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*Hover over items in the right column for instructions / explanations.*

Piedmont Healthcare

verbal consent with hipaa authorization

**INTRODUCTION:**

Hello I am [ ]

I obtained your contact information from [ ]

Can I proceed?

Now I will tell you everything you need to know and consider before you decide whether or not to join 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.

The name of the study is [ ]

[ ] is the principal investigator in charge of how the study will be conducted.

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

**STUDY PURPOSE& PROCEDURES, RISKS AND BENEFITS**

If you agree to participate, you will be asked to

If you participate you may experience

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.

CONFIDENTIALITY:

Your privacy is very important to us. There is a law that protects your health information kept by your medical provider; this law is called HIPAA. Your health information that identifies you is your “protected health information” (PHI). If you join the study, the following persons or groups may use and /or disclose your PHI for this study: If any research record is reviewed by any of these groups, they may also need to review your entire medical record.

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 the principal investigator know right away.

**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.

You may revoke your authorization for use of data at any time by calling the Principal Investigator and by completing the revocation form you will be provided. If identifiers (like your name, address, and telephone number) are removed from your PHI, then the remaining information will not be subject to the Privacy Rules. This means that the information may be used or disclosed with other people or organizations, and/or for other purposes.

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.

CONSENT

Do you have any questions about anything I just said? Were there any parts that seemed unclear?

Do you agree to take part in the study?

Would you like a copy of this verbal consent? □ Yes □ No

Participant agrees to participate: □ Yes □ No

If Yes:

Printed Name of Participant

Printed Name of Legally Authorized Representative (if applicable)

Authority of Legally Authorized Representative or Relationship to Subject

Signature of Person Conducting Informed Consent Discussion Date Time

Printed Name of Person Explaining Consent