effective for treating breast cancer. However, some patients have difficulty tolerating the treatment, and some even decide to stop treatment because of the side effects. Research has shown that over half of patients who take aromatase inhibitor medications have joint pain and stiffness.

Cannabinoids, which are compounds derived from the cannabis plant, have been shown to reduce pain. Cannabidiol, or CBD, is one of these compounds. It does not have the psychoactive properties that people usually think of when they think about marijuana. CBD has been shown to improve arthritis pain and anxiety in small studies. CBD is now available as an FDA approved medication (Epidiolex) to treat children with severe forms of seizures. This study is being conducted to test whether taking CBD will improve bothersome joint pain and other symptoms in women with breast cancer who are taking aromatase inhibitor medications and who have aggravating joint pain and stiffness. This research will help to answer the following research questions:

1. We know that some women have side effects when they take an aromatase inhibitor medication. Does taking CBD in addition to an aromatase inhibitor medication make it easier to tolerate the aromatase inhibitor medication? What, if any, side effects might you have when you receive the combination study intervention?
2. What effect does CBD have on the amount of estrogen and inflammation in your body?

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?

Postmenopausal women who are taking an aromatase inhibitor to treat breast cancer that has not spread beyond the breast and nearby lymph nodes and who are experiencing bothersome joint pain or stiffness may be eligible to participate. If you have taken CBD, tetrahydrocannabinol (THC), or marijuana in the past 6 weeks you are not eligible. You are also not eligible to participate if you have chronic liver disease or a seizure disorder.

Every study has strict guidelines for determining which people may participate. These are called eligibility criteria. You will need to meet all of these criteria before you can participate in this study. If you agree to consider participating in this study, you will undergo evaluations to see if you meet the eligibility criteria for this study. Even though you may meet all of the criteria for participation, it is possible that you may not be enrolled in this study for other reasons.

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

44 subjects are expected to participate in this study, all at the University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

The study team will explain the research study and answer any questions you have about the study. If you still want to participate in the study, the study team will request you sign the consent form prior to any activities occurring that pertain to the study. Once your consent is obtained, the study team will look through your medical chart, ask you questions, and begin scheduling tests and procedures to determine if you are eligible for the study. The study team will inform you of the types of tests and procedures required before the study begins.

Tests and procedures that you will do in order to determine if you are eligible for the study include:

- You will have measures of your vital signs, including height and weight. If this has been done recently it might not need to be repeated.
- You will have blood drawn to check labs to assess the level of blood counts, kidney function, liver enzymes, estrogens, and inflammation markers in your blood. About 2.5 tablespoons of blood will be collected. You will be asked to fast for 8 hours prior to having your blood drawn. (Some of this is for Research)
- You will complete questionnaires about your symptoms. These questionnaires can either be on your smartphone or tablet, an iPad, or on paper, and are expected to take about 5 minutes.
- You will be asked if you have any thoughts about suicide or if you have ever attempted suicide.
- You will also be asked about what medications, vitamins, and other supplements you are currently taking.
- The study team will collect information about you from your medical record, including your age, information about your cancer, the treatments you have received, and your other medical problems.

Once it is determined you are eligible to enter the study, tests and procedures done at your study visits as part of your regular cancer care will continue, but some may be done more often because you are participating in this research study. Also, some of the tests or procedures may have to be repeated if, for example, they were done too long ago or the results are not normal.

Tests or procedures that are performed only for this research study will be identified below as "Research".

If you decide you will take part in the study and you sign this informed consent form, you will undergo baseline assessments and then begin the study intervention.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, take your study medication as directed, and report any adverse reactions you may have during the study.

Study Procedures at the Baseline Visit:

You will be asked to come to the study clinic and the following tests and procedures will be performed:

- You will be asked about what medications, vitamins, and other supplements you are currently taking.

- You will complete questionnaires about your symptoms. These questionnaires can either be on your smartphone or tablet, an iPad, or on paper, and are expected to take about 30 minutes. It is possible to complete the questionnaires online up to 2 days before the clinic visit.
- You will be given a "dosing diary" to track when you take the CBD study intervention.

Study Procedures During the Study Intervention Period (Week 1 through Week 15):
After the baseline visit you will be given the study intervention to take at home starting either that evening or the following Wednesday. You will take the liquid medication twice a day. You should take it approximately every 12 hours with food. If you forget to take the medication for more than 8 hours, then you should wait until the next scheduled time to take it. You will complete the dosing diary each time you take the study intervention, or make a note if you miss a dose.

Once a week for 3 weeks you will be sent a link via email or text message to a short questionnaire about your symptoms. You should report all symptoms on the questionnaires, whether or not they are related to the cancer or the study intervention.

You will also receive a phone call from the study coordinator to discuss any symptoms you are having from the study intervention. Each week they will tell you how much to increase the dose of the study medication that you take.

After you have increased the dose of the study intervention to the maximum dose, you will continue to take that dose until you have been on the study for 15 weeks.

Study Procedures at Week 4 (or sooner if you stop taking the study intervention early):
You will not have to be seen in clinic this week, but you will be required to undergo the following tests and procedures:

- You will have blood drawn to check labs to assess the level of blood counts, kidney function, and liver enzymes in your blood. About 2 tablespoons of blood will be collected.
- You will complete questionnaires about your symptoms. These questionnaires can either be on your smartphone or tablet, an iPad or on paper, and are expected to take about 5 minutes. It is possible to complete the questionnaires online up to 2 days before the clinic visit.

During Week 6 you will be sent a link via email or text message to a short questionnaire about your symptoms.

Study Procedures at the Week 8 visit (or sooner if you stop taking the study intervention early):
You will be asked to return to the clinic for this visit for the following tests and procedures:

- You will have blood drawn to check labs to assess the level of blood counts, kidney function, liver enzymes, estrogens, and inflammation markers in your blood. About 2 tablespoons of blood will be collected. **You will be asked to fast for 8 hours prior to having your blood drawn.** (Some of this is for Research)
- You will complete questionnaires about your symptoms. These questionnaires can either be on your smartphone or tablet, an iPad or on paper, and are expected to take about 5 minutes. It is possible to complete the questionnaires online up to 2 days before the clinic visit.

- You should return your dosing diary.
- You will be given a new bottle of study intervention and a new dosing diary.

During Week 12 you will be sent a link via email or text message to a short questionnaire about your symptoms.

Study Procedures at the Week 15 visit (or sooner if you stop taking the study intervention early):
You will be asked to return to the clinic for this visit for the following tests and procedures:

- You will have blood drawn to check labs to assess the level of blood counts, kidney function, liver enzymes, estrogens, and inflammation markers in your blood. About 2 tablespoons of blood will be collected. **You will be asked to fast for 8 hours prior to having your blood drawn**. (Some of this is for research)
- You will complete questionnaires about your symptoms. These questionnaires can either be on your smartphone or tablet, an iPad or on paper, and are expected to take about 30 minutes. It is possible to complete the questionnaires online up to 2 days before the clinic visit.
- You will return your 2 bottles of study medication and the second dosing diary.

You will stop taking the CBD (study intervention) after this visit. If you wish to continue taking it, you should discuss the option with your cancer doctor who may be able to provide you with a prescription or discuss obtaining CBD from other sources, such as local cannabis dispensaries in Michigan. The cost of the prescription medication can be quite high, and there is no support available to provide this medication after you finish participating in the clinical trial.

Follow-up
Once you complete the Week 15 visit, you will continue your usual clinic visits with your cancer team.

OPTIONAL: *Unspecified Future Research*
Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your blood samples 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 blood samples and medical information for future research.

If you give us your permission, we will use your blood samples and medical information for future research. Even if you give us permission now to keep some of your blood samples 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 blood samples, we may not be able to take the information out of our research.

We may share your blood samples 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 blood samples and medical information with other researchers, we will not be able to get it back.

As the testing will be performed on samples that were already collected during the main study, there are no physical risks associated with this testing. There are non-physical risks associated with taking part in future research, such as the risks associated with the loss of privacy or confidentiality. See Section 5.1 and Section 9.1 of this consent form for more information about these risks. 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 the future research on your blood samples. Allowing us to do future research on your blood samples and medical information will not benefit you directly.

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

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent. You will not find out the results of future research on your blood.

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.

You will make your choice in Section 12 of this consent form about whether or not you agree to let the study team keep your blood samples for unspecified future research.

4.2 How much of my time will be needed to take part in this study?
Each subject will receive the study intervention for a total of 15 weeks. Each subject will have a total of 3 study visits at baseline, week 8, and week 15, or sooner if she stops taking the study intervention after less than 15 weeks. Each visit is expected to last about 30 minutes, plus the time needed to complete questionnaires. At these timepoints, questionnaires are expected to take about 30 minutes (except for week 8, when the questionnaires are expected to take 5 minutes), and may be completed online before the clinic visit. Between visits, each subject will complete a brief set of questionnaires a total of 6 times; each is expected to take about 5 minutes. At week 4, each subject will also have a blood draw.

4.3 When will my participation in the study be over?
Your participation will be over after the Week 15 study visit. The entire study is expected to last about 2.5 years.

If you wish to continue taking CBD after the 15-week study visit, you should discuss the option with your cancer doctor who may be able to provide you with a prescription or discuss obtaining CBD from other sources, such as local cannabis dispensaries in Michigan. The cost of the prescription medication can be quite high, and there is no support available to provide this medication after you finish participating in the clinical trial.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information and biospecimens may also be shared with other researchers, both here or around the world, or with companies. Any sharing is subject to contractual obligations with the Sponsor. Additionally:

- With appropriate permissions, your identifiable collected information and biospecimens may be shared, and/or,
- Without your additional consent, your identifiable private information and identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies.

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?
Your study doctor and study staff will monitor you closely for side effects. Even with frequent blood tests and other examinations, taking the study intervention involves risks, and some side effects cannot be predicted. Many side effects will get better when you stop taking the study intervention, but some may be long lasting or may never go away. You should tell your study doctor immediately about any side effects that you have or any change in how you feel while on this study. If you have side effects, your dose may have to be reduced, or you may have to stop taking the study intervention and wait until you feel better before you start again. Your study team may give you medicines or lower your dose of study intervention to help lessen side effects. If any side effect is intolerable, you may have to permanently stop taking the study intervention.

The known or expected risks are:

Study Intervention

The Study Intervention (CBD) may cause one or more of the side effects listed below. This information is based on data from patients in other clinical trials with the Study Intervention. In addition, there may be side effects that are not yet known that may occur. You should tell your doctor or nurse right away about any possible side effects that you experience.

MORE COMMON SIDE EFFECTS
In 100 people receiving CBD, as many as 26 and up to 50 may have:

- Infection

COMMON SIDE EFFECTS
In 100 people receiving CBD, as many as 11 and up to 25 may have:

- Decreased appetite
- Sleepiness or difficulty sleeping
- Tiredness
- Weakness or lack of energy
- Fever
- Vomiting

LESS COMMON SIDE EFFECTS
In 100 people receiving CBD, as many as 1 and up to 10 may have:

- Increased liver function tests (AST, ALT)
- Diarrhea
- Decreased weight
- Abdominal pain
- Irritability or aggression
- Rash
- Low oxygen levels
- Increased saliva
- Difficulty walking

Studies have shown that some subjects treated with CBD have low levels of red blood cells (mild anemia). Increased creatinine (lowered kidney function) has also been seen in otherwise healthy adults treated with CBD, although it generally improved when the drug was stopped.

After you start taking the study medication, if you have any thoughts about suicide you should contact the study doctor or your oncologist immediately.

Taking CBD may change how your body reacts to other drugs, which can increase side effects. It is important that you check with the study team before making any changes to your medications.

There may be additional unforeseen risks associated with the use of the CBD study intervention in combination with aromatase inhibitor treatment. You should tell your study doctor or study staff immediately about any side effects that you have or about any change in how you feel while on this study.

Other Risks and Inconveniences
Blood Draws
Collection of blood samples may cause pain, bleeding, bruising, or infection. It is also possible that you may feel lightheaded or faint. Please tell your study doctor or the study nurse if you do not feel well after having your blood drawn at any time during your study participation.

Questionnaires
As part of the study, you will be asked to complete questionnaires. Some of the questions may seem very personal or embarrassing. They may make you uncomfortable. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you uncomfortable, we can help you to find a counselor.

If you are experiencing bothersome symptoms you should inform the research staff or your health care provider. The answers you provide on these questionnaires will not be given to your study doctor, and will not be looked at by the researchers until the end of the study.

These risks will be minimized by:
We will minimize the risks by monitoring you carefully. We will provide the usual supportive care that would be routinely given to someone with your condition. If you have side effects from the investigational study intervention, we will make appropriate adjustments as defined by the study protocol. You may need to discontinue the investigational study intervention if the side effects are too serious. If you have signs of infection, you will receive appropriate antibiotics. If you have signs of bleeding, you may need to receive transfusions of platelets, plasma, or red blood cells. If your hemoglobin level is too low, you may receive a red blood cell transfusion. If you start feeling sick to your stomach, you may be given medications to help reduce nausea. If you have vomiting, you may be given fluids through an IV.

Additionally, there may be a risk of loss of confidentiality or privacy. For example, if your identity as a participant in this research or your identifiable health information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers or insurance providers. The researchers believe that the risks of such improper disclosure are very small because strict privacy and confidentiality procedures for this research have been adopted. 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**.**

If you think you have an injury or illness that is related to your participation in this clinical trial, it is important that you tell your study doctor immediately. If you have a clinical trial related injury or accident, the study staff will make sure that you get medical treatment.
You will receive appropriate medical care for any side effects you have while participating in this study. Your study doctor may also lower the study intervention dose or stop the study intervention if you experience side effects.

You must inform your study doctor immediately if there are any changes in your health/condition, or if you have any concerns regarding the study. If for any reason you are seen by another healthcare provider or admitted to another hospital, you should make known your participation in this research study. These healthcare providers may wish to contact your study doctor to discuss your condition. Your study doctor may need to contact your other doctors if you develop any potentially significant, unexpected diseases or conditions that may have been caused by the study intervention or procedures or are discovered during the study.

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.

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. It is possible that you may have improvement in how well you tolerate aromatase inhibitor therapy because you are taking the study intervention. In addition, others may benefit from the knowledge gained from this study.

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?
Participating in this trial is voluntary. Alternatives to joining this study include taking the aromatase inhibitor medicine while not participating in a clinical trial, or participating in a different clinical trial to try to improve your joint pain.

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”.

Please note that any information collected before you withdraw will be kept and used to complete the research.

Please note that even if you withdraw consent for further follow-up or contacts, if the study doctor becomes aware of additional safety information this will be reported to the sponsor in order to comply with legal or regulatory requirements.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
Tell the study doctor if you are thinking about stopping or decide to stop. It is important to tell the study doctor if you are thinking about stopping so any risks can be evaluated by your study doctor. The study doctor will also tell you how to stop safely and discuss what follow-up care and testing could be most helpful for you. If you decide to leave the study before it is finished, please tell your study doctor or one of the researchers listed in Section 10 “Contact Information” (below).

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 stop taking the aromatase inhibitor medicine for more than 7 days
- You stop taking the CBD study intervention for more than 14 days
- You have serious side effects
- 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. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care, including the aromatase inhibitor medication and standard laboratory tests
- Items or services needed to give you study intervention or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

The CBD liquid medication (study intervention) will be provided at no cost to you.

<u>What if I am injured while taking part in this study?</u>
If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

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?
Yes. You will be paid $25 dollars per visit after completion of the baseline, week 8, and week 15 visits. If you only complete baseline visit you will only receive $25 dollars, but if you complete all three visits you will receive $75 dollars. You will receive the payment loaded on a gift card.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of this study.

The University of Michigan is receiving payments from Conquer Cancer - Rising Tide Foundation for Clinical Cancer Research to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from Conquer Cancer - Rising Tide Foundation for Clinical Cancer Research for conducting 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 below 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 my information?
Your participation will occur at the University of Michigan medical center. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code: a subject ID number, and initials
- Your identifying information will be kept secure

The study team will assign a code number to the study data and may use your initials. Some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth). The study team will use the study data for research purposes to support the scientific objectives of the study. Study data (that does not directly identify you) may be published in medical journals or shared with others as part of scientific discussions.

We will do everything we can to keep your information private, but we cannot guarantee this. Your research information will be stored in a secure computer with password protection and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record. We may need to disclose information about you as required by law.

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
- All records relating to your breast cancer, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers

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
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in 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 will not expire unless you cancel it. 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:	N. Lynn Henry, MD, PhD
Mailing Address:	1500 E. Medical Center Drive, Rm 7322 Ann Arbor, MI 48109
Telephone:	(734) 936-6000; (734) 936-4000 (Hospital Operator – 24-hour paging)

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 (For International Studies, include the appropriate calling codes.)
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 signature in the next section means that you have received copies of all of the following documents:

- 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.)*

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. 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.

Print Legal Name: _____

Signature: _____

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

Consent/Assent to Collect for Optional Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. 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.

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

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

Print Legal Name: _____

Signature: _____

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

Principal Investigator or Designee

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): _____

UMCC 2020.041

PERSONAL CENSUS FORM

Name _____ Date _____

The National Cancer Institute requires that The University of Michigan Comprehensive Cancer Center report race and ethnicity information about people who participate in clinical research to ensure that all populations are offered the opportunity to participate.

☐ Check here if you do not wish to provide some or all of the information below.

1. What race do you consider yourself to be? (Please select *one or more*)
   - ☐ American Indian/Alaska Native[a]
   - ☐ Asian[b]
   - ☐ Black or African American[c]
   - ☐ Native Hawaiian or Other Pacific Islander[d]
   - ☐ White[e]
   - ☐ More than one race[f]

2. Do you consider yourself to be Hispanic[g]? ☐ Yes ☐ No

---

[a] American Indian or Alaska Native- A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

[b] Asian- A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

[c] Black or African American- A person having origins in any of the black racial groups of Africa. (Terms such as “Haitian” or “Negro” are sometimes used in addition to “Black” or “African American.”)

[d] Native Hawaiian or Other Pacific Islander- A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

[e] White- A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

[f] More than one race- (It is preferred that this be selected in addition to the selection of the specific races listed above, but this may also be solely selected.)

[g] Hispanic or Latino- A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race. The term “Spanish origin” is sometimes used in addition to “Hispanic” or “Latino.”