Regional Health Command-Central Institutional Review Board
Brooke Army Medical Center

CONSENT TO PARTICIPATE IN RESEARCH

1. **PROTOCOL TITLE:** Exploring the Value of the DoD/VA Clinical Practice Guidelines for Non-Surgical Management of Knee Osteoarthritis in the Military Health System

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. 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, including the risks and possible benefits to you.

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

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.

Your decision will not affect your future care at Brooke Army Medical Center.

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 seeking care for your knee pain. The purpose of this study is to explore and compare an approach that utilizes guidance provided from the Department of Defense and Veterans Administration Guidelines Committee for managing chronic knee pain and what a physical therapy program might add. The duration of participation in the study will be over a period of 2 years. Your treatment won't last that long, but we want to see how you are doing over a longer period of time so we can better understand the long-term impacts of these treatments.

There will be about 300 people taking part in this study overall, with approximately 100 participants to be enrolled at several different military hospitals that include: Brooke Army Medical Center, Madigan Army Medical Center, and Wilford Hall Ambulatory Surgical Center, over a period of two years.

During your participation in this study, you will be asked to make some follow-up visits with the research team. These appointments may be in person or done electronically (via email or a phone call) at 6 weeks, 6 months, 1 year and 2 years from your initial enrollment. These will allow us to

ask you some questions about how your symptoms and quality of life have been changing over this period of time. We are also interested in how you are doing on a monthly basis. We will contact you monthly through a text-message service that will ask you just a couple questions about how you think things are coming along and what might be limiting your progress. These are really short, typically 1-3 character replies, with very few questions compared to the regular follow-ups we mentioned earlier. We estimate it will take you about 1 minute or less to respond. Because we are using a text-messaging service for this, the responses you send back are stored in a very secure database for us to be able to access. They won't contain any private information. You can always opt out of the text-messages at any time and we can instead call you or have you come in person to answer the questions if you prefer. No additional outpatient treatment appointments are necessary beyond the physical therapy appointments you may be assigned to attend upon enrollment into the study. This does not include the follow-up visits that were referred to earlier in this paragraph however.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, we need to examine your knee to confirm that you qualify for the study. This is really a standard clinical exam, that even if you were not a part of the study, we would likely be doing at least a part of, just to help us better understand the nature of your symptoms. We also may need you to answer a few questions related to the history of medical care that you have already had for your knee to date. This is called the "Screening Process". Some of this information may have been already recently collected as a part of your regular medical care or exam with your primary care provider.

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

You will be screened to make sure you are eligible to participate in the study. Once researchers confirm you are eligible, you will be randomly assigned to one of two different treatment plans for your knee pain. Randomization is a process like flipping a coin and means you will have a 50% chance of being assigned to either of the plans. Both plans actually involve components of care that you could be receiving from medical providers even if you didn't participate in the study. That is, they are considered standard of care treatments and we are looking at any differences between the two treatment types and their impact on patients over the long term. The treatment will include education about what we know works and doesn't work for treating knee osteoarthritis, tools to help you better manage your condition on your own, how exercise can help, and possibly some physical therapy. If physical therapy is part of your treatment plan, those appointments usually occur 2 or 3 times each week for probably 3 or 4 weeks, but will vary depending on the individual physical therapist you may be assigned to. Either way you will be given some management tools and "homework" to do on your own to help contribute to the goal of getting better. We will ask that it be your responsibility to adhere to the schedule provided to you. After the treatment is complete, the research team will ask you to fill out some surveys according to the timeline we discussed in Section 1.

We will also review your medical records so that we can evaluate the care you have had for your knee pain (for example, medications, visits to other providers, number and types of X-rays and MRIs, etc.). This will help us better understand how different treatment decisions might be

influencing your progress. We will review the records of care for the year leading up to enrollment in this study, and then during the 2 years that we follow you in this study. You will not need to do anything else for this as it will be automatically collected by the investigators from the TRICARE medical database that tracks and stores health care for beneficiaries. This will include all care in the Tricare Network. This information will be collected based on your DoD identification number (DoD ID), but at the end of the study your DoD ID and any identifying information will be destroyed so that none of the study data can be directly linked to you. The information from medical records will be anonymized and tied to a random subject identification number assigned to you, rather than using any DoD ID.

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

If you choose to take part in this study: The risks for this study are minimal. In fact these treatments are already standard treatments used for clinical care, meaning you could receive any and all of them even if you were not participating in this study. Due to randomization, you may or may not receive the same treatment plan that would have occurred if you were not in the study. Unrelated to the research, but associated with some of the treatment you might receive are some potential discomforts. For example, it is possible to experience some increased pain or muscle soreness from doing exercises. Usually the soreness lasts less than 24 hours, but in some cases can go out to 3-4 days. Based on our clinical experience, the chances of this are unlikely, and these extended cases occur in less than 1% of individuals. Again, this could be just as likely to happen if you were doing the exercises outside of the study. You will always be able to discuss your individual situation with either your physical therapist or your primary care provider at any time during the study.

Although very strong efforts are made to protect your research study records, and this is unlikely, 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. However, this will be difficult as we are required to keep data safe (secured and encrypted data files, removal of identifiable information, etc.) and follow processes to minimize the chances of this happening.

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

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

There is no guarantee you will receive any benefit from this study other than knowing that the information may help future patients. The information we learn through this study may help us better manage patients with knee osteoarthritis in the future. You may benefit from the treatment provided, as it may help you better manage your symptoms.

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

There may be other options for treatment. Alternative treatments and/or procedures that may be available to you include: self-management strategies and seeing other medical providers. You should talk with your personal primary care provider (if applicable) about these options.

Choosing not to take part in this research study is also an option.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes, there may be compensation for participating in this study.
Compensation will be provided upon successful completion of all required surveys and outcomes at 3 key follow-up periods: 6 months, 1 year and 2 years. This will consist of an electronic gift card that will be emailed to you upon verification that your survey has been completed for each time point. You will receive 1 gift card for $25 after completing the 6-month surveys, $50 after completing the 1-year surveys, and $75 after completing the 2-year survey, for a total of $150. You must allow us to enter your email into a 3rd party service that will manage the gift card delivery in order to receive the gift cards.

If you are on active duty, we will ONLY be able to compensate you if you fill out the surveys during off-duty time. Because your follow-up will occur electronically, you will be able to do this on your own time when checking your email (evenings, weekends, etc). No compensation can be legally made if you do this during duty hours or have to come in to the clinic to fill these out during duty hours according to existing regulations (DoD Instruction 3216.02).

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. WHO IS CONDUCTING THIS RESEARCH?

The Department of Rehab Medicine, Brooke Army Medical Center, in collaboration with the University of Utah, is conducting this clinical trial.

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

As the 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:

The Department of Defense (DoD) is funding or supporting the study through the Congressionally Directed Medical Research Program by way of the Geneva Foundation, a non-profit agency that supports research in military medicine. The Geneva Foundation is providing the direct funding support for this study and is responsible for delivery of compensation funds for participation.

13. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Principal Investigator: MAJ Bryan Pickens PT, DSc

14. LOCATION OF THE RESEARCH:

Brooke Army Medical Center
3551 Roger Brooke Drive
JBSA Fort Sam Houston, 78234

15. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

16. 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.

Procedures to protect the confidentiality of the data in this study include but are not limited to: We will assign an anonymous identification number that is linked to your file, and will use that to organize your study data instead of any personal identifiers (name, DoD ID, etc). Data will be locked in drawers in locked offices of the investigators, in HIPAA-compliant files on encrypted and secure computers. Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, a description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of results. You can search this website at any time.

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.

Investigators involved in this study will have access to your de-identified data, to include the study team at the University of Utah. De-identified data means that there is no way for them to know who you are based on the type of data they have. Investigators outside of DoD will not have access to anything that is identifiable or any data which contains any of the 18 guarded HIPAA variables. Approved research coordinators and assistants will have access to your personal data as they help collect, store, and prepare it for analysis. After it has been collected and prepared, all the identifying information is deleted permanently.

In some cases, we will use 3rd party services to communicate by text message and/or email with you (for example, to send surveys or communication). This means that we may have to enter your name, email address, and phone number into 3rd party platforms. Your information will only be placed within accounts that belong to the research team and that only the research team has authorized access to; however, it will be kept in the storage maintained by the 3rd party service and subject to their security policies. This information will never include other personal health or private information. You can always opt out in the future if you change your mind by notifying the Primary Investigator, but we will not be able to provide you the gift card compensation.

-U.S. Food & Drug Administration (FDA)
-Other U.S. government agencies
-Regional Health Command-Central Institutional Review Board
-Department of Defense (DoD)

Those listed above may 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.

17. <u>WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?</u>

If you think that you have a research-related injury, notify your Principal Investigator immediately at MAJ Bryan Pickens at 210-808-2247.

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.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: 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.

18. <u>WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?</u>

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. Should you choose to withdraw, you must notify the principal investigator in writing. Your condition will continue to be treated in accordance with acceptable standards of medical treatment. You may be asked if you wish to provide further data collection from routine medical care. The data collected prior to your withdrawal, and the healthcare utilization data from medical records, will still remain part of the study database and will not be removed.

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 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, or if you no longer meet eligibility criteria.

19. <u>VOLUNTARY PARTICIPATION:</u>

The decision to take part in this research study is completely voluntary on your part. 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. <u>PERMISSION FOR CONTACT AFTER COMPLETION OF THIS STUDY</u>

This study is currently approved for a follow-up period of 2 years and that is the final time we will reach out to try and understand how these treatments have influenced your knee condition. It is often helpful to see how patients are doing over a longer period of time. We would like to be able to reach out to you over the next 10 years following completion of this study. If we do reach out, we will call or email you first to ask your permission to send you an additional survey at that time. You may or may not be compensated for that survey, but we will let you know those details at that time we contact you, and you are always free to decline participation. In order for us to contact you and send an additional survey, we will need to:

1. Get that additional survey and the reason for it approved by the Human Protections Office and the Institutional Review Board at Brooke Army Medical Center
2. Have your permission now to reach out to you in the future and ask if you want to participate at that time (you will always be free to decline).

Please let us know if you are okay with us reaching out to you within 10 years from the study completion to ask if you want to participate in one last survey. We will not reach out to you until permission is granted from the Institutional Review Board, and you will be able to decline at that time. If you do not want us to reach out to you in the future, it will not affect your current participation in this study. Please initial one of the 2 statements below.

_____ I agree to be contacted once at some point within 10 years after the end of the study to hear about participation in a final survey. I can be contacted at the contact information that is on file for me.

_____ I DO NOT want to be contacted for any additional surveys in the future after this study is over.

21. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: MAJ Bryan Pickens
Phone: 210-808-2247
Mailing Address: Jennifer Moreno Clinic, Garden Avenue #1179, JBSA Fort Sam Houston 78234

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 IRB Office at:

Regional Health Command Central IRB Office
(210) 916-2598
3551 Roger Brooke Drive
Fort Sam Houston, TX 78234-6315

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

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

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