NAVAL MEDICAL CENTER CAMP LEJEUNE
CONSENT TO PARTICIPATE IN RESEARCH
Title: Cervical Plexus vs Infiltration for Clavicular Operations
Principal Investigator: CDR Michael A. Lee, M.D.

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 that 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 any consequence.

1. KEY INFORMATION:

Your clavicle, or collarbone, is a bone that connects your breastbone to your shoulder blade. There can be a lot of pain after you have clavicle surgery. Your doctors normally choose what pain control they think will be best for you, but there isn't one best way to manage your pain after clavicle surgery. One type of medicine can numb the area where you had surgery. You can get this type of numbing medicine in different ways.

Local Infiltration Analgesia is when the surgeon injects numbing medicine into the surgical area during your surgery. A **Cervical Plexus Block** is when the anesthesiologist injects numbing medicine around the nerves that can feel pain near your clavicle.

However, doctors have not studied if Local Infiltration Analgesia is better or worse than a Cervical Plexus Block to help with pain after clavicle surgery. The goal of this study is to compare pain between people who got Local Infiltration Analgesia to people who got a Cervical Plexus Block.

If you take part in this study, at the beginning of your surgery, the anesthesiologist will give you a Cervical Plexus Block. At the end of your surgery, your surgeon will give you Local Infiltration Analgesia. One of these injections will be numbing medicine and the other will be saline. This decision will be made at random, like by the flip of a coin. Information will be collected about you, your surgery, and your pain. You will also get a phone call from the research team the day after your surgery to ask about your pain.

Taking part in this study is optional. If you choose to take part, you will be in the study from the time you come into the hospital for surgery until two days after surgery.

There are risks any time you get an injection. It is not very common, but it is possible you may have an infection or bleeding where the injection was or numbness in places other than the surgery site. Some of these risks can be serious, like an allergic reaction to the medicine, damage to your nerves, or life-threatening injuries if the injection is put in the wrong spot.

There are no guaranteed benefits to being in this study. However, you might have less pain, may need less pain medicine, or have fewer side effects from pain medicine.

If you choose not to participate in this study, your doctors will choose a pain control plan based on their experience and judgment.

Your decision will not affect your future care at Naval Medical Center Camp Lejeune. 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. Please read 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 OF THIS RESEARCH STUDY?

You are being asked to take part in this research study because you will be receiving a surgery on your clavicle under general anesthesia.

Your clavicle, or collarbone, is a bone that connects your breastbone to your shoulder blade. If your clavicle bone breaks, you may need surgery. There can be a lot of pain after you have clavicle surgery. Your doctors normally choose what pain control they think will be best for you, but there isn't one best way to manage your pain after clavicle surgery.

Most people get pain medicine they take by mouth (oral medications), or medicine put directly into their bloodstream (intravenous, or IV, medication). There is also medicine that can numb the area where you had surgery. This type of medicine is called a local anesthetic. You can get a local anesthetic in different ways.

Local Infiltration Analgesia, or LIA, is when the surgeon injects local anesthetic into the surgical area during your surgery.

A **Cervical Plexus Block, or CPB,** is when the anesthesiologist, the doctor who keeps you comfortable during surgery, injects local anesthetic around the nerves that can feel pain near your clavicle.

However, doctors have not studied if LIA is better or worse than a CPB to help with pain after clavicle surgery. The goal of this study is to compare pain after surgery between people who got Local Infiltration Analgesia to people who got a Cervical Plexus Block.

There will be 40 people taking part in this study at Naval Medical Center Camp Lejeune, over about two years.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH AND HOW LONG WILL IT TAKE?

If you choose to participate, you will be in the study for the time required for pre-surgery preparations, your planned surgery, and the first 48 hours after surgery. You will not have to make any extra hospital or doctor visits.

You will be randomly assigned to one of two groups: the CPB group or the LIA group. Randomization is a process like flipping a coin and means you will have a 50% chance of being assigned to either group.

A chart showing the timeline of the research study is on the next page (Figure 1). It is a brief summary of the information written here.

Before your surgery, information about you will be collected, like your age, height and weight, heart rate and blood pressure.

During your surgery you will be under general anesthesia to keep you comfortable and control your pain during the surgery. This is sometimes called "being put to sleep" or "being put under." Information about your surgery, like the time it starts and ends, what medicines are used for general anesthesia, and any complications will be collected.

At the beginning of the surgery, while you are under general anesthesia, you will be given a CPB injection.

- If you are in the **CPB group**, then the CPB injection will have **local anesthetic** in it.
- If you are in the **LIA group**, the CPB injection will have **saline** in it.

Local anesthetic is a drug to reduce pain at a single location. Saline is like salt water and is not a drug. During the surgery, your surgeon will fix your clavicle. The anesthesiologist will keep making sure you are breathing well and don't have any pain.

At the end of your surgery, while you are still under general anesthesia, you will be given a LIA injection.

- If you are in the **CPB group**, then the LIA injection will have **saline** in it.
- If you are in the **LIA group**, the LIA injection will have **local anesthetic** in it.

After your surgery you will go to a room where a nurse will make sure you don't have any bad reactions to the surgery or anesthesia. Information about your pain, your comfort, and any medicines you need will be collected.

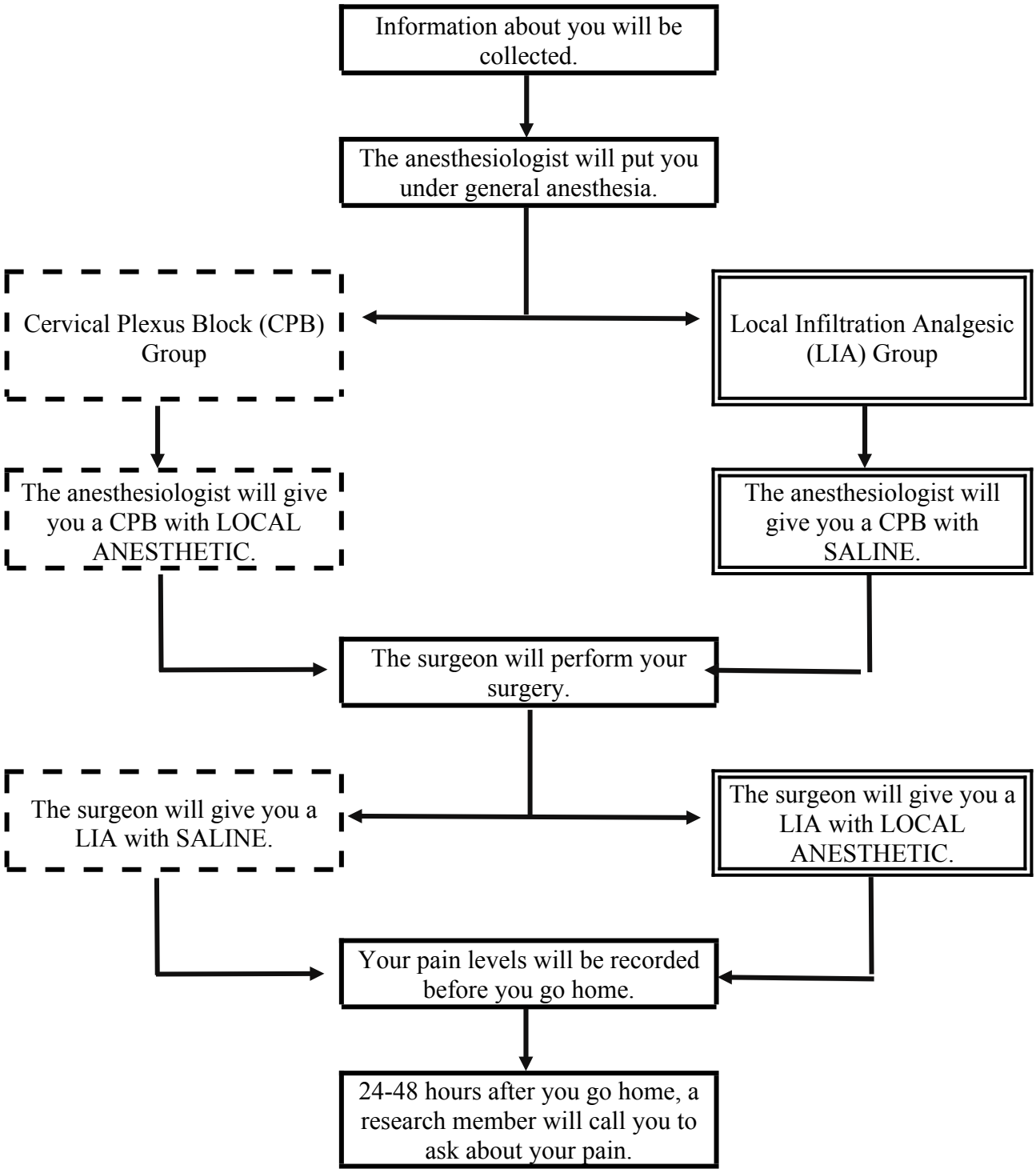
You will be given pain medicine when you go home. You will be asked to keep track of your pain for 24 hours after leaving the hospital. To help you keep track, you will be given a pain diary. The day after you've been home for 24 hours, a member of the research team will call you. They will ask you about your pain, using the same questions that will be on your pain diary.

After this phone call, you will be all done with the study.

This research study is a blinded study, which means that you, your surgeon, your anesthesia provider, and the rest of the care team will not know which injection has local anesthetic and which injection has saline.

At the end of this research study, after all 40 participants have taken part, the results (including research results about you), will not be shared with you.

Figure 1. Brief Study Timeline



4. 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 injury from additional injections. Both CPB and LIA injections are normally very safe, but sometimes injuries can happen. Examples of mild injuries that can happen when getting an injection are:

- Mild allergic reactions to the local anesthetic,
- Bleeding or bruising where the injection was placed, or
- Temporary numbness near where the injection was placed.

Mild injuries can happen in 1 in 10 people who get an injection.

Examples of severe injuries that can happen when getting an injection are:

- Permanent nerve damage,
- Severe allergic reactions to the local anesthetic,
- Heart problems caused by injections are given in the wrong place, or
- Overdose of local anesthetic.

Severe injuries are rare but can happen in 1.3-3 in 10,000 people.

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 are ABLE TO BECOME PREGNANT and you want to take part in this study, you should know that anesthesia might be harmful to (1) an unborn child if you are pregnant; or (2) an infant if you are breast-feeding. You will take a pregnancy test before you can participate in this study. You should not get pregnant or breastfeed while in this study. The only completely reliable methods of birth control are not having sex or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy.

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.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no guaranteed benefits to being in this study. However, you might have less pain, may need less pain medicine, or have fewer side effects from pain medicine. Others may also benefit in the future from the information learned in this study. Surgeons and anesthesiologists may be able to help future patients have less pain after their clavicle surgery.

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

Your alternative is not to participate in this research. If you choose not to participate in this study, you can still have surgery. Your doctors will work with you to decide how to control your pain after surgery.

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

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

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

9. IS THERE A SOURCE OF FUNDING?

No funding is being provided for this research study.

10. WHAT IS THE LOCATION OF THE RESEARCH STUDY?

Naval Medical Center Camp Lejeune, NC, Department of Anesthesia and Pain Medicine

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

No financial interests or personal arrangements to disclose.

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

Your records related to this research study may only be shared 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. You can locate and read the form online (https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf), or a copy of the form can be given to you upon request.

The research team will keep your research records. These records may be looked at by staff from the Department of Anesthesiology and Pain Medicine, the Institutional Review Board (IRB), and the DoD Higher Level Review 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.

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

- Saving your electronic data on computers that can only be used by authorized people who have the password,

- Locking drawers and offices where any paper copies of your data is being kept, and
- Removing information that can identify you from the collected data.

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

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.

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.

13. WHAT HAPPENS IF THE RESEARCHERS SEE AN INCIDENTAL FINDING?

There is a possibility that while reviewing your medical information 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. If you are 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. A qualified person (usually a member of the research team) will talk to you if there is an incidental finding.

14. 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.

15. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must tell your anesthesiologist or surgeon before receiving any anesthetic medicines. If you decide to no longer participate in this research study, the researcher may use any data collected prior to your withdrawal for research purposes. If you choose to proceed with surgery but withdraw from this study, your anesthesia provider and surgeon will choose a pain control plan based on their experience and judgment.

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 the investigator 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.

16. 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 in the section below.

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.

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.

17. 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: CDR Michael A. Lee, MD
Phone: (910) 450-4786
Mailing Address: Naval Medical Center Camp Lejeune, Department of Anesthesia and Pain Medicine, 100 Brewster Blvd, Camp Lejeune, NC 28745

Naval Medical Center Portsmouth Human Research Protection Program (HRPP) Office
The Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator: Chemely Walker, MS
Phone: (910) 450-3460

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

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

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

18. HIPAA AUTHORIZATION

An Authorization is your signed permission to use or reveal 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 reveal 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 below.

The consent above describes the purposes of the requested use and disclosure of your health information. 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. If you do not wish to give permission to use and disclose your health information, you may not be able to participate in the study.

A. What health information will be used or disclosed?

We will collect information about:

- Your personal data, like your age, sex, weight, height, and physical status,
- Your vital statistics, like your blood pressure, heart rate, and oxygen levels,
- Why you are having surgery and how long it took,
- What medicines you got before, during, and after surgery,
- Any complications you might have from the surgery or anesthesia, and
- Your pain levels after surgery, when you leave the hospital, and for the first 24 hours after you are home.

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

- Naval Medical Center Camp Lejeune
- TRICARE

C. Who may receive your health information?

The research team will collect and use your health information. As part of the research study, your information may be seen by:

- NMCCL's Clinical Investigations Department,
- NMCCL's Anesthesiology Department,
- NMCCL's Surgery Department,
- Institutional Review Boards (IRBs) at NMCCL and Naval Medical Center Portsmouth, and
- The DOD.

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

You do not have to sign this Authorization, but if you do not, you will be able to participate in the study.

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 revoke this authorization?

- You may change your mind and take back your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

  CDR Michael A. Lee MD
  Department of Anesthesia and Pain Medicine
  100 Brewster Blvd, Camp Lejeune, NC 28745

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 disclosed 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.

19. 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 as described in the HIPAA Authorization;
- 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 have 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 approved to administer consent)

_____
Printed Name of Administering Individual

_____ __ __ / __ __ __ / __ __ __ __
Signature of Administering Individual Date (DDMMMYYYY)