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

*Self-Directed Exercise Program (SDEP) versus Physical Therapy (PT)*

| | |
|---|---|
| **Sponsor / Study Title:** | **Orthopaedic Trauma Association / Use of a Self-Directed Exercise Program (SDEP) Following Selected Lower Extremity Fractures: A randomized clinical trial** |
| **Protocol Number:** | **(03-18-03)** |
| **Principal Investigator: (Study Doctor)** | **Rachel Seymour, PhD** |
| **Telephone:** | **(704) 355-6947 (24 Hours)** |
| **Additional Contact(s): (Study Staff)** | **Michael J. Bosse, MD** |
| **Address:** | **Carolinas HealthCare System<br>Carolinas Medical Center-Main<br>1000 Blythe Boulevard<br>Charlotte, NC 28203** |

## INTRODUCTION

Drs. Rachel Seymour and Michael Bosse and their colleagues are asking you to participate in this research study to determine the best physical therapy program for treatment of leg injuries like yours at the Orthopaedic Surgery Department at Carolinas HealthCare System (CHS). You are being asked to participate in this study because you are between the ages of 18 and 65 and have a lower leg injury. This makes you eligible to take part in this study which aims to see if people who follow a self-directed exercise program at home do as well as people who receive traditional physical therapy (PT).

The goal of physical therapy is to get you back to your normal level of function and your regular activities, including work, as safely and quickly as possible. The number of physical therapy sessions and the types of exercises your physician recommends depends on the type of fracture you have. The number of physical therapy sessions you receive and the timing and amount of weight bearing you do may impact how quickly you recover. Currently, some patients receive physical therapy in a clinic with a licensed physical therapist, while others are instructed to complete the exercises at




Affix Participant Barcode Label Here

home (self-directed exercise program (SDEP)). However, the best course of physical therapy is not known.

This study is designed to better understand which patients may benefit most from SDEP and which may benefit most from traditional, clinic-based therapy among patients with lower extremity injury. Patients in a research study are referred to as study "subjects." Subjects in both types of therapy will do the same types of exercises, but subjects in the SDEP group will perform these exercises at home, using a manual and subjects in the standard, clinic-based therapy will perform their exercises at the physical therapy office of their choosing, like they normally would.

You will be one of 100 subjects in this study. Your participation will last for 12 months. This study is funded by the Orthopaedic Trauma Association.

**HOW THE STUDY WORKS**

If you agree to participate, you will be assigned by chance (like flipping a coin), to one of the two therapy programs. You have a 50% chance of getting either program. We are using this method for deciding which program you will get because it is not clear at the present time which type of physical therapy program is better for you and people like you with similar injuries.

If you are assigned to **Program A**, you will receive a prescription for physical therapy. It will be up to you to decide what physical therapist to use. We will ask you to keep track of how often you go, and what exercises you do when you are there.

If you are assigned to **Program B**, you will be provided with a manual of exercises with pictures and instructions. You will need to do these exercises at home or at a gym, as often as your study doctor tells you to. We will ask you to keep track of all the exercises that you do.

After you review this informed consent and agree to be part of the study, the following things will happen:

- You will be asked to complete surveys about your health and function.
- You will be asked questions about your medical history and about the activities and work you did before you were injured.
- Information about your injury and treatment will be collected and entered into a database by a member of the research team.

You will then be randomly assigned to one group or the other, and you will follow the physical therapy program you are assigned to.

In addition to performing your physical therapy exercises, you will be asked to return to the clinic 3, 6 and 12 months following discharge from the hospital when you were treated. During these visits the following things will happen:

- You will be asked questions about the activities and work you are doing.



Affix Participant Barcode Label Here

- You will be asked to complete surveys about your health and well-being.
- You will be asked to perform tests that involve you walking a short distance down a hallway, completing an agility test, and running and pivoting. An Inertial Measurement Unit (IMU) will be used to measure time and body movement while performing these tests. These tests are done to see how well you are functioning after your injury.

**RISKS**

There are some risks associated with starting a new exercise program. You may feel stiff or sore when you start doing the exercises, no matter which group you are assigned to. If you are in the traditional physical therapy group, you will not have any study treatment-related risks greater than you would have if you were not in the study. If you are in the self-directed exercise program, there is a risk that you could be doing the exercises incorrectly, which could either result in injury or slower progress than if you were doing the exercises correctly. It is important that you carefully follow the manual and videos, and if you have questions, call your study doctor's office or the research team to be sure you are doing everything correctly.

No matter which group you are in, if you feel increased pain or feel like you are getting worse, you must call your study doctor to help decide whether or not the problem is serious.

Additionally, any time information is collected for a study, there is a small risk of breach of confidentiality. As described below, your research data will be identified by a unique study number rather than your name and all measures allowed by law to protect your confidentiality will be taken by the research staff.

**BENEFITS**

Both interventions in this study may improve your condition, but this cannot be guaranteed. You may not benefit from being in this study. The information gained from your case may benefit others with your condition.

**ALTERNATIVE PROCEDURE/TREATMENT**

Your alternative is to not take part. If you choose not to take part, your healthcare will not be affected.

**ADDITIONAL COST**

There are no additional costs for taking part in this research study above the reasonable and customary costs of caring for patients with injuries like yours who are not in the study. Medical bills for on-going treatment of your injury will be covered by your insurance. If you have any costs that are not covered by insurance, they are your responsibility.

**COMPENSATION FOR INJURY**

If you become ill or are hurt while you are in the study, get the medical care that you need right away. In the event that you are harmed as a result of your participation in this study, we will provide



Affix Participant Barcode Label Here

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. You do not waive any legal rights by signing this consent form.

**COMPENSATION**

You will receive an honorarium in recognition of your time and effort. You will receive $25.00 at the 3-month and 6-month visits and $50.00 at the final visit. You will be paid for study visits that you complete, even if you do not complete the overall study.

Federal Regulations about payment of research subjects require that you fill out a form called a W-9 form. The W-9 is a tax form that asks for information including your name and Social Security number. Choosing to complete a W-9 is up to you. If you decide you do not want to complete a W-9 form, you can still be in this study. Choosing not to fill out a W-9 will not harm your relationship with your doctor or Carolinas HealthCare System. But if you choose not to complete the W-9 form, you cannot receive any payment.

Greenphire is a company working together with Carolinas HealthCare System (CHS) to manage the study participant payment process. You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto at the completion of each study visit. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2 business days and can be used at your discretion. You will be issued one card for the duration of your participation.

In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you, including:

*name*
*address*
*date of birth*
*email address (optional)*
*SSN*
*W9 or W8.*

This information will be collected from you by CHS teammates.

All information is stored in a secure fashion on Greenphire's system. Your information will not be shared with any third parties and will be kept completely confidential. By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up the ClinCard payments. You agree that the information you provide is used by Greenphire to perform payments to you.



Affix Participant Barcode Label Here

**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. If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits. If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

We will tell you about new medical findings that may affect your willingness to continue in the study.

**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 the drug/device manufacturer,) by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

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

**AUTHORIZATION**

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study investigator to collect, process and pass on to the sponsor organizations 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:



Affix Participant Barcode Label Here

- the clinical study doctors, Dr. Seymour and Dr. Bosse, and research staff
- the study sponsor, Orthopaedic Trauma Association, and/or its associated companies,
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor,
- 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:

- check your suitability to take part in the study,
- monitor your treatment with the study assignment
- compare and pool 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 doctor, Rachel Seymour, PhD, 1025 Morehead Medical Plaza Drive, Suite 300, Charlotte, NC 28203 and (704) 355-2000 in writing. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.



Affix Participant Barcode Label Here

**FINANCIAL INTEREST OF INVESTIGATOR**

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

**GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY**

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Other questions, concerns, or complaints.

*Contact the study doctor or study staff at Carolinas Healthcare, listed on the first page of this form, with any questions, concerns or complaints.*

**GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT**

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the study subject adviser: Pro00024283.

**(This space intentionally left blank.)**



Affix Participant Barcode Label Here

**STATEMENT OF CONSENT**

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

**STATEMENT OF PERSON EXPLAINING CONSENT**

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent



Affix Participant Barcode Label Here

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

*(Observational)*

*Physical Therapy (PT) vs Standard of Care - Surgeon Exercise Instructions (SOC-SEI)*

| | |
|---|---|
| **Sponsor / Study Title:** | **Orthopaedic Trauma Association / Use of a Self-Directed Exercise Program (SDEP) Following Selected Lower Extremity Fractures: A randomized clinical trial** |
| **Protocol Number:** | **(03-18-03)** |
| **Principal Investigator: (Study Doctor)** | **Rachel Seymour, PhD** |
| **Telephone:** | **(704) 355-6947 (24 Hours)** |
| **Additional Contact(s): (Study Staff)** | **Michael J. Bosse, MD** |
| **Address:** | **Carolinas HealthCare System<br>Carolinas Medical Center-Main<br>1000 Blythe Boulevard<br>Charlotte, NC 28203** |

## INTRODUCTION

Drs. Rachel Seymour and Michael Bosse and their colleagues are asking you to participate in this research study to determine the best physical therapy program for treatment of leg injuries like yours at the Orthopaedic Surgery Department at Carolinas HealthCare System (CHS). You are being asked to participate in this study because you are between the ages of 18 and 65 and have a lower leg injury. This makes you eligible to take part in this study which aims to see if people who follow a self-directed exercise program at home do as well as people who receive traditional physical therapy (PT).

The goal of physical therapy is to get you back to your normal level of function and your regular activities, including work, as safely and quickly as possible. The number of physical therapy sessions and the types of exercises your physician recommends depends on the type of fracture you have. The number of physical therapy sessions you receive and the timing and amount of weight bearing

you do may impact how quickly you recover. Currently, some patients receive physical therapy (PT) in a clinic with a licensed physical therapist, while others are instructed to complete the exercises at home (self-directed exercise program (SDEP)) or receive exercise instructions from their physicians (SOC-SEI). However, the best course of physical therapy is not known.

This study is designed to better understand which patients may benefit most from SDEP and which may benefit most from traditional, clinic-based therapy among patients with lower extremity injury.

Patients in a research study are referred to as study "subjects." Subjects in both types of therapy will do the same types of exercises, but subjects in the SOC-SEI group will perform these exercises at home, using instructions from their study doctor and subjects in the standard, clinic-based therapy will perform their exercises at the physical therapy (PT) office of their choosing, like they normally would. You are being asked to consent to the "observational" arm of this study because you have expressed a preference not to have your exercise regimen determined by chance (like flipping a coin). Instead, you will be able to choose whether you prefer PT, SDEP, or SOC-SEI.

You will be one of 100 subjects in this study. Your participation will last for 12 months. This study is funded by the Orthopaedic Trauma Association.

**HOW THE STUDY WORKS**

If you agree to participate in this study, we will observe the outcomes of your study treatment and we will follow our recovery. You will have the standard of care treatment that you and your study doctor decide upon.

After you review this informed consent and agree to be part of the study, the following things will happen:

- You will be asked to complete surveys about your health and function.
- You will be asked questions about your medical history and about the activities and work you did before you were injured.
- Information about your injury and treatment will be collected and entered into a database by a member of the research team.

In addition to performing your physical therapy exercises, you will be asked to return to the clinic 3, 6 and 12 months following discharge from the hospital when you were treated. During these visits the following things will happen:

- You will be asked questions about the activities and work you are doing.
- You will be asked to complete surveys about your health and well-being.
- You will be asked to perform tests that involve you, walking a short distance down a hallway, completing an agility test, and running and pivoting. An Inertial Measurement Unit (IMU) will be used to measure time and body movement while performing these tests. These tests are done to see how well you are functioning after your injury.



Affix Participant Barcode Label Here

**RISKS**

There are some risks associated with starting a new exercise program. You may feel stiff or sore when you start doing the exercises, no matter which group you are assigned to. If you are in the traditional physical therapy group, you will not have any study treatment-related risks greater than you would have if you were not in the study. If you are in the self-directed exercise program, there is a risk that you could be doing the exercises incorrectly, which could either result in injury or slower progress than if you were doing the exercises correctly. It is important that you carefully follow the study doctor's instructions, and if you have questions, call your study doctor's office or the research team to be sure you are doing everything correctly.

No matter which group you are in, if you feel increased pain or feel like you are getting worse, you must call your study doctor to help decide whether or not the problem is serious.

Additionally, any time information is collected for a study, there is a small risk of breach of confidentiality. As described below, your research data will be identified by a unique study number rather than your name and all measures allowed by law to protect your confidentiality will be taken by the research staff

**BENEFITS**

Since you will be getting the same PT for your lower leg injury that you would get whether or not you were in this study, it is expected that you will not directly benefit from being in this study. The information gained from your case may benefit others with your condition.

**ALTERNATIVE PROCEDURE/TREATMENT**

Your alternative is to not take part. If you choose not to take part, your healthcare will not be affected.

**ADDITIONAL COST**

There are no additional costs for taking part in this research study above the reasonable and customary costs of caring for patients with injuries like yours who are not in the study. Medical bills for on-going treatment of your injury will be covered by your insurance. If you have any costs that are not covered by insurance, they are your responsibility.

**COMPENSATION FOR INJURY**

If you become ill or are hurt while you are in the study, get the medical care that you need right away. 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. You do not waive any legal rights by signing this consent form.



Affix Participant Barcode Label Here

**COMPENSATION**

You will receive an honorarium in recognition of your time and effort. You will receive $25.00 at the 3-month and 6-month visits and $50.00 at the final visit. You will be paid for study visits that you complete, even if you do not complete the overall study.

Federal Regulations about payment of research subjects require that you fill out a form called a W-9 form. The W-9 is a tax form that asks for information including your name and Social Security number. Choosing to complete a W-9 is up to you. If you decide you do not want to complete a W-9 form, you can still be in this study. Choosing not to fill out a W-9 will not harm your relationship with your doctor or Carolinas HealthCare System. But if you choose not to complete the W-9 form, you cannot receive any payment.

Greenphire is a company working together with Carolinas HealthCare System (CHS) to manage the study participant payment process. You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto at the completion of each study visit. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2 business days and can be used at your discretion. You will be issued one card for the duration of your participation.

In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you, including:

*name*
*address*
*date of birth*
*email address (optional)*
*SSN*
*W9 or W8.*

This information will be collected from you by CHS teammates.

All information is stored in a secure fashion on Greenphire's system. Your information will not be shared with any third parties and will be kept completely confidential. By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up the ClinCard payments. You agree that the information you provide is used by Greenphire to perform payments to you.

**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. If you do not want to be in a study or you stop the study at a later



Affix Participant Barcode Label Here

time, you will not be penalized or lose any benefits. If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

We will tell you about new medical findings that may affect your willingness to continue in the study.

**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 the drug/device manufacturer,) by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

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

**AUTHORIZATION**

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study investigator to collect, process and pass on to the sponsor organizations 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, Dr. Seymour and Dr. Bosse, and research staff
- the study sponsor, Orthopaedic Trauma Association, and/or its associated companies,
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor,
- Carolinas HealthCare System employees,



Affix Participant Barcode Label Here

- 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:

- check your suitability to take part in the study,
- monitor your treatment with the study assignment
- compare and pool 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 doctor, Rachel Seymour, PhD, 1025 Morehead Medical Plaza Drive, Suite 300, Charlotte, NC 28203 and (704) 355-2000 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 has received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor may give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor or study staff is associated.



Affix Participant Barcode Label Here

**GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY**

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Other questions, concerns, or complaints.

*Contact the study doctor or study staff at Carolinas Healthcare, listed on the first page of this form, with any questions, concerns or complaints.*

**GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT**

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the study subject adviser: Pro00024283.

**(This space intentionally left blank.)**



Affix Participant Barcode Label Here

**STATEMENT OF CONSENT**

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

**STATEMENT OF PERSON EXPLAINING CONSENT**

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent



Affix Participant Barcode Label Here

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

*Self-Directed Exercise Program (SDEP) vs Standard of Care - Surgeon Exercise Instructions (SOC-SEI)*

| | |
|---|---|
| **Sponsor / Study Title:** | **Orthopaedic Trauma Association / Use of a Self-Directed Exercise Program (SDEP) Following Selected Lower Extremity Fractures: A randomized clinical trial** |
| **Protocol Number:** | **(03-18-03)** |
| **Principal Investigator: (Study Doctor)** | **Rachel Seymour, PhD** |
| **Telephone:** | **(704) 355-6947 (24 Hours)** |
| **Additional Contact(s): (Study Staff)** | **Michael J. Bosse, MD** |
| **Address:** | **Carolinas HealthCare System<br>Carolinas Medical Center-Main<br>1000 Blythe Boulevard<br>Charlotte, NC 28203** |

## INTRODUCTION

Drs. Rachel Seymour and Michael Bosse and their colleagues are asking you to participate in this research study to determine the best physical therapy program for treatment of leg injuries like yours at the Orthopaedic Surgery Department at Carolinas HealthCare System (CHS). You are being asked to participate in this study because you are between the ages of 18 and 65 and have a lower leg injury. This makes you eligible to take part in this study which aims to see if people who follow a self-directed exercise program at home or receive exercise instructions from their physician do as well as people who receive traditional physical therapy (PT).

The goal of physical therapy is to get you back to your normal level of function and your regular activities, including work, as safely and quickly as possible. The number of physical therapy sessions and the types of exercises your physician recommends depends on the type of fracture you have. The number of physical therapy sessions you receive and the timing and amount of weight bearing you do may impact how quickly you recover. Currently, some patients receive physical therapy in a clinic with a licensed physical therapist, while others are instructed to complete the exercises at home (self-directed exercise program (SDEP) or receive exercise instructions from their physicians(SOC-SEI). However, the best course of physical therapy is not known.




Affix Participant Barcode Label Here

This study is designed to better understand which patients may benefit most from exercise instructions from their physician, SDEP and traditional PT. Patients in a research study are referred to as study "subjects." You will be one of 100 subjects in this study. Your participation will last for 12 months. This study is funded by the Orthopaedic Trauma Association.

**HOW THE STUDY WORKS**

If you agree to participate, you will be assigned by chance (like flipping a coin), to one of the two therapy programs. (The PT outside of the home is being assessed in a different part of this study.) You have a 50% chance of getting either program. We are using this method for deciding which program you will get because it is not clear at the present time which type of physical therapy program is better for you and people like you with similar injuries.

If you are assigned to **Program A**, you will be provided with a manual of exercises with pictures and instructions. You will need to do these exercises at home or at a gym, as often as your study doctor tells you to. We will ask you to keep track of all the exercises that you do.

If you are assigned to **Program B**, your study doctor will give you exercise instructions. You will need to do these exercises at home and as often as your study doctor tells you.

After you review this informed consent and agree to be part of the study, the following things will happen:

- You will be asked to complete surveys about your health and function.
- You will be asked questions about your medical history and about the activities and work you did before you were injured.
- Information about your injury and treatment will be collected and entered into a database by a member of the research team.

You will then be randomly assigned to one group or the other, and you will follow the physical therapy program you are assigned to.

In addition to performing your exercises, you will be asked to return to the clinic 3, 6 and 12 months following discharge from the hospitalization when you were treated. During these visits the following things will happen:

- You will be asked questions about the activities and work you are doing.
- You will be asked to complete surveys about your health and well-being.
- You will be asked to perform tests that involve you walking a short distance down a hallway, completing an agility test, and running and pivoting. An Inertial Measurement Unit (IMU) will be used to measure time and body movement while performing these tests. These tests are done to see how well you are functioning after your injury.

**RISKS**

There are some risks associated with starting a new exercise program. You may feel stiff or sore when you start doing the exercises, no matter which group you are assigned to. If you are in the self-directed exercise program or physician exercise instructions, there is a risk that you could be



Affix Participant Barcode Label Here

doing the exercises incorrectly, which could either result in injury or slower progress than if you were doing the exercises correctly. If you are in the SDEP group, it is important that you carefully follow the manual and videos, and if you have questions, call your study doctor's office or the research team to be sure you are doing everything correctly.

No matter which group you are in, if you feel increased pain or feel like you are getting worse, you must call your study doctor to help decide whether or not the problem is serious.

Additionally, any time information is collected for a study, there is a small risk of breach of confidentiality. As described below, your research data will be identified by a unique study number rather than your name and all measures allowed by law to protect your confidentiality will be taken by the research staff

**BENEFITS**

It is hoped that the exercises you are assigned will help your condition, but this cannot be guaranteed. Thus, you may not directly benefit from being in this study. If necessary, you can be referred for PT under closer supervision after the study. The information gained from your case may benefit others with your condition.

**ALTERNATIVE PROCEDURE/TREATMENT**

Your alternative is to not take part. If you choose not to take part, your healthcare will not be affected.

**ADDITIONAL COST**

There are no additional costs for taking part in this research study above the reasonable and customary costs of caring for patients with injuries like yours who are not in the study. Medical bills for on-going treatment of your injury will be covered by your insurance. If you have any costs that are not covered by insurance, they are your responsibility.

**COMPENSATION FOR INJURY**

If you become ill or are hurt while you are in the study, get the medical care that you need right away. 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. You do not waive any legal rights by signing this consent form.

**COMPENSATION**

You will receive an honorarium in recognition of your time and effort. You will receive $25.00 at the 3-month and 6-month visits and $50.00 at the final visit. You will be paid for study visits that you complete, even if you do not complete the overall study.

Federal Regulations about payment of research subjects require that you fill out a form called a W-9 form. The W-9 is a tax form that asks for information including your name and Social Security number. Choosing to complete a W-9 is up to you. If you decide you do not want to complete a W-9 form, you can still be in this study. Choosing not to fill out a W-9 will not harm your



Affix Participant Barcode Label Here

relationship with your doctor or Carolinas HealthCare System. But if you choose not to complete the W-9 form, you cannot receive any payment.

Greenphire is a company working together with Carolinas HealthCare System (CHS) to manage the study participant payment process. You will be issued a Greenphire ClinCard, which is a debit card that your funds are loaded onto at the completion of each study visit. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 2 business days and can be used at your discretion. You will be issued one card for the duration of your participation.

In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you, including:

*name*
*address*
*date of birth*
*email address (optional)*
*SSN*
*W9 or W8.*

This information will be collected from you by CHS teammates.

All information is stored in a secure fashion on Greenphire's system. Your information will not be shared with any third parties and will be kept completely confidential. By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up the ClinCard payments. You agree that the information you provide is used by Greenphire to perform payments to you.

**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. If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits. If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.



Affix Participant Barcode Label Here

We will tell you about new medical findings that may affect your willingness to continue in the study.

**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 the drug/device manufacturer,) by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

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

**AUTHORIZATION**

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study investigator to collect, process and pass on to the sponsor organizations 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, Dr. Seymour and Dr. Bosse, and research staff
- the study sponsor, Orthopaedic Trauma Association, and/or its associated companies,
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor,
- 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:

- check your suitability to take part in the study,
- monitor your treatment with the study assignment
- compare and pool 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



Affix Participant Barcode Label Here

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 doctor, Rachel Seymour, PhD, 1025 Morehead Medical Plaza Drive, Suite 300, Charlotte, NC 28203 and (704) 355-2000 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 has received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor may give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor or study staff is associated.

**GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY**

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Other questions, concerns, or complaints.

*Contact the study doctor or study staff at Carolinas Healthcare, listed on the first page of this form, with any questions, concerns or complaints.*



Affix Participant Barcode Label Here

**GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT**

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the study subject adviser: Pro00024283.

**(This space intentionally left blank.)**



Affix Participant Barcode Label Here

**STATEMENT OF CONSENT**

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____

Signature of Research Subject Date Time

_____

Printed Name of Research Subject

**STATEMENT OF PERSON EXPLAINING CONSENT**

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____

Signature of Person Explaining Consent Date Time

_____

Printed Name of Person Explaining Consent



Affix Participant Barcode Label Here