# The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization
# Weekly Paclitaxel

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| **Study Title:** | **A Phase Ib Study of the Safety and Pharmacology of Nilotinib to Prevent Paclitaxel-Induced Peripheral Neuropathy in Patients with Breast Cancer** |
| **Principal Investigator:** | **Nicole Williams, MD** |
| **Sponsor:** | **The Ohio State University / National Cancer Institute (NCI)** |

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

**Key Information About This Study**
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This study is being performed to test the use of a drug called nilotinib to help to prevent nerve damage caused by paclitaxel chemotherapy, also known as neuropathy causing numbness and tingling in patients who are receiving paclitaxel therapy for breast cancer. Nilotinib may prevent or reduce a patient's nerve damage by blocking the organic anion transporting polypeptide (OATP1B). This is a type of protein that occurs naturally in the body, and is the way paclitaxel is carried into the nerve cells. Nilotinib is a pill that is currently approved for treating a blood cancer called Philadelphia chromosome positive chronic myeloid leukemia.

This study is being done to assess if nilotinib is safe to give with chemotherapy drug paclitaxel, to assess if it can potentially reduce the development of damage to nerves. The nilotinib will be taken alongside the standard of care paclitaxel therapy that patients will receive whether they participate in the study or not. You will have blood samples taken in order to determine if nilotinib blocks the OATP1B peptide in your body and determine the amount of paclitaxel in your blood.

Patients would be expected to return for study visits once a week for approximately three weeks on top of their usual study visits. Additionally, study visits may last longer than normal while you are participating in this study. After stopping study treatment, participants would return for follow-up visits at approximately 3 months and six months after stopping.

Participants in this study will take nilotinib 4 times over a 2 week time period, until it is no longer safe for them to do so, or they choose to no longer participate in the study.

Common side effects of nilotinib include nausea, vomiting, rash, pain in the joints or muscles, headache, feeling tired, or cold symptoms. Less common but more serious risks include stroke, high blood pressure, and vision impairment. A full summary of the potential risks of participating in this study is provided in section 6 of this consent form.

However, since you will be receiving nilotinib only 4 times instead of daily, your risk of developing side effects may be lower.

It is hoped that your health will improve as a result of participating in this study, however, you may or may not benefit directly from participating in the study. It is the researchers' hope that information gained in this clinical study will help reduce the risk of nerve damage for future cancer patients. Participating in this study is entirely voluntary, and you have other options such as receiving standard of care therapy, being on another study, or receiving no therapy. You should talk to your doctor about your options before you agree to participate in this study.

## 1. Why is this study being done?

You are being asked to take part in this study because you have breast cancer, and your doctor thinks chemotherapy is the best way to treat it. Chemotherapy is the usual or 'standard' treatment for your type of breast cancer. It kills cancer cells and lowers the chance that the cancer will come back. Your doctor has ordered a type of chemotherapy called paclitaxel. Sometimes, this treatment can cause numbness and tingling, especially in the hands and feet. This is called Chemotherapy-Induced Peripheral Neuropathy (CIPN). This study aims to test the safety and effectiveness, both good and bad, of taking another drug called nilotinib as a possible way to help prevent this CIPN. Nilotinib is approved by the FDA for patients with a condition called Philadelphia-chromosome positive chromic myeloid leukemia. The FDA has not approved nilotinib for the specific use of preventing CIPN or for breast cancer. Earlier research studies have shown that

nilotinib can prevent CIPN in animals, but this has not previously been studied in humans.

This is a phase Ib study, which will test different amounts of the study drug nilotinib. After completion of this phase of the study and if the results are promising, there is a larger phase II study that will be completed.

## 2. How many people will take part in this study?

Approximately 20 people will take part in this portion of the study.

## 3. What will happen if I take part in this study?

Prior to taking part in this study, you will be asked to review and sign this consent form.

Before you begin participation in this study, you will need to have the following exams and tests to see whether you are able to be in the study. These exams and tests are part of your regular cancer care, and may be done even if you did not participate in the study. If you have had some of these tests done recently, they may not need to be repeated. This will be decided by your study doctor.

- Physical Examination and medical history. We will also collect information about your current medications
- Performance status, to see how well you are able to complete daily tasks
- Blood draw – about two tablespoons of blood will be drawn from a needle inserted into your arm. If you are able to get pregnant, we will also perform a pregnancy test
- Electrocardiogram (ECG), where patches are applied to your chest, arms, and legs to measure of the electrical activity of your heart

Whether or not your results indicate that you are able to participate in the study, you will begin treatment. Paclitaxel will be given for four cycles of 21 days (a total of 12 weeks of treatment), and is given once a week. Paclitaxel is given either intravenously through a needle placed into a vein, or if you have one, through a port that is implanted semi-permanently into a vein. You may also be given medicines to prevent and treat some of the side effects of this paclitaxel treatment, including dexamethasone (a steroid), diphenhydramine (an antihistamine), and cimetidine (an H2 blocker). These are all part of your standard of care treatment, and you would receive this treatment whether or not you choose to participate in the study.

If your results indicate that you are able to participate in the study, you will also begin taking the study drug nilotinib. Nilotinib is a capsule that you will swallow. You will take nilotinib on the day before each visit to receive paclitaxel, and take another dose about 30

minutes before beginning your paclitaxel treatment each week. You will take nilotinib for the first cycle of paclitaxel treatment, minus the very first treatment (two weeks). You will be asked to bring your nilotinib bottle with the remaining pills for each clinic visit you have while taking the nilotinib.

When taking nilotinib, it must be taken on an empty stomach. You should not eat anything for at least two hours before taking nilotinib, and you should not eat anything for at least one hour after taking nilotinib.

While on the study, you will have regular blood draws. Approximately two tablespoons of blood will be drawn each time you have a blood draw. You will also receive physical exams, ECGs, and questionnaires at regular intervals throughout your time on the study. The schedule for these procedures is outlined in a table on the next page.

You will also be asked to undergo pharmacokinetic (PK) blood tests during the first two weeks in cycle one of treatment. These PK tests check to make sure that the nilotinib does not affect the amount of paclitaxel that is in your blood. This will require that blood is drawn from you at several times throughout the day including before you receive treatment and up to four and a half hours after treatment. You will have blood drawn 6 times throughout the day through one peripheral IV. Approximately one teaspoon of blood will be drawn each time for these PK tests.

***Study Calendar***

| | *Pre study* | *C1 D1* | *C1 D7* | *C1 D8* | *C1D 14* | *C1 D15* | *C2 D1* | *C2 D8* | *C2 D 15* | *C3-4 D1* | *C3-4 D8* | *C3-4 D 15* | *(3 month follow up after completion of paclitaxel)* | *6 month follow up) after completion of paclitaxel* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nilotinib | | | *X* | *X* | *X* | *X* | | | | | | | | |
| Paclitaxel | | *X* | | *X* | | *X* | *X* | *X* | *X* | *X* | *X* | *X* | | |
| Informed consent | *X* | | | | | | | | | | | | | |
| Medical History | *X* | | | | | | | | | | | | | |
| Concurrent Medications | *X* | *X* | *X* | | *X* | | *X* | | | *X* | | | *X* | *X* |
| Physical Exam | *X* | *X* | | | | | | | | | | | | |
| Blood pressure % heart rate check | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* |
| Height | *X* | *X* | | | | | | | | | | | | |
| Weight | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* |
| Ease of doing daily tasks check | *X* | *X* | *X* | *X* | *X* | *X* | *X* | | | *X* | | | *X* | *X* |
| Blood tests | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | | |
| ECG (checks electrical activity in heart) | *X* | *X* | *X* | | *X* | | | | | | | | | |
| Side effects report | | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* | *X* |
| Pregnancy test for premenopausal women | | *X* | | | | | | | | | | | | |
| PK blood test | | *X* | *X* | *X* | | | | | | | | | | |
| Symptom Questionnaires | *X* | *X* | | *X* | | *X* | *X* | | | *X* | | | *X* | *X* |

C = Cycle (there are four cycles of study treatment)
D = Day (there are 21 days in each cycle)

This table outlines the different tests and procedures you will undergo while on this study. Each ‘X’ marks that you will have that test or procedure on that day.

## 4. How long will I be in the study?

You will be on study treatment for approximately 12 weeks. After this treatment, you will be asked to return for follow-up visits 3 months and 6 months after you stop treatment.

Your doctor may decide to stop treatment early if you get another illness or any side effects that would make it dangerous for you to continue.

## 5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or with your doctor.

Tell the study doctor if you are thinking about stopping or you decide to stop. They will tell you how to safely stop study treatment. The study doctor may stop your treatment if they believe it is in your best interest to stop, if you do not follow the study expectations, or if the study is stopped.

## 6. What risks, side effects or discomforts can I expect from being in the study?

While participating in this study, you may experience side effects. These side effects may be mild, or may be very serious. These side effects can be different from person to person, and the study doctors don't know all of the side effects that may happen. You will be watched closely by your study doctor for any side effects. If you experience any side effects, you should tell your study doctor immediately. If your doctor feels as though it is not safe for you to continue on the study, they may stop you from continuing to be in the study.

Your doctor may give you medicines to help with any side effects. Many side effects go away soon after you stop taking the medicine. In some cases, side effects can be serious, long lasting, or may never go away.

While on this study, you should not drink grapefruit juice or eat any grapefruits.

You will not be able to donate blood for 12 months after the last dose of nilotinib.

Other studies using nilotinib show that nilotinib does not have many side effects. Only a few people in these studies stopped taking nilotinib because of side effects. Most people had no side effects from nilotinib therapy. **You should talk to your study doctor about any side effects that you have while taking part in this study.**

There have not been any large studies to evaluate if adding nilotinib to your treatment could possibly decrease the activity of the medication given for breast cancer.

A condition called "myelosuppression" can be a side effect of both nilotinib and paclitaxel. "Myelosuppression" means that certain blood counts are low (white or red blood cells and/or platelets). This means that the combination of nilotinib and paclitaxel could increase the chance that these low blood counts happen. Low blood counts can increase the risk of infection, anemia, and/or bleeding. When a patient has low blood counts, they may not get the cancer-fighting paclitaxel as scheduled (low blood counts can delay getting a planned paclitaxel treatment). This means that taking nilotinib and paclitaxel together could increase the risk of delaying future paclitaxel treatments. *Because nilotinib will not be given continuously in this study, we believe this increase in risk is very low.*

***Nilotinib side effects include:***

Common side effects (experienced by 10-20% of people taking nilotinib)

- Nausea, vomiting, diarrhea, constipation, abdominal pain
- Rash
- Temporary hair loss
- Night sweats
- Pain in your bones, spine, joints, or muscles
- Headache
- Feeling tired or weak
- Runny or stuffy nose, sneezing, coughing, or a sore throat
- Low blood counts (white or red blood cells and/or platelets may decrease, which can increase the risks of infection, anemia, and/or bleeding)

Rare side effects (experienced by 1-10% of people taking nilotinib)

- Itching
- Increased liver enzymes in the blood
- Fever, cough
- Muscle spasm
- Swelling of the face, hands, and/or feet
- Shortness of breath
- High blood glucose levels
- Changes in the electrical activity of the heart

Very rare but serious side effects (experienced by less than 1% of people taking nilotinib)

- Liver toxicity
- Extremely high blood pressure
- Stroke or mini stroke
- Joint swelling

- Gout
- Vision impairment
- QTcF prolongation (a potentially fatal condition which can cause fast or irregular heartbeats)
- Sudden death

***Reproductive risks:***

Nilotinib can hurt a fetus when taken by a pregnant female in animal studies. Low levels of nilotinib are present in human milk if the drug is taken by someone who is breastfeeding. You should not become pregnant or nurse while on this study, or while receiving chemotherapy as part of your standard of care treatment. If it is possible for you to get pregnant, you must have a negative pregnancy test to be able to participate in this study. If you become pregnant while on this study, you must notify your study doctor immediately, and you will stop being in the study. Your study doctor can provide counselling and further information about preventing pregnancy while on this study.

If it is possible for you to get pregnant, you should use acceptable methods of contraception while taking study medication and for three months after stopping study medication to ensure that you do not get pregnant while you are participating. Acceptable methods of contraception include:

- Condom with contraceptive foam
- Oral, implantable, or injectable contraceptives
- Contraceptive patch
- IntraUterine Device (IUD)
- Diaphragm with spermicidal gel
- Sterilized male partner
- Abstinence from sexual activity (if this is your preferred lifestyle)

You cannot donate ova for 12 months after the last dose of nilotinib.

***Blood draw risks:***

You may experience side effects from having your blood drawn. These side effects include pain, swelling, bruising, redness, or scarring around the blood draw site, and possibly feeling dizzy or faint while your blood is being drawn.

***ECG risks***
You may experience redness or swelling where the patches are applied.

***Standard of Care risks:***

There are risks associated with your standard of care treatment that you would have whether or not you participate in this study. Your doctor can tell you more about these risks.

## 7. What benefits can I expect from being in the study?

Taking part in this study may or may not benefit you. It is hoped that taking nilotinib while being treated with paclitaxel will help to prevent CIPN. The results of this study may help researchers learn things to better treat future breast cancer patients.

## 8. What other choices do I have if I do not take part in the study?

Taking part in this research study is voluntary. Instead of being in this research study, you have other options which may include the following:

- Taking part in another research study, if one is available
- Receiving standard of care treatment
- Receiving comfort care, also called palliative care. This type of care may help to reduce the symptoms caused by cancer, but does not treat the cancer directly
- Receiving no treatment

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

## 9. What are the costs of taking part in this study?

You and/or your insurance company will be financially responsible for any hospital inpatient, outpatient, and follow-up visits that would normally or routinely as part of your standard of care treatment. This includes the drug paclitaxel as well as charges for treatments, other medications, physician visits, laboratory tests, and procedures. You and/or your insurance company will be responsible for these routine charges. You will be responsible for any costs not covered by your insurance company, including deductibles, co-payments, and all out of pocket expenses. Before you agree to be in this study, you should contact your health insurer to see if your plan will cover the costs required as part of your participation.

If you are a Medicare Advantage Plan participant (HMO or PPO), original Medicare is billed first for routine, study-related services while you participate in an approved trial. Your Advantage Plan is billed second for their share of your costs. You may or may not have additional out of pocket costs after Medicare or your Advantage Plan pays. Additional information can be obtained from your Advantage Plan and online at:

https://www.medicare.gov/Pubs/pdf/02226-Medicare-and-Clinical-Research-Studies.pdf

You and/or your insurance company will not be responsible for paying for study-related items and services that are specifically required for this research study and that are not considered part of the routine management of your disease. This includes:

- Nilotinib, which will be provided to you at no charge while you are participating in this study
- PK blood tests

Your study doctor or coordinator can tell you, specifically, which costs are covered by the study

## 10. Will I be paid for taking part in this study?

You will not be paid to take part in this study.

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

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

## 12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

## 13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

Any leftover samples from blood samples you provide for the PK tests for this research may be stored for future research in Dr. Shuiying Hu's lab at Ohio State University. Researchers will use these samples to study markers that may be unique to the type of cancer that you have, which will assist researchers in understanding how to better treat cancer. Your samples will be coded with a unique identifier, and all personal identifiers will be removed. Only authorized individuals who are approved by the study principal investigator will be able to use the samples.

The samples will be stored indefinitely. You will not be notified about the specific results of your samples if they are analyzed. If results from your samples are published or shared, no personal information about you will be released. You may refuse to have your samples stored for future research. If at any time you decide you do not want your samples stored for future research, you may notify the principal investigator who will destroy any leftover samples that have not already been used. If Dr. Shuiying Hu leaves Ohio State, the samples will be transferred to another member of the study team.

Please indicate whether you would like to allow the researchers to store your samples for future research: **circle one (YES/NO)** **Patient Initials: _____**

## 14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;

- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

If we find information that significantly impacts your health, we **will not** share it with you. Some of the testing that will be performed on your samples will not be performed in such a way that it will provide diagnostic information about you. The results of these tests will not be returned to you.

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

## 15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

### I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Physical exams
  Laboratory, x-ray, and other test results
  Diaries and questionnaires
- Records about any study drug you received

## II. Who may use and give out information about you?

Researchers and study staff.

## III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: The National Cancer Institute (NCI), who are providing funding for this study

## IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

## V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and

- To make sure that the research was done right.

## VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

## VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

## VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

## IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

## X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

# 16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Nicole Williams, MD** at **614-293-0066** or by mail at:

1310K Lincoln Tower
1800 Cannon Dr.
Columbus, OH, 43210

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the HIPAA Privacy Officer in the College of Medicine at **614-293-4477** or by mail at:

HIPAA Privacy Officer
Suite E2140
600 Ackerman Rd.
Columbus, OH, 43202

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Nicole Williams, MD** at **614-293-0066** or by mail at:

1310K Lincoln Tower
1800 Cannon Dr.
Columbus, OH, 43210

## Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

| | |
|---|---|
| **Printed name of subject** | **Signature of subject** |
| | **AM/PM** |
| | **Date and time** |
| **Printed name of person authorized to consent for subject (when applicable)** | **Signature of person authorized to consent for subject (when applicable)** |
| **Relationship to the subject** | **AM/PM** **Date and time** |

## Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

| | |
|---|---|
| **Printed name of person obtaining consent** | **Signature of person obtaining consent** |
| | **AM/PM** |
| | **Date and time** |

**Witness(es) -** *May be left blank if not required by the IRB*

| | |
|---|---|
| **Printed name of witness** | **Signature of witness** |
| | **AM/PM** |
| | **Date and time** |
| **Printed name of witness** | **Signature of witness** |
| | **AM/PM** |
| | **Date and time** |