1) Hover over items in the right column for instructions / explanations.
2) Use lay terminology whenever possible and complete or delete blanks.

PIEDMONT HEALTHCARE
INFORMED CONSENT TO PARTICIPATE IN A CLINICAL STUDY

What a clinical study is and its purpose.
A clinical study involves research using human volunteers with the main purpose gaining knowledge that may be used to help others. Clinical studies are not intended to benefit you directly, though some might.

What this document is.
This form is an informed consent document. It will describe the purpose, study risks, procedures, benefits, alternatives, and any costs to you.

Signing this form means that you are willing to take part in the study and allow your health information to be used.

Why this clinical study is being done.
This study is being done to_____.

Commented [MP1]: Explain in lay terms the main purpose(s) of the study .

You do NOT have to participate.
Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the study.

Taking part in a study is separate from medical care. The decision to join or not join the study will not affect your status as a patient here at Piedmont Healthcare.

How long you would be in the clinical study.
It is expected that your participation will last_____.

Commented [MP2]: Give time expectation.

What you should do next.
1. Read this form to completion, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.

3. Ask as many questions necessary to feel you understand what will occur and what is expected of you_____.
4. Take time to consider the information in this document and the discussion the study team.
5. Talk things over with your family and friends.

Title:

Principal Investigator (The Study Doctor):

Sponsor:

INTRODUCTION:

You are being asked to join this research study because …

This form will give you information about the research study for you to consider in order to agree (consent) to be in this study or not be in this study. The decision to join the study is entirely yours. If you decide to join the study you may change your mind at any point and withdraw your consent to participate. You will not lose any medical benefits based on your decision to join or not join the study. If you decide not join this study, your doctor will continue to treat you.

If there are any words or information printed in this consent form that you do not understand, ask your doctor to explain them to you. You are encouraged to take as much time as you need to arrive at an informed decision to join this study.

After signing this informed consent form you will be given a copy of the form for your records.

_____, the sponsor of the study, is paying Piedmont Healthcare [and Dr. _____] to perform this research. Dr. _____ also

BACKGROUND AND STUDY PURPOSE:

[If this study will be registered on clinicaltrials.gov insert the text below. If not delete.]:

Commented [MP3]: (e.g., time commitment, unfamiliar words, specific procedures, what is or is not research, etc.)

Commented [MP4]: Provide full study title

Commented [MP5]: Identify individual responsible for the conduct of the research and provide 24 hour contact information

Commented [MP6]: Indicate entity providing funding and/or drug or device for this study. If none, delete this field from the form.

Commented [MP7]: Give reason for invitation to the study.

Commented [MP8]: If a non-employed physician, include him/her below. If the PI is an employed physician, ok to just include Piedmont Healthcare. Also, include disclosure of any other financial interest, other than minimal ownership interest in a publicly traded company.

Commented [MP9]: If applicable, include: 'serves on the board, serves as a consultant for, has an ownership in, etc…'

Commented [MP10]: Provide statement(s) explaining the purpose of this research study:

If this a drug trial include the following:
- Study phase and explanation of what that means.
- If the study is to compare drugs or devices explain why the comparison is being done.
- Explanation of experience with drug(s) and/or device(s) to date.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

How many people will take part in the study?
Approximately _____ patients are expected to take part in this study. We are approved to enroll up to _____ patients at Piedmont Healthcare.

STUDY PROCEDURES:

STUDY RISKS:

Piedmont Healthcare, your doctor, and _____ will take steps to protect your confidential information, as discussed on page __. However, there is always a risk that your confidential information could be improperly released or accessed.

There may be side effects from the study drug or procedures that are not known at this time.
The most common risks and discomforts expected in this study are:
The less common risks and discomforts expected in this study are:
Rare but possible risks include:

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately.
If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the study drug and for _____ days/weeks/months after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

STUDY BENEFITS

You may or may not benefit from study participation or your condition may worsen. It is hoped that the knowledge gained from your participation may help others.

OTHER TREATMENT OPTIONS:
If you decide not to join this study, there is care available to you outside this research.
Your doctor will discuss these options with you. You do not have to be in this study to be treated for

Commented [MP11]: [This section should explain:
- Exact procedures to be followed on a step-by-step basis. A visual aid (chart or table) may be useful.
- If the study design involves random assignment.
  - If yes, explain the randomization process and probability of group assignment.
- Which study procedures are investigational and which are standard of care procedures.
- If applicable, if the study drug/device is/is not FDA approved.
- If applicable, if the study drug/device is FDA approved but this is an off-label use.
- The number and frequency of study visits.
- What will happen at each visit, and their duration.
- If any blood, tissue, or other biological samples will be collected and the sample size – example: volume of blood]

Commented [MP12]: **[This section should explain:**
- All reasonably foreseeable risks and discomforts associated with participation in the study.
- A quantification of risk, if possible (e.g. less common risks are those experienced by 10% or less of subjects).
- Whether this study could involve a loss of confidentiality that may affect employability, insurability, or social standing.
- Whether this study may cause discomfort through the recall of traumatic or uncomfortable experiences.
- Risks that are shared by multiple drugs can be grouped together in one heading. Those risks that are unique to a drug or device must be itemized separately.

There are risks in any study. This section should never state "there are no risks." Breach of confidentiality may be the only risk, but it should always be listed.

Commented [MP13]: describe

Commented [MP14]: describe

Commented [MP15]: describe

Commented [MP16]: this language should be used and modified to fit this research proposal – delete whatever is not applicable. Also, whenever applicable, add, 'you should not try to become pregnant for at least _____ days/weeks/months after the last dose.

Commented [MP17]: [Be sure to include what will happen should a participant become pregnant. (removed from the study, continue off treatment, followed for pregnancy outcome, etc…].

Commented [MP18]: [If there will be direct benefit to the subject it should be indicated below]

Commented [MP19]: [list the major standard of care options and/or possibility of other research studies]

Commented [MP20]: [indicate condition/disease].

CONFIDENTIALITY:

This section explains how personal health and financial information related to your treatment and follow-up care may be collected and used for this study. Your personal health information includes, but is not limited to, information that is collected for your entry into the study and any information that is collected and/or created during your participation in this study. State law and Federal Privacy Regulations provide safeguards for privacy, security, and authorized access to your confidential information. Piedmont Healthcare, Dr. _____, and __[the sponsor]___ will take steps to protect your confidential information. Should the results of this study be published in scientific journals or presented at medical meetings, your identity will remain confidential.

As part of the study, your doctor and the research team will report the results of your study-related treatment and tests to In addition, your records may be reviewed and copied in order to meet federal or state regulations. Reviewers may include the sponsor its representatives, the United States Food and Drug Administration (FDA), The Office of Human Research Protections (OHRP), the Piedmont Healthcare Institutional Review Board (IRB), the Piedmont Healthcare Office of Research Services (ORS), and other international regulatory authorities. If any research record is reviewed by any of these groups, they may also need to review your entire medical record.

You understand that you will be asked to sign a separate authorization for the use and disclosure of your medical record and confidential information for the purpose of this study. If you do not sign this informed consent and the separate authorization, you will not be able to participate in this study. You will be given a copy of this consent form and the authorization form.

COSTS:

Some of the healthcare providers performing services in this facility are independent contractors and are not Piedmont Healthcare employees. These non-Piedmont Healthcare providers may issue separate billing statements for services they provide for you.

COMPENSATION:

You will not be paid for participating in this study.
OR

IN CASE OF INJURY:

Every effort to prevent any injury that could result from this study will be taken by Immediate necessary care, emergency treatment, and professional services will be available to you just as they are to the community generally.

If you think that you have suffered a research related injury, you must let [PI] know right away.

Commented [MP21]: **Below is a new required basic element of consent:**
Research collecting identifiable private information and/or identifiable biospecimens must:
- State that collected samples/data may be de-identified and used for future research or be given to another investigator for future research without additional informed consent, OR
- State that collected samples/data will not be used or distributed for future research even if de-identified.

Commented [MP22]: Sponsor name – delete if not applicable.

Commented [MP23]: Sponsor name – delete if not applicable

Commented [MP24]: Scenarios and suggestions:
1) Scenario:
There are no costs, research or standard of care related, associated with the study.

Suggested language:
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. Your financial risks are unchanged by your participation in this research study as you will experience no greater impact then if you do not enter this study.

2) Scenario:
The sponsor will pay for certain items or services associated with the study.

Suggested language:
The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Your financial risks are unchanged by your participation in this research study as you will experience no greater impact then if you do not enter this study.

Commented [MP25]: Include all appropriate language below:
- You may be reimbursed for your travel expenses related to participation in this study. We will reimburse you for mileage and/or meals at the federal reimbursement rate.
- This study may require an overnight stay in a local hotel. If you are required to spend the night in a hotel, you will be reimbursed for your expenses according to the federal rates for reimbursement. If the cost of the hotel is less than the reimbursement rate, you will only be reimbursed for the actual cost of the hotel. On the other hand, if the cost of the hotel is more than the reimbursement rate, you will be responsible for the difference.]
- You will be paid for your time related to the study visits. You will receive _____ for each study required visit (break it down if each visit is a different amount) you complete, for a total of $_____ for completing all study visits. If you leave the study before completing all study required visits you will be paid only for those visits you completed.
- You should know that payments you receive may be considered taxable income. You may need to complete an IRS W-9 form.

Commented [MP26]: phy sician's name and Sponsor's name – delete if not applicable.

EXTREMELY IMPORTANT!

When completing this section of the consent document please choose one of the three paragraphs below ***WITH confirmation of language from the CTA (when applicable).***

The sponsor [name] of the study has agreed to pay for the care of certain injuries directly resulting from this research. If you think that you have suffered a research-related injury, you must contact [PI] right away. The study doctor can help you obtain more information about the sponsor's agreement to pay for research-related injuries.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, [Piedmont] will provide such treatment at [Piedmont] at no cost to you. You must notify [PI] as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition.

[Include the following if Sponsor does not reimburse for subject injury; confirm consistency with CTA.] The costs of any non-emergency care for such an injury will be billed to you or your insurance, or the study sponsor in the ordinary manner. You will continue to be responsible for any copays, deductibles and coinsurance amounts that are required under your insurance plan.

You are encouraged to discuss your participation in this study with your insurer before agreeing to participate to avoid any unexpected costs.

Piedmont _____ has not set aside funds for additional payment or compensation, such as for lost wages and/or pain and suffering, to a person who is injured while participating as a subject in a research study. However, by agreeing to participate in the study, you are not giving up your legal rights to seek compensation in the event of malpractice, fault, or blame on the part of those conducting the research study, including Piedmont _____.

PARTICIPANT RIGHTS AND STUDY WITHDRAWAL:

You may choose not to be in this study. If you agree to be in the study you may withdraw from the study at any time without penalty or loss of benefits to which you are entitled. Your access to health care at Piedmont _____and from your doctor will not be affected by the withdrawal.

It is important to tell the study doctor if you are thinking about stopping so he/she can evaluate any risks from the treatment and discuss what follow-up care and testing could be most helpful for you.

If you withdraw from the study:

- No new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes will be sent to the study sponsor.

- Contact the study doctor or any member of the study team to inform them that you are withdrawing from the study. You may contact the study doctor at:
- We ask that you follow up a verbal withdrawal with a written confirmation by signing the Piedmont Healthcare Research Subject Authorization Revocation Letter that you will be given.

- The date of the verbal notification is the effective date of your withdrawal from the research.

- It is important that you know that the researcher may ask if you are willing to provide continued follow-up and further data collection subsequent to your withdrawal from the intervention portion of the study. This limited participation will consist of follow up associated with clinical outcomes rather than study-related interventions. This limited participation is voluntary and your decision alone. You must indicate your agreement to the limited participation by making the selection on the Piedmont Healthcare Research Subject Authorization Revocation Letter and signing it.

It is also possible that your being part of the study may be stopped at any time without asking you. This might happen if you do not follow the instructions given by the study doctor or if the study is stopped for administrative, medical, or other reasons as determined by the Sponsor **Piedmont _____,** the United States Food and Drug Administration (FDA), or other regulatory authorities. In addition, your doctor may remove you from this study, if it is believed to be in your best interest.

NEW INFORMATION:

If new findings develop during the course of the study that may affect your willingness to continue taking part in this study, your study doctor will provide this information to you or your legal representative in a timely manner.

CONTACTS:

Dr. _____the Principal Investigator (study doctor) of the study at _____

- with questions about this research study or your part in it,
- with questions, concerns or complaints about the research study, or
- if you feel you have had a research-related injury or bad effect to the study

If you have any questions regarding your rights as a participant in a research study, or if you are concerned or have complaints about the study, you may contact the Chairman of the Piedmont Healthcare Institutional Review Board at 404-605-3638.

Commented [MP27]: [provide address and contact telephone number]

Commented [MP28]: sponsor name – delete if not applicable

Commented [MP29]: telephone number and 24 hour contact number

Commented [MP30]: drug or device

CONSENT

If you are willing to volunteer for this research, please sign below. By signing this form you do not give up any legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Time (hh:mm)

_____ _____
Signature of Legally Authorized Representative Date Time

_____
Authority of Legally Authorized Representative or Relationship to Subject

[delete signature lines for the legally authorized representative when not applicable]

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date

_____
Time (hh:mm)

I attest that I or my representative discussed this study with the participant named above.

Signature of Principal or Sub-Investigator **(if required)** Date

[Genetic and other sample research options]
If genetic information is being collected the following statement must be included in the consent:

This study involves genetic testing. The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits health insurers from using individual's genetic information in setting eligibility, premium, or contribution amounts and employers from using individual's genetic information in employment decisions such as hiring, firing, job assignments, and promotion. However, GINA does not include protection from genetic discrimination in life insurance, disability insurance, or long-term care insurance.

[see the 'Genetic and Other Sample Research Guidance' document available in IRBNet to additional consent form considerations/additions]