“How do the neck muscles influence head acceleration during sport-associated impact events in high school athletes?”

NCT03883165

Date: 12/9/2023

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: How do the neck muscles influence head acceleration during sport-associated impact events in high school athletes?

Company or agency sponsoring the study: National Institutes of Health (NIH)

Names, degrees, and affiliations of the principal investigator and study coordinator:
Principal Investigator: James T. Eckner, MD, MS – Department of Physical Medicine & Rehabilitation
Study Coordinator: Dan Farkas, MS – Department of Physical Medicine & Rehabilitation

1.1 Key Study Information

This research is studying neck strengthening exercises in a small number of people to learn about its safety and its effect on your body as a potential way to prevent sport related concussions. This study will attempt to determine how neck strengthening exercise affects head acceleration during sport-associated impacts. Your health-related information will be collected for this research study.

You, or your child, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child'. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This study uses a process called randomization to assign participants to one of two exercise groups described below (like the flip of a coin). The participants or researchers cannot choose the assignment and one-in-two study participants will be assigned to each group. Participants will be evenly assigned between Groups 1 and

2. If you decide to be in the study, you must be comfortable not selecting which group you will be assigned to.

- Group 1: Workouts ***without*** neck strengthening exercises
- Group 2: Workouts ***with*** neck strengthening exercises

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. More detailed information will be provided later in this document. The main risks for participants in this study are neck pain/discomfort, muscular discomfort/pain or headache associated with the strengthening activities or as a possible response to laboratory measurements.

This study may offer some benefit to you now, and to others in the future by reducing the risk of sport-related concussion by completing a neck strengthening exercise program. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be approximately up to 16 weeks.

You can decide not to be in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: Sport-related concussion is a common and serious injury that can affect athletes of all ages in any sport. The study team believes that greater neck strength may lower an athlete's risk of sport-related concussion. The purpose of this project is to study the effect of a 12-week strengthening exercise program on athletes' neck size and strength, as well as how their heads and necks move when test forces are applied in a controlled laboratory setting.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? Healthy male and female soccer players between the ages of 13 – 19 years can take part in this study.

Athletes cannot take part in this study if they have participated in a neck strengthening exercise program in the last 3 months; have a history of concussion(s) in the last 6 months; a history of significant neck injury or recent moderate-severe neck pain; recent low back pain for 30 or more days; a personal or family history of diagnosed, and unmanaged anxiety disorder in the last 3 years; a personal history of migraines diagnosed by a medical provider in the last 3 years requiring treatment; history of claustrophobia; recent exposure to or infection with head lice; known allergy to nickel/metal jewelry; personal or family condition known to be associated with an unstable cervical spine, or cervical spine abnormality [parental history of Down Syndrome, Ehlers-Danlos Syndrome, or Marfan syndrome; parental, or sibling history of rheumatoid arthritis/other systemic inflammatory disease with joint involvement or mucopolysaccharidosis], cervical radiculopathy (numbness/tingling), or history of cervical spine surgery; current or suspected pregnancy; are unable to speak

and understand English; or ***any abnormality found in a basic medical examination performed by the study team.***

3.2 How many people are expected to take part in this study? Up to 72 athletes are expected to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study? There are four parts to this study:

Visit 1: Participants will meet with a study team member(s) to talk about the study and have a targeted screening medical examination to evaluate for any study exclusion criteria to make sure it is safe for you to take part in the study. This will include looking at things like reflexes, neck range of motion, etc. If you/your child is eligible to take part in the study you will be enrolled at this visit.

Lab Visits: You/your child will provide basic demographic and sport-related information and undergo a set of baseline measures related to neck size and strength during a session in the University of Michigan Biomechanics Research Laboratory. This will include:

- Manual and ultrasound neck size and muscle measurement.
- Neck strength and head motion measurement by using your neck to pull a fixed cable attached to your head by soft headgear.
- Head motion measurement by voluntary soccer heading with standardized scenarios to imitate sport activities. **[We may use camera(s) during this task to record your movements.]**
- Head/body motion measurement by checking/blocking activities with a punching bag with standardized scenarios to imitate sport activities. **[We may use camera(s) during this task to record your movements.]**

You/your child will have 3 additional lab visits during the study to repeat the activities performed at the first lab visit. These will be at approximately at the 4, 8, and 12-week time points.

Exercise Sessions: After the first visit is complete, you will participate in a 12-week exercise program. This will involve 2 weekly exercise sessions at the Ann Arbor YMCA, or an alternate UM-affiliated location. At the beginning of the program, you will receive standardized instructions for your exercise program from a strength coach with CSCS credentials, who will monitor your progress in this program over the 12 weeks.

As described above in Section 1.1, you/your child will be randomly assigned to one of the exercise groups following Visit 1 if you/your child are eligible to take part in the study. The participants or researchers cannot choose the assignment.

- Group 1: Workouts ***without*** neck strengthening exercises
- Group 2: Workouts ***with*** neck strengthening exercises

The workouts will include exercises for large muscle groups (Ex: quadriceps, hamstrings) along with some accessory muscle groups (Ex: biceps, triceps).

MRI Visits: Some participants will complete an MRI study of their neck. You may be asked to complete up to 2 MRI visits during the approximate 16 weeks.

4.2 How much of my time will be needed to take part in this study?

- Visit 1: The first visit will take about **1.5 – 2 hours**
- Lab Visits 1 – 4: The 4 lab visits will take about **3 – 4 hours** per session
- Exercise Sessions: The 2x weekly exercise sessions for 12 weeks will take about **1 – 2 hours** per session
- MRI Visit(s): The MRI visit(s) will take about **1 – 2 hours** per session

4.3 When will my participation in the study be over?

Your participation in the study will be over after the 4th session in the University of Michigan Biomechanics Research Laboratory and final MRI, approximately up to 4 months after your first visit.

4.4 What will happen with my information and/or biospecimens used in this study?

Your de-identified collected information may be shared with the National Institutes of Health (NIH).

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent. Allowing us to do future research on your medical information will not benefit you directly.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The study team expects this research will be safe and well-tolerated by our research participants.

The known or expected risks are:

- Risk of neck pain, muscular discomfort/pain or headache, or "feel like they have the wind knocked out of them" associated with the neck strength or response to laboratory measurements. We expect this may occur infrequently and if it does occur that it will be temporary and non-serious. We will minimize the risk of pain or headache by selecting participants who are healthy athletes without a prior history of these problems or physical exam findings that might make these problems more likely to occur. You will also perform a set of warm-up exercises prior to the laboratory measurements. The forces applied to your head, neck and/or body during the experiments will be less than those you commonly experience while participating in normal recreational activities in your daily life.
- Risk of fainting/near fainting during neck ultrasound measurement. We expect this may occur rarely and if it does occur that it will be non-serious. We will limit the potential risk of fainting by asking you to sit in a chair with arm supports during the ultrasound assessment so that you will not be at risk for falling in the unlikely event that you might faint.
- Risk of skin irritation, allergic reaction to the tape/adhesives/gel or other equipment used during this experiment. We expect this may occur rarely and if present to be non-serious. We will avoid the use of any latex products and be careful when fitting the mouth guard to minimize this risk.
- Risk of skin reaction to the light emitting diodes for the kinematic camera system. This is expected to occur rarely and if present to be non-serious. We will not affix the diodes directly to the skin, and will pause recording between trials to minimize this risk.

- Risk of nervousness or claustrophobia during the MRI component of the protocol. This is expected to occur rarely and is considered non-serious. Participants will be able to notify the study team if they become claustrophobic or anxious while in the MRI scanner, and if this occurs they will be removed from the scanning tunnel. Participants will be given a separate safety screening for eligibility to undergo MRI scanning.
- Risk of neck/shoulder/back pain or headache associated with the neck strengthening exercise program. We expect that neck/shoulder/back pain may occur commonly, but that it will be brief and non-serious. The most likely reason for neck/back/shoulder pain after a neck strengthening session will be delayed onset muscle soreness, a normal and desirable effect of a muscle strengthening exercise. We will limit the risk of neck pain or headache by selecting subjects who are healthy athletes without a prior history of these problems or physical exam findings that might make these problems more likely to occur, and program intensity/volume will slowly increase over time. Furthermore, every exercise session will be supervised and administered by a strength coach who is a Certified Strength and Conditioning Specialist.
- Risk of trunk or extremity muscle pain associated with the general resistance exercise program. We expect this may occur commonly, but that it will be brief and non-serious. The most likely reason for trunk or extremity muscle pain resulting from participation in the general resistance training program will be delayed onset muscle soreness, a normal and desirable effect of a muscle strengthening exercise. We will limit the risk of trunk or extremity muscle pain due to a muscle strain by selecting subjects who are healthy athletes without a prior history of problems or physical exam findings that might make these problems more likely to occur, and program intensity/volume will slowly increase over time. Furthermore, subjects will receive instruction in the general resistance exercise program from a strength coach who is a Certified Strength and Conditioning Specialist.
- Risk of loss of privacy and confidentiality. We expect this risk is likely, but when it occurs will be non-serious. Participants may notice one another while arriving for study visits and/or exercising at the YMCA (or other exercise location), with or without the study-appointed strength coach, and may recognize one another as fellow research participants. No sensitive information is expected to be overheard in this scenario. The study team will ensure that all screening and lab-based testing occurs in a private and confidential manner.

It will be important for you to tell the researchers of any adverse reactions you may have during the study.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

If a potentially significant, unexpected disease or condition is identified incidentally during a study procedure the participant will be promptly informed. If the participant is a minor the parent/guardian(s) will also be notified. Additionally, a written notification of the finding(s) may be sent to the participant, as well as to their medical provider if this is their preference.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Participants may receive beneficial effects from the 12-week exercise program. Additionally, if having a stronger neck reduces your risk of concussion and your neck strength does increase as a result of participating in this study then your risk of concussion may be reduced by participating in this study.

It is still important to realize that there is no way to completely eliminate the risk of concussion from sport participation.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is strictly voluntary. You do not have to participate in this study if you do not want to.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no known or expected harm to you if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.

- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you will have to arrange for treatment on your own, as the study will not provide medical treatment or provide any compensation to you. You or your insurance provider will be billed for all costs of treatment for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
As part of your participation in this study you may receive a 4-month membership to the Ann Arbor YMCA, if used for strength sessions. (Dependent on current pandemic conditions in the Ann Arbor community.)

You will also be given up to $530 for your participation in all study sessions. The incentive for participation will be distributed as follows:
- $40 for completing the initial testing session in the Biomechanics Research Laboratory
- $20 for completing the initial MRI session
- $64 for completing the first 4 week set of scheduled exercise sessions ($8/session)
- $50 for completing the 2nd testing session in the Biomechanics Research Laboratory
- $80 for completing the second 4 week set of scheduled exercise sessions ($10/session)
- $60 for completing the 3rd testing session in the Biomechanics Research Laboratory
- $96 for completing the third 4 week set of scheduled exercise sessions ($12/session)
- $80 for completing the final testing session in the Biomechanics Research Laboratory
- $40 for completing the final MRI session

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Research records will be stored in a locked, secured area with limited access. The collected information stored electronically will have restricted access and password protection. All collected data will be coded and will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.
Michigan law requires the reporting of actual or suspected abuse, exploitation, or neglect by certain persons (called mandated reporters). Mandated reporters include physicians, nurses, therapists, and other medical professionals.

- If you tell us or we learn something that makes us believe that you, your child or others have been or may be physically harmed, we may be required to report that information to the appropriate agencies.

A study team may consist entirely of mandated reporters, a combination of mandated and non-mandated reporters, or entirely of non-mandated reporters. The above language accommodates each of these scenarios.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in articles, but would not include any information that would let others know who you are.

If identifiable pictures of you will be used in any publications or presentations, the researchers will ask for your separate written permission.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: James T. Eckner, MD
Mailing Address: 325 East Eisenhower Pkwy, Ann Arbor, MI 48108
Telephone: 734.936.7200

Study Coordinator: Dan Farkas MS
Mailing Address: 325 East Eisenhower Pkwy, Ann Arbor, MI 48108
Telephone: 734.936.7704
Email: UMConcussionResearch@umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111. *When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Age:_____ Date of Signature (mm/dd/yy): _____

Sig-B

Consent/Assent to video/audio recording/photography solely for purposes of this research

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you ***CANNOT*** take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my data. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-E

Legally Authorized Representative or Parent Permission for participants ages 13 - 17

Subject Name:

_____

Parent/Legally Authorized Representative:

Printed Legal Name:

_____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____