KELLER ARMY COMMUNITY HOSPITAL
CONSENT TO PARTICIPATE IN RESEARCH
Research Title: The Effect of Battlefield Acupuncture and Physical Therapy versus Physical Therapy Alone Following Shoulder Surgery: A Randomized Clinical Trial
Principal Investigator: LTC Jamie B. Morris, PT, DSc

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

Please take time to carefully review this information. 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 potential participation in this research 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:

Voluntary Participation	You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study. Your decision will not affect your current or future care at Keller Army Community Hospital. 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.
Purpose	The purpose of this research study is to learn about the effectiveness of Battlefield Acupuncture on post-surgical pain, mood, and prescription pain medication use. The duration of your participation in this study would be approximately 1 month.
Duration	During the study, you will attend five follow-up (24-48 hours, 72 hours, 1 week, and 4 weeks post-surgery) visits with a physical therapist.
Procedures	At each visit the principal investigator (or one of the associate investigators) will assist you with completion of data collection forms. Your physical therapist will prescribe and supervise the progression of your post-operative rehabilitation program.
Why might you want to participate in this research (benefits)?	The most likely benefit of your participation in this study is reduced pain. Additional benefits may include improved mood and reduced opioid usage.

Why might you choose not to participate in this research (risk)?	Complications associated with Battlefield Acupuncture are very rare. The greatest risk is infection at the acupuncture site. Discomfort at the insertion site and minimal skin irritation may occur.
What are the alternatives to participating?	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.

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

2. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to learn about the effect of Battlefield Acupuncture on post-surgical pain, mood, and prescription pain medication use.

This study is looking at Battlefield Acupuncture, which is a form of auricular acupuncture performed in the ears at specific sites. The Battlefield Acupuncture technique involves inserting one needle at a time into specific acupuncture pain control points in your ear using a specific sequence. You may require one, two, or up to 10 needles to get maximum pain relief. You are in control, and we can stop at any time or when your pain level had been reduced to 0-1/10. Battlefield Acupuncture after orthopedic surgery has not been well-studied. This means that Battlefield Acupuncture is considered experimental for post-surgical pain control and rehabilitation.

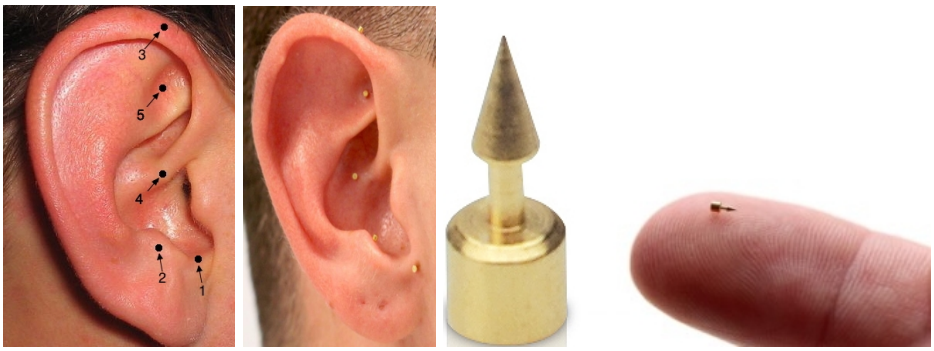

Figure. Battlefield Acupuncture needle insertion points on the ear

At the end of this research study the clinical results, including research results about you will be shared with you. Study results shared will include changes in pain level, changes in mood, and medication utilization.

3. WHY ARE YOU BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you have chosen to have shoulder surgery.

4. HOW LONG IS THE RESEARCH STUDY?

Participation in the study involves four visits to the physical therapist over the course of 1 month. The duration of participation per visit is approximately 30 minutes. During each visit, we estimate that it will take approximately 5 to 10 minutes to fill out data collection forms and 3 to 10 minutes to complete the Battlefield Acupuncture procedure.

There will be about 106 people taking part in the study at the Keller Army Community Hospital (KACH) Physical Therapy Clinic and Arvin Gym Cadet Physical Therapy Clinic over a period of 4 years.

During the study, you will have about four visits with a physical therapist and study investigator. You may need to return to the KACH PT Clinic or Arvin Gym Cadet Physical Therapy Clinic 24-48 hours, 72 hours, 1 week, and 4 weeks post-surgery.

5. 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 been collected as a part of your regular medical care. The information includes confirming you meet the qualifications for the study, specifically:

- You are a Department of Defense beneficiary or Cadet between 18 and 55 years old, or that you are an emancipated 17-year-old
- You had or will have a shoulder stabilization surgery within 24-48 hours
- You are fluent in speaking and reading English
- You are experiencing a minimum of minor, mild, or discomforting shoulder pain
- You are not currently pregnant
- You have never been diagnosed with a bleeding disorder or are currently taking blood thinners/ anti-coagulant medication (for example: Xarelto, Lovenox, Eliquis, etc)
- You do not have a current active infection and have never been diagnosed with a blood borne pathogen (for example: hepatitis B (HBV), hepatitis C (HCV), human immunodeficiency virus (HIV))
- You do not have a metal allergy

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

You will: Attend outpatient physical therapy and receive standard post-surgical rehabilitation for four visits over four weeks after your specific shoulder surgery. If assigned to the experimental group, you will also receive one to four treatments of Battlefield Acupuncture. The procedure of Battlefield Acupuncture is relatively quick, taking 3-10 mins to complete. Data collection forms will be filled out during each follow-up visit. Completion of the data collection forms will take 5-10 minutes.

You will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to the experimental or control group. If assigned to the experimental group, you will receive Battlefield Acupuncture at five sites in both ears for one to four sessions, as determined by a licensed/privileged physical therapist,

during the first four weeks of treatment. All patients in the experimental group will also perform standard post-surgical rehabilitation for your specific shoulder surgery. All acupuncture treatments will be done prior to start of your physical therapy session and data collection forms will be completed at time intervals post-surgical of 24-48 hours, 72 hours, 1 week, and 4 weeks after surgery. If assigned to the control group, you will perform standard post-surgical rehabilitation for your specific shoulder surgery and complete the data collection forms at the same intervals (24-48 hours, 72 hours, 1 week, and 4 weeks after surgery).

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

If you choose to take part in this study, there is a risk of:

- Rare but serious (Event Rate < 1%): infection
- Less likely (1% ≤ Event Rate < 5%) headache, nausea, somnolence, euphoria
- Likely (5% ≤ Event Rate < 10%): headache, nausea, euphoria
- More likely (Event Rate ≥ 10%): site irritation (redness, dermal thickening), pain with needle insertion

The most common discomfort is from the insertion of the needles at their Battlefield Acupuncture sites and minimal skin irritation. Some of the Battlefield Acupuncture insertion points are very tender, so the intensity and duration of discomfort from the needles may vary among the points. You will be monitored throughout the entire process for adverse effects of Battlefield Acupuncture.

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.

If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document.

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

8. ARE THERE BENEFITS TO TAKING PART IN THIS RESEARCH STUDY?

The possible benefits to you as a research participant in this research study are reduced pain, improved mood, and reduced opioid medication usage. However, there is no guarantee that you will benefit from being in this research.

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

There may be other options for rehabilitation after shoulder surgery. Alternative treatments and/or procedures that may be available to you include: the standard Keller Army Community Hospital rehabilitation guidelines after shoulder surgery. You should talk with your personal physician (if applicable) about these options.

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

10. WILL YOU GET PAID FOR TAKING PART IN THIS RESEARCH STUDY?

No, you will not receive any compensation for participating in this study.

11. ARE THERE COSTS FOR TAKING PART IN THIS RESEARCH?

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

12. WHO IS THE 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.

The Department of Defense (DoD) Defense Health Agency (DHA) provided funding for this research study. As a sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

13. IS THERE A SOURCE OF FUNDING?

Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

14. WHAT IS THE LOCATION OF THE RESEARCH?

Keller Army Community Hospital, West Point, NY 10996

15. ARE THERE ANY DISCLOSURES OF FINANCIAL INTERESTS OR OTHER COMMERCIAL RELATIONSHIPS?

None of the investigators has any financial interests or other personal arrangements that the institution, the research team members, or their immediate family members, might have with this study, with its sponsors/funding sources, with the manufacturer of the tested drug, device, biologic or medical supply, or with a storage bank where any study specimens could be subsequently sent. Such interests may include but are not limited to: direct/indirect money payments; transfers of value; ownership interests; significant investment interests; or proprietary rights in the tested product.

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.

The coded electronic research data for this study will be stored in Research Electronic Data Capture (REDCap), an encrypted, access controlled, password protected electronic data capture and management system housed on a Department of Defense (DoD) server and maintained by the Uniformed Services University Information Technology (USU IT). No Personally Identifiable Information (PII) will be entered into REDCap.

This coded electronic research data will only be accessible by research staff designated and authorized by the Principal Investigator and authorized staff from Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University in Bethesda, MD, and is serving as the data coordinating center for this research study. Staff from MIRROR/USU will not have access to identifiable research data. Access to the coded research data will be governed strictly on an individual-by-individual basis within REDCap. Individual data access as well as privileges will be clearly delegated, audited, and monitored by MIRROR/USU. 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:

These records may be examined by staff from the Keller Army Community Hospital Department of Clinical Investigation, the RHC-A Institutional Review Board (IRB), Clinical and Translational Research Program Office US Army Medical Command (CTRPO) and other government agencies as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your name will not appear in any published paper or presentations related to this study. This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

Every effort will be taken to protect your identity as a participant in this study. You will be assigned a unique study number. The information that you provide will be stored with your study number, not with your name and SSN. All records will be maintained in a secured cabinet in a secured room. Only the investigators and their associates conducting or auditing this study will

have access to the records from this study. If you sustain an injury during sports participation, the medical staff at KACH will treat you per established procedures.

You will not be identified in any report or publication of this study. In all publications or presentations resulting from this research project, your anonymity will be protected to the maximum extent possible, unless you give consent below to allow the researchers to use photographs or videotapes containing a portion of your testing at professional forums such as scientific meetings. You will be asked to give permission for this at the end of this form.

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

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.

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.

The researchers 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.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

17. WILL YOUR INFORMATION BE USED IN THE FUTURE?

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. This future research may be in the same area as the original study, or it may be for a different kind of study or distributed to another investigator for future research studies. The specifics of these research studies are unknown at this time, but these studies will frequently be in the area of rehabilitation after shoulder surgery. For example, in future studies we may want to merge the outcomes of this study with studies at the Keller Army Community Hospital you may have consented to previously that have longer term follow-up.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) 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.

The research team in the Arvin Physical Therapy Clinic will keep your research data for up to six years following the end of this study. The master code list which connects your identity with your unique study number will be destroyed as soon as all data collection is completed and analyzed. This consent form and HIPAA authorization will be maintained for a period of six years after the study is completed.

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.

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 others for future approved research studies.

HIPAA AUTHORIZATION

I. Purpose

An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information:

The purpose of this randomized clinical trial is to determine the effectiveness of Battlefield Acupuncture (BFA) in addition to standard post-surgical shoulder physical therapy compared to a standard shoulder rehabilitation program in reducing medication use and pain in patients who have undergone shoulder surgery. Due to the nature of the military's work in austere environments and the need for constant deployment readiness, prolonged use of prescribed pain medications (opioids specifically) drastically limits readiness. Side effects from narcotic pain medications directly increase duty limitations. It is important for the military to identify alternative pain management interventions after orthopedic surgery.

A. What health information will be used or disclosed?

If you choose to participate in this study the following health information will be collected: surgical history, previous injury history, self-reported pain and mood, and pain medication usage. This information will be protected. If you decide to participate in this study, you will be assigned a number upon entrance into the study and subsequently given consent forms and data collection forms with the corresponding number. A master spreadsheet document linking subject names and

their subject numbers will be kept secure on a government computer assigned to the PI. The computer is password and CAC-card protected, and the system is firewall protected. This document will not be shown to anyone except for the investigators in this study or governmental agencies only in accordance with federal law.

Any data submitted to an approved agency for review will be linked only to your study number and not your personal identity (i.e., protected health information such as name, SSN, address, phone number, etc.). If the data are used in scholarly presentations or journal articles, the investigators will protect the anonymity of individual patients and will report only aggregate data (e.g. group means) where appropriate. Subjects will not be specifically identified in any publication or presentation of research results.

The disclosure of your protected health information is necessary in order to be able to conduct the research project Records of your participation in this study may only be disclosed according to federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations and the Health Insurance Portability and Accountability Act (HIPAA), and its implementing regulations, when applicable, and the Freedom of Information Act, 5 U.S.C. Sec 522, and its implementing regulations when applicable. 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.

Note: Protected health information of military service members may be used or disclosed for activities deemed necessary by appropriate military command authorities to ensure the proper execution of the military mission.

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

B. Who will be authorized to use or disclose (release) your health information?

The participant's health information will be accessed using the Armed Forces Health Longitudinal Technology Application (AHLTA) and Cadet Injury and Illness Tracking system (CIITS). Information will be obtained at Keller Army Community Hospital (KACH) Physical Therapy department, Arvin Gym Physical Therapy Clinic, and/or Mahan Hall.

The Principal Investigator may use and share your protected health information with:

- State and Federal Government representatives, when required by law.
- Department of Defense representatives for compliance and oversight
- Naval Medical Center Portsmouth

C. Who may receive your health information

Only researchers involved in this specific study will have access to your health information.

D. What if you decide not to sign this Authorization?

The MHS **will not** refuse treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?

No, your health information *is not* requested for future research studies.

F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you take back this authorization?

You may change your mind and take back your Authorization at any time. However, if you take back this Authorization, any person listed above may still use or share any already obtained health information as necessary to maintain the integrity or reliability of this research.

If you take back this Authorization, you may no longer be allowed to take part in this research study.

If you want to take back your Authorization, you must write to: Erin Miller at erin.m.miller45.ctr@health.mil

The KACH HIPAA/Privacy Officer is Mrs. April Guardi, 845-938-5033, april.a.guardi.civ@health.mil

H. Does this Authorization expire?

Yes, it expires at the end of the research study.

I. What else may you want to consider?

No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you

If all the information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or shared for other purposes

In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

18. WHAT HAPPENS IF YOU WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must contact the principal investigator (LTC Morris) and the physical therapist who is providing your treatment as soon as possible. By leaving this study at any time, you in no way risk losing your right to medical care and there will be no penalty to you and you will not lose any of your benefits to which you are otherwise entitled. If you decide to no longer participate in this research study, the researcher will still retain and analyze any previously collected data that was part of this research study.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your referring physical therapist 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. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military and their dependents), you are entitled to 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 Army hospitals or clinics. If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are entitled to medical care for your injury at an Army hospital or clinic. Medical care charges will be waived. It cannot be determined in advance which Army hospital or clinic will provide care. If you obtain care for research-related injuries outside of an Army hospital or clinic, you or your insurance will be responsible for medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries:
Transportation to and from hospitals or clinics will not be provided. No 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. If you believe you have sustained a research-related injury, please contact the Pl. If you have any questions, please contact the PI.

20. WHO DO YOU CONTACT IF YOU HAVE QUESTIONS?

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: LTC Jamie B. Morris, PT, DSc
Phone: 845-938-3067
Mailing Address: 900 Washington Rd, West Point, NY 10996

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

Human Protections Administrator/HRPP POC: Ms. Lori Cartwright
Phone: 845-938-2680

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:
Naval Medical Center Portsmouth
620 John Paul Jones Circle
ATTN: CID
Portsmouth, VA 23708
(757) 953-5939
usn.hampton-roads.navhospporsva.list.nmcp-irboffice@health.mil

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.

21. <u>FUTURE USE OF INFORMATION:</u>

_____I *<u>do not</u>* wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that my current principal investigator may use any appropriate identifier to locate me in the future.

22. SIGNATURES

SIGNATURE OF PARTICIPANT

Your signature below indicates that:

- You authorize the Military Health System to use and reveal your health information for the research purposes stated above;
- You have read (or someone has read to you) the information in this consent including the HIPAA Authorization;
- You agree that you 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 you. You have been provided with the opportunity to ask questions
- You voluntarily consent to take part in this research 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 (DDMMMYYYY)

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 (DDMMMYYYY)