Official Title: WFBCCC60121: Phase II Study of First Line Weekly Chemo/Immunotherapy for Metastatic Head/Neck Squamous Cell Carcinoma Patients
NCT04858269
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Department/Section of *Hematology/Oncology*

# Informed Consent Form to Participate in Research

## Phase II study of First line weekly chemo/immunotherapy for metastatic HNSCC patients – *WFBCCC 60121*

Wake Forest Baptist Comprehensive Cancer Center
*Thomas Lycan D.O,* Principal Investigator

## SUMMARY

You are invited to participate in a research study. The purpose of this research is to find out what effects (good and/or bad) chemotherapy drugs, carboplatin and paclitaxel, added to to your immunotherapy drug pembrolizumab has on you and your cancer.

You are invited to be in this study because you have head and neck squamous cell carcinoma (HNSCC), you have not received any other drugs for your cancer, and you are not a candidate for a different drug called 5-fluorouracil. Your participation in this research will involve multiple visits and last about 126 days for the drug intervention and up to two years follow up .

Participation in this study will involve donating blood and saliva for this project and future undesignated research and receiving immunotherapy with a drug called pembrolizumab and, at your physician's discretion chemotherapy with carboplatin and paclitaxel. All research studies involve some risks. A risk to this study that you should be aware of is the risks of side effects related to the drugs used in this study. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include participating in a different clinical trial or receiving the same medication combinations as listed above without participating in a clinical trial. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Thomas Lycan, DO. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, please call Dr. Lycan at [redacted].
If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

## INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. The purpose of this research is to find out what effects (good and/or bad) adding chemotherapy drugs, carboplatin and paclitaxel, to your immunotherapy drug pembrolizumab has on you and your cancer.

You are asked to take part in this study because you have head and neck squamous cell carcinoma (HNSCC), you have not received any other drugs for your cancer, and you are not a candidate for a different treatment called 5-fluorouracil. Please take your time in making your decision whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research is to see what effects the treatment regimen chemotherapy (carboplatin and paclitaxel) plus immunotherapy (pembrolizumab), has on patients who have been diagnosed with HNSCC and are unable to take the drug 5-fluorouracil.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Thirty-two (32) people at one research site will take part in the study.

## WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study, you will be asked to take your regularly scheduled medications, 24 treatment clinic visits and 1 post-treatment visit, have blood drawn, donate saliva, and complete some questionnaires that ask questions about your health and your experience with cancer.

ALL subjects will intravenously receive:

- Pembrolizumab on day 1 of each 3-week cycle for 6 cycles.

  PLUS
- Carboplatin IV on days 1, 8, 15 of each 3-week cycle
  PLUS
- Paclitaxel on days 1, 8, 15 of 3-week cycle.

At your Pre-Study visit (which is the same visit where you sign this consent, if you choose to participate) you will have the following procedures. Please note that most of these procedures would be done at your clinic visit(s) whether or not you chose to participate in this study. Items that will be billed to you or your insurance are marked as (SOC). If there are procedures that are done for research-only, they will be marked as (RES) below.

You will:

- Be asked about your medical history and current medications
- (SOC) Receive a physical exam including collection of your vitals, height, and weight
- (SOC) Have blood drawn for medical laboratory analysis
- (SOC) CT scan

- (RES) Have blood drawn for future research (6ml or about 1 teaspoon.)
- (RES) Complete study questionnaires that ask about things such as your mobility, daily activity level, your overall health, and how cancer affects your daily activities.

At each of your Treatment Visits, you will:

- Be asked about your medical history and current medications
- Be asked about any side effects you may have experienced after receiving the chemotherapy drugs
- (SOC) Receive a physical exam and record your vitals and weight
- (SOC) Have blood drawn for medical laboratory analysis
- (RES) Complete study questionnaires that ask about your health and how cancer impacts your daily activities.

At your Post Treatment visit you will have the following procedures:
You will:

- Be asked about your medical history and current medications
- Be asked about any side effects you may have experienced after receiving the chemotherapy drugs
- (SOC) Receive a physical exam including vitals
- (SOC) Have blood drawn for medical laboratory analysis
- (SOC) CT scan
- (RES) Have blood drawn for future research (6ml or about 1 teaspoon.)
- (RES) Complete study questionnaires that ask about things such as your mobility, daily activity level, your overall health, and how cancer affects your daily activities.

Follow up Visit:
At your Follow Up Visit:

- We will ask you about any side effects or adverse events you are experiencing.
- (RES) You will receive a research blood draw (6ml) or about 1 teaspoon.
- (RES) You will complete study questionnaires.

You will have approximately 6 ml or a little over 1 teaspoons of blood withdrawn from a vein *(on five occasions)* for research purposes. The total amount of blood withdrawn during the study will be approximately 30mL or about 6.2 teaspoons.

You will be asked to provide saliva for research on 3 different occasions.

If you agree to participate in this study, these samples will be kept and may be used in future research to learn more about other diseases. Your samples will be obtained in the Cancer Center at Wake Forest University Baptist Medical Center. The samples will be stored in Dr. Christina Furdui's lab in the Department of Cancer Biology and will be given only to researchers approved by Dr. Thomas Lycan. An Institutional Review Board (IRB) must also approve any future research study using your tissue sample. In order to participate in this study, you must be willing to provide these samples for future research.

The research that may be performed with your *blood/saliva* samples is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your *blood /saliva* will not be given to you or your doctor. The results will not be put in your medical record. The research using your *blood/tissue* sample will not affect your care.

Your *blood/saliva* samples will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

Your *blood/saliva* samples will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

## HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about for about 6 months or until your cancer progresses (gets worse).
You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

## WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. The risks and side effects related to the drugs we are studying include:

**Risks of Pembrolizumab**

Call or see your doctor right away if you develop any symptoms of the following problems or these symptoms get worse:

- Lung problems (pneumonitis). Symptoms of pneumonitis may include:
- shortness of breath
- chest pain
- new or worse cough

Intestinal problems (colitis) that can lead to tears or holes in your intestine. Signs and symptoms of colitis may include:

- diarrhea or more bowel movements than usual

- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness
- Liver problems, including hepatitis. Signs and symptoms of liver problems may include:
- yellowing of your skin or the whites of your eyes
- nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine
- bleeding or bruising more easily than normal

Hormone gland problems (especially the thyroid, pituitary, adrenal glands, and pancreas). Signs and symptoms

- that your hormone glands are not working properly may include:
- rapid heart beat
- weight loss or weight gain
- increased sweating
- feeling more hungry or thirsty
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- muscle aches
- feeling very weak
- dizziness or fainting
- headaches that will not go away or unusual headache

Kidney problems, including nephritis and kidney failure. Signs of kidney problems may include:

- change in the amount or color of your urine

Skin problems. Signs of skin problems may include:

- rash
- shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis)

Infusion (IV) reactions that can sometimes be severe and life-threatening. Signs and symptoms of infusion reactions may include:

- chills or shaking
- shortness of breath or wheezing
- itching or rash
- flushing
- dizziness

- fever
- feeling like passing out

Rejection of a transplanted organ: people who have had an organ transplant may have an increased risk of organ transplant rejection. Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

Complications, including graft-versus-host-disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with pembrolizumab.

- Low blood cell count (the lowest point or Nadir: 8-10 days)
- Pharyngitis
- Rash, skin irritation

**Risks of Carboplatin:**

- Most people do not experience all of the side effects listed.
- Side effects are often predictable in terms of their onset and duration.
- Side effects are almost always reversible and will go away after treatment is complete.
- There are many options to help minimize or prevent side effects.
- There is no relationship between the presence or severity of side effects and the effectiveness of Carboplatin.
- The side effects of Carboplatin and their severity depend on how much of Carboplatin is given. In other words, high doses may produce more severe side effects).

The following side effects are common (occurring in greater than 30%) for patients taking Carboplatin:

- Low blood counts (including red blood cells, white blood cells and platelets)
- Nausea and vomiting usually occurring within 24 hours of treatment
- Taste changes
- Hair loss
- Weakness
- Blood test abnormalities: Abnormal magnesium level

These are less common (occurring in 10-29%) side effects for patients receiving Carboplatin:

- Burning sensation at the injection site
- Abdominal pain
- Diarrhea
- Constipation
- Mouth sores
- Infection

- Peripheral neuropathy: Although uncommon, a serious side effect of decreased sensation and paresthesia (numbness and tingling of the extremities) may be noted. Sensory loss, numbness and tingling, and difficulty in walking may last for at least as long as therapy is continued. These side effects may become progressively more severe with continued treatment, and your doctor may decide to decrease your dose.
- Central neurotoxicity: Infrequent but patients over age 65 are at increased risk. Symptoms include dizziness, confusion, visual changes, ringing in the ears.
- Nephrotoxicity: More frequent when Carboplatin is given in high doses or to people with kidney problems.
- Hearing loss (ototoxicity) - loss of high pitched sounds.
- Abnormal blood electrolyte levels (sodium, potassium, calcium).
- Abnormal blood liver enzymes (SGOT, Alkaline phosphatase).
- Cardiovascular events. Although infrequent, heart failure, blood clots and strokes have been reported with Carboplatin use. Less than 1% were life-threatening.
- Allergic reaction may occur. It would occur during the actual infusion. This may include itching, rash, shortness of breath or dizziness (especially in patients who have received cisplatin).

**Risks of Paclitaxel**

The following side effects are common (occurring in greater than 30%) for patients taking Paclitaxel:

- Low blood counts. Your white and red blood cells and platelets may temporarily decrease. This can put you at increased risk for infection, anemia and/or bleeding.
- Hair loss
- Arthralgias and myalgias, pain in the joints and muscles. Usually temporary occurring 2 to 3 days after Paclitaxel, and resolve within a few days.
- Peripheral neuropathy (numbness and tingling of the hands and feet)
- Nausea and vomiting (usually mild)
- Diarrhea
- Mouth sores
- Hypersensitivity reaction. Fever, facial flushing, chills, shortness of breath, or hives after Paclitaxel is given. The majority of these reactions occur within the first 10 minutes of an infusion. Notify your healthcare provider immediately (premedication regimen has significantly decreased the incidence of this reaction).

The following are less common side effects (occurring in 10-29%) for patients receiving Paclitaxel:

- Swelling of the feet or ankles (edema).
- Increases in blood tests measuring liver function. These return to normal once treatment is discontinued.
- Low blood pressure (occurring during the first 3 hours of infusion).
- Darkening of the skin where previous radiation treatment has been given (radiation recall).

- Nail changes (discoloration of nail beds - rare)

*Blood Drawing Risks:*
You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

## Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. Because NO method of birth control is 100% reliable, a pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential.

## Contraceptive Measures for Males

Your participation in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study and for 3 months afterwards. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should also promptly notify her doctor.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be a delay in the return of your cancer. However, this cannot be guaranteed. Additionally, researchers do not know if subjects who are sicker and/or less physically functional when they start the study will perform as well as the subjects who are not as sick and/or physically functional.

## WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

- Single agent pembrolizumab would be the standard-of-care for most 5FU-ineligible patients .
- You could receive these drugs without participating in the study, you could choose palliative or end of life care, or you could participate in another research study.

## WHAT ARE THE COSTS?

Any research procedures listed in this consent as RES will be paid for by the study and not billed to you or your insurance provider. Costs for your regular medical care, which are marked SOC in this consent document and not related directly to this study, will be your own responsibility and/or billed to your insurance provider. This includes the cost of the chemotherapy drugs you will be receiving, as they are the same drugs that you would receive while not on the study.

## WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and/or effectiveness of a combination of standard of care drugs between patients who are more or less active (functional.) The results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or

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

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

## WILL YOU BE PAID FOR PARTICIPATING?

You will not be paid for participating in this study. You will receive a voucher for parking for study visits.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Section of Hematology and Oncology. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

## WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and

the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Thomas Lycan, DO at [redacted] or [redacted]

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you] and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** name, medical record number, and information about your cancer treatment.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.
We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or

recorded media which are identifiable.

You can tell Dr. Thomas Lycan that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

**Dr. Thomas Lycan**
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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 this Web site at any time. Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

## What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study

at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study. Any clinically significant findings developed during the course of this research will also be provided to you.

## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Thomas Lycan, [redacted] or [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

## SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm