CAROLINAS HEALTHCARE SYSTEM CONSENT TEMPLATE
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Management of Coccydynia: A Prospective, Observational Study of Coccygectomy

INTRODUCTION

Drs. Edward Hanley, Nady Hamid, Bryan Loeffler, and Ben Jackson are asking you to participate in this research study of management of coccydynia (pain at the site of the "tailbone") at Carolinas Medical Center (CMC) and Carolinas HealthCare System (CHS). You are being asked to take part because you have a condition that may be treated with surgical removal of the "tailbone" (called coccygectomy).

The purpose of this study is to accurately review the results of this procedure in the treatment of your condition. There are no investigational procedures, devices or drugs being used in this study. You will sign a separate consent for the surgical procedure. You will be one of approximately one hundred people involved in this research project at CHS, and your participation will last for 24 months.

HOW THE STUDY WORKS

If you enroll in this study, you will be asked to complete a questionnaire to determine your level of pain in your tailbone, how long you are able to sit, and other questionnaires that measure your overall health and sense of wellbeing before surgery. You will then be examined and asked to complete brief questionnaires at regular time periods after your surgery to determine how your symptoms are progressing. You will be expected to attend follow-up appointments at 2 weeks, 6 weeks, 3 months, 6 months, 1 year, and 2 years after your treatment, and to complete the brief questionnaires at these visits. The longer questionnaires (SF-36 and Oswestry) should be completed at the time you enter the study, at one year and two years after treatment.

RISKS

The risks involved with surgery:

- Infection
- Damage to surrounding blood vessels, nerves and soft tissue structures
- Failure to improve symptoms
- Risks associated with general anesthesia.

Further description of surgical risks is included on the consent form for surgery and will be reviewed with you.

There are no investigational procedures or devices being used.

There is a small risk associated with loss of confidentiality with release of information from your medical records. The research team will follow strict confidentiality standards to minimize this risk to you

EXCLUSION CRITERIA

1. Previous coccyx surgery
2. Co-existing lower back pain
3. Age less than 18 years
4. Pregnant patients

BENEFITS

This study may or may not improve your condition, but the information gained from your case may benefit others in the future with your condition.

ALTERNATIVE PROCEDURE/TREATMENT

You may choose to not participate in the study. This will not affect the type of procedure or treatment that you receive. The other treatment options include rest, pain medicine, and use of a sitting cushion.

ADDITIONAL COST

There will be no additional cost to participate in this study. Your follow-up care and visits after the surgery will be the same whether or not you enroll in the study. You and/or your insurance company is responsible for the cost of your care.

COMPENSATION

In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner.

Patients who enroll in the study will be paid $20 at the first follow-up visit, $30 for completion of one year follow-up, and $50.00 for completion of two year follow-up. The money will be provided in cash at the end of each of these visits.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Carolinas HealthCare System. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Carolinas HealthCare System.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Carolinas HealthCare System. To that extent, confidentiality is not absolute.

AUTHORIZATION

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the surgeons conducting this study to collect and process any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study investigators (Drs. Hanley, Hamid, Loeffler, and Jackson) and research staff
- the study sponsor, Winkler Orthopaedic Fund,
- Carolinas HealthCare System employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- compare treatment results with those of other subjects in clinical studies

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed, it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctors, Drs. Hanley, Hamid, Loeffler, or Jackson at the Department of Orthopaedic Surgery, 1616 Scott Ave., Charlotte, NC 28203, and phone number: 704-355-5026, in writing. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

FINANCIAL INTEREST OF INVESTIGATOR

None of the doctors asking you to participate in this study have received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor of study staff is associated.

QUESTIONS

The researchers doing the study at Carolinas HealthCare System are Drs. Hanley, Hamid, Loeffler, and Jackson. You may ask them any questions you have now. If you have questions later, you may contact any of the investigators at:

Department of Orthopaedic Surgery
Carolinas Medical Center
1616 Scott St.
Charlotte, NC 28203
Telephone 704- 355-3184

The Institutional Review Board is a group of people who review the research to protect your rights. If you have questions about the conduct of this study or about your rights as a research subject, you may call the chairperson of the Institutional Review Board of Carolinas HealthCare System for information regarding patients' rights in a research study. You can obtain the name and number of this person by calling (704) 355-3158.

Patient Initials _____

MRN# _____

CONSENT

I have read the above information. I have asked any questions I had, and those questions have been answered. I agree to be in this study and authorize the use of my personal health information. Drs. Hanley, Hamid, Loeffler, Jackson or a member of the research staff will give me a copy of this form.

_____	_____	_____
Patient [guardian] Print Name	Date	Time
_____	_____	_____
Patient [guardian] Signature	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time
_____	_____	_____
Investigator Signature	Date	Time

Identity of representative:
___Next of Kin
___Parent/Guardian
___Healthcare Power of Attorney

MRN# _____