WALTER REED NATIONAL MILITARY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Title: Randomized Control Trial of Combined Cryotherapy with Compression Versus Cryotherapy Alone After Orthopaedic Surgery

Principal Investigator: Ashley Bee Anderson, MD, LCDR, MC, USN

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your participation in this study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to consent to participate in a voluntary research study. You are being asked to take part in this research study because you will be having an orthopaedic arthroscopic surgery and may have problems with pain after your surgery. The purpose of this research study is to learn about the pain-relieving effects of cold therapy (i.e., cryotherapy) with compression versus cold therapy without compression after arthroscopic surgery. If you choose to participate in this study, your involvement would last about 2 years. If you decide not to participate in the study, you and your doctor will decide on the treatment you receive instead of having the study decide on the treatment you receive.

Possible risks/discomforts include: a risk of temperature-related skin injury. Additionally, any time information is collected for a study there is a small chance of breach of confidentiality.

Possible benefits include: decreased post-operative prescription pain medication use, decreased post-operative pain, and possible earlier return to activities/readiness.

Your decision will not affect your future care at Walter Reed National Military Medical Center (WRNMMC). If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are Department of Defense (DoD) healthcare beneficiary over the age of 18 (inclusive) and will be receiving an orthopaedic arthroscopic surgery, which may lead to problems with pain after your surgery. The purpose of this research study is to learn about the pain-relieving effects of cold therapy (i.e., cryotherapy)

with compression versus without compression after shoulder, knee, and hip arthroscopic procedures. The duration of participation per visit is about 30-60 minutes.

There will be about 504 people taking part in the study at WRNMMC, over a period of a few years. During the study, you will have about 3 in-person visits with the research team. After consenting to participate in this research study, you will provide your contact information and complete some questionnaires, which are expected to take approximately 30 minutes. The home activities will take up to 2 hours per day for the first 14 days post-surgery. Then, you will be asked to return to the clinic at approximately 2 weeks and again at 6 weeks after your orthopaedic arthroscopy. You will also complete questionnaires from home (over the phone or via email) at 6 months, 12 months, and 24 months post-operation. Each follow-up visit will take about 30-60 minutes. Your study participation will end approximately 24 months after your orthopaedic arthroscopy.

At the end of this research study, a summary of collective study results from all participants will be available to the public on http://www.ClinicalTrials.gov.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process." This information may have already been collected as a part of your regular medical care. The researchers will ask both you and your physician questions to ensure you qualify. These include questions regarding your age, current condition, medical history, and medical care eligibility.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you agree to participate in this research study, the following research-related activities will take place outside standard of care:

Contact Information:
As soon as possible following consent, you will be asked to complete a questionnaire collecting your contact information. The local study team will use the information you provide on this form to contact you regarding study-related procedures and appointments. This questionnaire will take approximately five (5) minutes to complete.

Baseline Questionnaires:
On the first day of the study, before your surgery, you will complete a series of questionnaires. These questionnaires will ask about your demographic characteristics, your military and active-duty status, your current level of function, your current physical pain and related symptoms, mental health characteristics such as symptoms of anxiety and depression, and current sleep quality. These questionnaires will take approximately 20 minutes to complete.

Randomization:
Before your surgery, you will be randomly assigned to one of two (2) groups. Randomization is a process like flipping a coin and means you will have a 50/50 chance of being assigned to either of the groups.

You will be randomized into either the Game Ready® Cryotherapy with Compression Group or the standard Cryotherapy without Compression Group. Instructions will be provided regarding application and use of each type of therapy. Both groups will have the same number of study visits and will complete the same questionnaires. Both groups will also need to use their assigned therapy for at least three sessions per day, 30 minutes each session, for 14 days post-operation.

Post-Operative Days 1-14:

For the first two weeks (days 1-14) after your orthopaedic arthroscopy, you will be asked to do the following activities from home:

- **Cryotherapy Sessions.** You will need to complete at least three 30 minute sessions per day for the first 14 days after surgery.
- **Daily Logs.** You will be required to maintain a daily Therapy Log and a Medication Log during the first 14 days after your surgery. These Logs will be used to record the time, frequency, dosage, and pain levels when using the cryotherapy device and taking medications. You will also use the Therapy Log to record your pain rating first thing in the morning and right before going to bed. These logs will be given to you and reviewed with you at your pre-operative appointment. You will turn in your completed logs at your 2 week post-op in-person visit.

Two weeks after your surgery:

- **Two (2) Week Check-In.** At approximately 2 weeks post-operation, you will return to clinic for an in-person visit. You would return to clinic approximately two weeks after your operation even if you weren't in this study. At this appointment, you will be required to bring the provided cryotherapy equipment, both completed Daily Logs, and medication bottles. The medication bottles are needed for pill counts to quantify opioid usage.
- **Two Week Surveys.** You will be emailed a link to your "2 Week" surveys. Since you will be returning to WRNMMC for a follow up clinical appointment, if you do not complete the surveys prior to your appointment, you can complete them when you are in clinic. These surveys are the same as the ones you will complete before your operation, but you will not need to re-complete the demographics portion.

Six weeks after your surgery:

- **Six (6) Week Check-In.** At approximately 6 weeks post-operation, you will return to clinic for an in-person visit. You would return to clinic approximately six weeks after your operation even if you weren't in this study.
- **Six Week Surveys.** You will be emailed a link to your "6 Week" surveys. Since you will be returning to WRNMMC for a follow up clinical appointment, if you do not complete the surveys prior to your appointment, you can complete them when you are in clinic. These surveys are the same as the ones you will complete at your two-week post-op follow-up appointment.

Long Term Follow-Up:

- **Follow-Up Surveys.** You will complete surveys again at approximately 6 months, 12 months, and 24 months after your surgery. A link to your surveys will be sent to you via email, but you may also complete them in-person if you return to the clinic for a standard of

care follow-up appointment. These surveys are the same as the ones you will complete at your two week and six-week follow-up visits.

- **Participation End.** Your study participation will end after you complete your 24-month post-operative surveys.

Medical Record Review:

Finally, the study team is requesting that they can access your medical record so that they can track other characteristics about your health throughout your participation in this study. The study team will collect information on relevant health behaviors (e.g., tobacco and alcohol use), relevant comorbidities (e.g., diabetes, etc.), relevant medical/treatment history related to your current orthopaedic injury, and characteristics of your current surgery (e.g., surgery type and surgery date, etc.). This aspect of the study is completed entirely by the study team and requires no additional effort or time from you.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there are risks associated with the study activities:

- *Temperature-related skin injury.* Improper use of Game Ready ® Unit or Ice Packs may cause temporary or permanent damage to your skin. It is important to follow the instructions to minimize this risk.
- *A breach of confidentiality.* Although efforts are made to protect your research study records, there is always a risk that someone could get access the personal information in your medical records or other information researchers have stored about you. As described below, your research data will be identified by a unique study number rather than your name and all records will be securely stored. Access to this data will be limited to trained and approved study team members. All measures allowed by law to protect your confidentiality will be taken by the research staff.

There may also be other risks of taking part in this study that we do not yet know about.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no guaranteed direct benefits to you for taking part in the study. Some participants may experience possible decreased post-operative prescription pain medication use, decreased post-operative pain, and possible earlier return to activities/readiness.

Others may benefit in the future from the information learned during this study. The possible benefits to others are an understanding of who is at risk for long term pain and recovery after surgery. In the future, this information could be used to create cutting-edge treatments and help stop the opioid epidemic.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

You do not have to participate in the study. This study does not change the planned procedure with your orthopaedic surgeon. The alternative to participating in this study is using the clinics'

routine, standard of care post-operative cryotherapy device and **not** having the added option of cryotherapy with compression.

If you do not join, your medical care will not be affected.

8. **IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?**
No, you will not receive any compensation for participating in this study.

9. **ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?**
No, there are no costs to you for taking part in this research study.

10. **PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):**
Ashley Bee Anderson, MD, LCDR, MC, USN
Orthopaedic Surgeon, WRNMMC
Assistant Professor of Surgery, USUHS
Deputy Director, Limb Optimization and Osseointegration Program (LOOP)
Walter Reed National Military Medical Center
4494 Palmer Rd N, Bethesda, MD 20889
America Building 19, 2nd Floor Orthopaedic Department
Ashley.b.anderson16.mil@health.mil
301-295-4290

11. **STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):**
Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU), is overseeing this research study. As such, authorized staff from MIRROR and the USU will have access to your coded research data.

As a sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. **SOURCE OF FUNDING:**
This research study is unfunded. The Game Ready® Cool and Compression Therapy Units will be loaned to WRNMMC free of charge.

13. **LOCATION OF THE RESEARCH:**
Walter Reed National Military Medical Center (WRNMMC) Department of Orthopaedics and the Uniformed Services University (USU).

14. **DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS**:
The study team does not have any conflict of interests related to financial sponsors.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The local research team will keep your research records. Your research records will be stored in a locked cabinet inside a locked room accessible only by authorized local research staff. These records may be looked at by local research staff, staff from the WRNMMC Department of Research Programs (DRP) and Institutional Review Board (IRB), the Food and Drug Administration (FDA), and the Department of Defense (DoD) Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

Generally, only people on the local research team will know that you are in this research study. You and your research data will be identified only by a unique coded study number and not by your name, social security number, DoD ID, or other protected identifier. The unique coded study number cannot be linked to your name except at the clinic where you complete visits. The WRNMMC research team will maintain a separate confidential electronic enrollment log which matches the unique coded study numbers with participants' names and their DoD ID number. This enrollment log will be stored separately from all other electronic research data in a secure, password-protected database on a DoD computer and network that requires CAC access. The WRNMMC research team will also maintain an intake form that collects your preferred contact information. This intake form will be kept in a locked cabinet inside of a locked room and stored separately from your coded research records.

All data collected from your study visits will be labeled with your unique coded study number. Paper case report forms that collect your study data will be stored in a locked cabinet inside of a locked room separately from the enrollment log that connects your identity with your unique coded study number and the intake form which collects your contact information. Your coded study data will be entered into Research Electronic Data Capture (REDCap), a secure, access controlled, and password protected electronic data capture and management system housed on a DoD server and maintained by the Uniformed Services University (USU) in Bethesda, MD. Once your coded data is entered in REDCap, it will only be accessible by authorized members of the local study team, the WRNMMC DRP and IRB, and authorized staff from Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at USU, and is serving as the data coordinating center for this study.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

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 results. You can search this Web site at any time.

16. LONG TERM USE OF DATA

The investigator has requested to save selected de-identified data collected from your participation in this research study for possible use in future research. The data that may be used in future research will be de-identified, meaning that all of your personal identifiers will be removed. This future research may be in the same area as the original study or it may be for a different kind of study.

Any future research using your retained de-identified data will require a research protocol for the proposed study reviewed by an Exempt Determination Official (EDO) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

Your de-identified research data will be securely sent to Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) and stored at the Uniformed Services University (USU) alongside other de-identified research data. This de-identified research data will be kept indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

The local study team will keep this consent form and your signed HIPAA authorization for six (6) years following study closure. They will keep your coded paper research forms for five (5) years following study closure. The master code list which connects your identity with your unique study code will be destroyed as soon as all data collection is completed and analyzed, and no later than 1 year following study closure.

If you consent to participate in this research study, your de-identified data collected as part of this research may be kept for future research studies or given to other researchers for future approved research studies. If you do not want your de-identified data collected as part of this research study to be kept for use in future research studies, you should not sign this consent form.

17. USE OF INFORMATION

The information collected as part of this research will be used or distributed for future research studies. As described in Section 16 above, any information used or distributed for future research studies will be de-identified, meaning that all of your personal identifiers will be removed.

18. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. As long as you remain a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

You do not have an option to decline receiving information about an incidental finding.

19. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. If you leave the study early, we may retain and analyze all coded/de-identified data collected up to the time you withdraw if the data is necessary to maintain the integrity of the study. However, no additional data will be collected.

Should you choose to withdraw, you must contact the Principal Investigator in writing via mail or email:

Ashley Bee Anderson, MD, LCDR, MC, USN
Walter Reed National Military Medical Center
4494 Palmer Rd N, Bethesda, MD 20889
America Building 19, 2nd Floor Orthopaedic Department
Ashley.b.anderson16.mil@health.mil
301-295-4290

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to or email the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, if you no longer meet eligibility criteria, if you are no longer eligible to receive medical care at a military hospital, if the military mission requires it, or if the study is cancelled.

21. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information provided in this consent form.

Additionally, if you have a research-related injury, you may contact the WRNMMC Staff Judge Advocate Office at 301-295-2215.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active-duty military, dependent of active-duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

22. CONTACT INFORMATION:

The Principal Investigator or a member of the research staff at Walter Reed National Military Medical Center (WRNMMC) will be available to answer any questions throughout this study:

Ashley Bee Anderson, MD, LCDR, MC, USN
Walter Reed National Military Medical Center
4494 Palmer Rd N, Bethesda, MD 20889

America Building 19, 2nd Floor Orthopaedic Department
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301-295-4290

Human Research Protection Program (HRPP) Office

The WRNMMC Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will also be available to answer questions or discuss concerns you may have about this research study.

HPA/HRPP Phone Number: 301-295-8239

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the WRNMMC IRB Office, which is the overall IRB of Record for this study at:

Walter Reed National Military Medical Center
Department of Research Programs, Building 17B, 3rd Floor, Suite C
4650 Taylor Road, Bethesda, MD 20889
301-295-8239

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant | Date | Time

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____ _____
Signature of Administering Individual | Date | Time