Wake Forest®
School of Medicine

Department of Internal Medicine/Section on Infectious Disease

HRA PERCEIVED DISCOMFORT STUDY

Informed Consent Form to Participate in Research
Luis F. Barroso, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to see if the order of the parts of the High Resolution Anoscopy (HRA) exam affects discomfort. You are invited to be in this study because we are trying to learn more about people's perception of the HRA exam. Your participation in this research will involve taking a short survey after your visit today. The survey will ask you to rate how you felt during today's procedure.

Participation in this study will involve randomization, which means assignment by chance to a study group to determine the order of the parts of the HRA exam. Participation in this study will also involve completing a short survey. All research studies involve some risks. There is not the possibility that you may 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 not participating. 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 Dr. Luis Barroso. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: Luis Barroso, MD [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. You are being asked to take part in this study because your doctor has determined that you should have a High Resolution Anoscopy (HRA) Procedure. Your participation is voluntary. Please take your time in making your decision as to 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 the study is to see if there is a way to do the High Resolution Anoscopy Procedure (HRA) that is more comfortable. Some providers do the perianal exam (the outside part of the examination) first, and other providers do the perianal exam second. It is unknown if one way makes the exam more or less uncomfortable.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

54 people at Wake Forest will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

The HRA procedure involves putting a small plastic scope into the anal canal, putting in vinegar and iodine, then looking with magnification. Very often spots that look abnormal will be biopsied, which is when a sample of tissue is taken to send to the lab. The tissue is about the size of a pin head. The procedure also involves looking on the outside of the anal canal, around the opening, to see if any parts of the skin are abnormal. A biopsy (sample of tissue) is sometimes taken from this area in a similar manner.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.

One way is to do the perianal exam in the beginning, the other way is to do it at the end. Either way the exam is done, the only thing that changes is whether the perianal exam occurs at the beginning or end of the procedure. The exam as a whole will not be different between the two groups and there will be no extra parts. The order of the parts may change. One way may be less uncomfortable than the other, but this is unknown. If you do not take part in the study, then you will have the HRA exam as usual. You and your provider can decide how to perform the exam, and the order of the perianal exam.

After your HRA exam, you will complete a questionnaire. As part of this study, you will be asked questions about today's procedure. This questionnaire should take no more than a minute to complete.

How Long Will I Be in the Study?

You will be in the study for today only. After you complete the short survey you will be finished.

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, but we do not believe that there are any serious consequences from stopping early.

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. Risks and side effects related to the HRA procedure we are studying include:

During the procedure you will feel a lot of pressure that is often uncomfortable but usually not described as painful, but pain is a risk of the procedure and a rare complication afterwards. The biopsies are usually, but not always, painless. Slight bleeding is expected after the biopsies for a few days, heavy bleeding is not expected but it is a risk. If you experience pain sometimes there are numbing injections that can help. Infection is very rare but is also a risk after the procedure. Please note that your doctor recommends the HRA procedure today whether or not you participate in this study. Taking part in the study is completely up to you. The study will not alter any parts of the procedure other than the order in which the parts are done.

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.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

What Are the Costs?

There are no direct costs for participating in this study. The HRA procedure, which is not part of this study, will be billed to your insurance or directly to you as usual. Taking part in this study will not affect your bill or costs to you in any way.

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.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is departmentally sponsored and conducted within the Infectious Diseases Clinical Trials Unit.

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].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

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 Luis F. Barroso, M.D. at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information about your health or behaviors is considered Protected

Health Information. The information we will collect for this research study includes**:** details from the HRA procedure (how many biopsies, etc), and a quick survey at the end.

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.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Luis Barroso, M.D. 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:

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.

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 the HRA Procedure is no longer required or the provider feels that it may be unsafe. 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.

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, Luis Barroso, MD at (336) 716-4070 or (336) 716-2700 after hours.

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