INFORMED CONSENT AND ASSENT FORM TO PARTICIPATE

IN A CLINICAL RESEARCH TRIAL

**NAME OF SPONSOR COMPANY:**  Sean Rose, M.D.

**PROTOCOL NUMBER AND TITLE OF STUDY:** 5: “Longitudinal Brain Health in Youth Tackle Football Players”

**NAME OF PERSON IN CHARGE OF THE RESEARCH**

**STUDY (STUDY DOCTOR/INVESTIGATOR):** Sean Rose, M.D.

24 HOUR NUMBER: (248) 485-7045 Option 1

### INTRODUCTION

This consent form may have words and information that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not understand. You must read, sign, and date this consent form, and initial the bottom of each page in order to participate in the study.

Throughout this document, the words "your child" and "your child's" shall be substituted for "you" and "yours" when a parent is consenting for a minor.

The investigator is the sponsor, and is being funded by Riddell, Inc. and ElMindA.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

DESCRIPTION AND/OR PURPOSE

This research project is being done to figure out if getting hit in the head while playing football affects how well your brain works.

You will wear a football helmet that has a sensor called InSite that measures when and how hard the helmet is hit. The sensor is made by Riddell (the same company that makes the helmet). The InSite sensor is already available for any team to buy and use at practice and games.

**HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY**

There will be two groups of football players ages 9-19 years old who will be in this study:. The total number of subjects is expected to be up to 280 athletes.

* 5th and 6th grade tackle football players from the Brighton Bulldogs Football and Cheer league (about 80 players)
* Varsity football players from Brighton High School (about 200 players with new players added over the next 4 years)

The study is expected to last for up to 4 years.

PROCEDURES - What will everyone in the study do?

Your head will be measured to get the best fitting helmet with the InSite sensor in it. The sensor will measure hits to the helmet. You will wear this helmet during practices and games.

Twice each year (one time before the start of fall football camp, and one time in the winter after the football season is over), you will come to The Sports Neurology Clinic for a check-up on your brain activity. The following will be done during your visit:

* History and exam – you will talk to the doctor and the doctor will check how well your brain works by testing things like strength and reflexes. At the visit, the doctor will ask you questions about your school, your family and how you feel. (The test will take 60 minutes the first time, and 30 minutes every visit after that).
* CogState – this is a computer test with playing cards (about 15 minutes)
* Neuropsychology tests – these are thinking tests you will do with pencil and paper, testing things like memory and concentration (paying attention) (about 1 hour)
* Brain Network Activation (BNA) test – you will wear a special hat on your head that measures brain waves (a message used by the brain to talk with the body) while you look at a computer and listen to noises with headphones (about 1 hour)
* Vestibular/Ocular Motor Screening (VOMS) test – you will move your eyes quickly to look at things and turn your head while looking at things (about 5 minutes)
* Balance test – you will stand in front of an X-Box Kinect video camera while you try to balance in different positions (about 5 minutes)
* Questionnaires – you will answer questions on paper (approximately 4 minutes)

What will happen if you get a concussion (brain injury)?

Your coach or athletic trainer will have a handheld device (similar to an iPhone) that tells them if your helmet sensor measures a big hit. If that happens, they will check you to see if you might have a brain injury. If it doesn’t look like you have a brain injury, you can keep playing. If it looks like you might have a brain injury, you will be held out of the game until you can see one of the study doctors. You have the option to visit any physician after your brain injury. If the doctor decides that you have a brain injury, you will schedule more doctor visits for the brain injury. You will go to the doctor’s office as many times as needed to get better, but at least the following three times:

* Within three days of the brain injury
* Seven days after the brain injury
* Seven days after you fully return to playing football

During your doctor visits, you will do many of the same tests that you did at the visits before and after the season. If you get a brain injury, you will do the following things at each visit: History and exam, CogState, BNA, VOMS, and Balance test.

All players who join this study will be treated the same, including use of the helmet sensor.

RISKS AND SIDE EFFECTS

This study should not involve any physical harm to you. None of the testing will be painful or hurt you. The risk of being in this study is the chance that someone else might hear or read the information you tell

the doctor and research team about yourself. More information about who can see personal information about you is in the section of the consent form titled “Data Privacy – Confidentiality – Authorization to Disclose Health Information”.

BENEFITS

This study may help people know more about the risks of head hits and brain injuries from playing football when you are young. This could help children in the future. Being in the study may help you by making it easier to see a doctor trained in brain injuries if you get a brain injury.

There is no guarantee that you will benefit (get money or favors) from taking part in this study.

ALTERNATIVES

You do not have to be in this study to see the doctor in the clinic. There are other doctors who can care for brain injuries in athletes. You can continue to play football without being in this study.

Your study doctor will explain these in more detail, including the important risks and benefits.

NEW FINDINGS

Any new information which is learned during the study and which may change your mind to continue taking part in the study will be made available to you.

VOLUNTARY PARTICIPATION AND EARLY WITHDRAWAL

Your decision to be in this study is your choice. You may decide not to be in the study or you may leave the study at any time. Your decision will not result in any punishment. If you decide not to be in the study, or stop being in the study, your team will provide you with a standard helmet without the InSite sensor.

INVOLUNTARY TERMINATION

The investigator, the sponsor company or IntegReview, may take you out of the study without your permission, at any time, for the following reasons:

* If you do not follow the investigator’s instructions
* If we find out you should not be in the study
* If the study is stopped
* If it becomes harmful to your health

The funder (pays for the study), the Food and Drug Administration (if applicable) or the Institutional Review Board (IRB) can also stop the study at any time.

CONFIDENTIALITY

A description of this clinical trial will be available on [http://](http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.Clinical)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 the results. You can search this website at any time.

# Data Privacy – Confidentiality – Authorization to Disclose Health Information

Release of Health Information – If you decide to be in this study, information about your health may be used or given for the purposes of conducting this study.  This information may include your medical information that was collected for the study, such as your medical history (past sickness and injuries), medications, test results, diagnoses (doctor told you of a sickness or problem), treatments, operative reports (reports from operations that you have undergone), and discharge summaries (a note of what happened at the hospital).  Information gathered by the study doctor and/or research staff for this study, such as test results, physical examinations (doctor exam of your body), information about possible side effects (sickness or problems happening after taking medicine or having a concussion), and surveys you might be asked to complete could also be used or disclosed.

Individuals that may use or get this information include: doctors, doctor’s office staff, hospital staff, the study doctor, and authorized members of the study doctor’s research staff.  These individuals may release this information to authorized members of the study doctor’s staff, the data safety monitoring boards (a group of people who watch over the safety of the study), IntegReview IRB (a group of people watching the safety of the study and how you are treated in the study), Food and Drug Administration representatives (when applicable), and other regulatory agencies. The CORE Institute, MORE Foundation, Riddell, ElMindA, and Mimic are companies who make the study possible by providing assistance, equipment, money or other support to cover the cost of doing this research. Because they are helping, they could have access to the information about the study and about you.

The information given to the people listed will not contain your name or social security number. However, people who work for the CORE Institute, MORE Foundation, Riddell, ElMindA, Mimic, IntegReview IRB, FDA or other regulatory agencies may review records with your name and social security number to make sure that the study information is right.  Because of the need to give information to these parties, total confidentiality cannot be guaranteed.

Use of Information – This information might be used to decide if you will be allowed to be in the study, to watch your healthcare during the study, to let the sponsor answer science questions about the study, and to make sure that the study has been done correctly.  Examples of why this information might be used are:  the sponsor might use the information in submissions to regulatory agencies (people that make sure we are doing the study correctly), to get approval of the product we are using in this clinical research study; and to use the information for reporting events that are not expected to regulatory agencies, such as the FDA; the sponsor may also give the information to business partners or companies it hires to help with the study; the study doctor might use the information to make reports or publications about the study; the sponsor may also give results and your information to other study doctors; the sponsor may review the information from this study in the future or mix it with information from other studies.

Once your information has been released, it is not protected by US federal regulations about information privacy and might be used or given out in ways that are not listed in this part of the consent form.

You have the right to see and be given a copy of your records related to the study for as long as the study doctor has this information.  However, you might not be allowed to see these records until after the study is finished.

Authorization to Disclose – By signing this consent form, you are letting us give information to the funders, and you are also letting them look at your medical records. Other people indicated in this section are allowed to look at your medical records, too.  You do not have to allow us to release this information by signing this consent form. But if you do not, you are not allowed to be in this study. You will be given a copy of this signed consent form that lets us give out your health information for reasons relating to this research study.

## Expiration of Authorization – Because this information is being given out for research use, there is no date when your health information cannot be given out anymore.  The sponsor may keep and continue to use your study information for many years.  The doctor may need to add to or fix information about you even after you are finished with the study, including updates of your health if that is important for the study.  People might review your medical records after the study is over.  We are allowed to do this unless you tell us we cannot anymore.

Revoking Authorization to Disclose – You may change your mind and take back this Authorization at any time. However, once you do so, you cannot be in the study anymore. Even if you take back this Authorization, the study doctor and his/her research staff might still use or disclose your health information already collected to help the current research. To take back this Authorization, you must write to:

Dr. Sean Rose

The Sports Neurology Clinic at the CORE Institute

8273 Grand River Avenue, Suite 210

Brighton, MI 48114

You do not have to sign this Authorization. However, if the study involves medical care that you would not get if you were not in the study, then you may not get research-related treatment if you do not sign this Authorization.

Also, whether or not the study involves medical care, ***The Sports Neurology Clinic*** may not put rules on treating you (not give treatment) on whether you sign this Authorization.

# COMPENSATION

You will receive a $37.50 gift card in the mail after completing the Summer and Winter bi-annual clinic visits (total $75.00 per year). This payment is in appreciation of your time and effort. Information about you, such as your name and address will be released to persons outside the research team (such as the accounting department) to process your compensation.

**COSTS**

The InSite sensor system will be provided to you for free to use while you are in the study. Tests and visits that are done only for the study will not be billed to you or your insurance company.

# Tests and visits that are standard medical care will be billed to your insurance. Post-concussion visits will be billed to insurance and players are responsible for any deductibles or copays associated with the visits.

# The summer and winter bi-annual clinic visit and the visit 7 days after return-to-play are not standard of care and will be fully covered by the research study.

# You might have unexpected costs from being in this study. Ask your doctor to talk about the costs that will or will not be covered by the study. This talk should include who will pay the costs of treating possible side effects.

# RESEARCH-RELATED INJURY

If you are injured or made sick from taking part in this research study, medical care will be provided. No funds have been set aside to pay you or provide any payment for medical treatment in the event of a research related injury. No additional compensation for medical care will be provided.

By signing this consent form you will not be waiving any of your legal rights which you otherwise would have if you were not participating in a research study.

# WHO TO CONTACT

If you have any questions about this study or your part in it, if you feel you have had an injury or a bad reaction or if you have questions, concerns or complaints about the research, you should contact:

Sean Rose, M.D.

8273 Grand River Ave, Suite 210

Brighton, MI 48114

Office Phone: (248)-485-7045 Option 1

Email: sean.rose@thesportsneurologyclinic.com

If you do not want to talk to the investigator or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study subject you may contact IntegReview. IntegReview’s policy indicates that all concerns/complaints are to be submitted in writing for review at a convened IRB meeting to:

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| --- |
|  **Mailing Address: OR Email Address:** |
| ChairpersonIntegReview IRB3815 S. Capital of Texas Highway Suite 320Austin, Texas 78704 | integreview@integreview.com |

If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact our office at:

512-326-3001 or

toll free at 1-877-562-1589

between 8 a.m. and 5 p.m. Central Time

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

**THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT**

***What is a consent form?***

The informed consent document contains information required by federal regulations. The informed consent document must be approved by an Institutional Review Board (IRB).

***What is an Institutional*** ***Review Board (IRB)?***

An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and well being of the human subjects participating in research studies.

##### ***IntegReview, the IRB for this study***

IntegReview is an IRB whose board members provide IRB services across the United States, Latin America and Japan.

To meet requirements of the law, the IntegReview Boards currently include:

* Doctors
* Pharmacists
* Nurses
* Toxicologists (people who study the harmful effects of chemicals)
* Other specialists
* Others who do not have a background in science/medicine

**SIGNATURE SECTION FOR ADULT STUDY SUBJECT**

The study, as well as the risks, benefits, alternatives, procedures and purpose has been explained to me. I have been given the opportunity to ask questions of Dr. Sean Rose and/or the research staff and have received answers that fully answer those questions.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this informed consent form for the purposes described above.

I freely agree to participate in this study. I understand that I will receive a signed and dated copy of this informed consent form.

 (Print) Name of Adult Study Subject

Signature of Adult Study Subject Date

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A signed and dated copy of this consent will be given to the participant.

Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

I certify that the “Person Obtaining Consent” is an authorized “Designee.”

(Print) Investigator

Signature of Investigator Date

**SIGNATURE SECTION FOR PARENT/GUARDIAN OF CHILDREN**

I have read this consent form (or it has been read to me). All my questions about the study and my child’s part in it have been answered.

The study, as well as the risks, benefits, alternatives, procedures and purpose has been explained to me. I have been given ample opportunity to ask questions of Dr. Sean Rose and/or the research staff and have received answers that fully satisfy those questions.

Your signature below records your permission for the child named below to be in this research and to the use and disclose this child’s protected health information.

You will receive a signed and dated copy of this form. Please keep the copy so you can look over it at any time. You may be asked to sign a new form if new information becomes available.

By signing this consent form, I have not given up any of my legal rights.

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Printed Name of Minor Study Subject

My child appears to understand the research to the best of his or her ability and has agreed to participate.

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Signature of parent, guardian or Legally Authorized Representative Date

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Printed name of parent, guardian or Legally Authorized Representative Relationship

Name and signature of second parent/guardian where required by state law

My child appears to understand the research to the best of his or her ability and has agreed to participate.

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Signature of parent, guardian or Legally Authorized Representative Date

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Printed name of parent, guardian or Legally Authorized Representative Relationship

**Note on permission by guardians**: An individual may provide permission for a child only if that individual can provide a written document indicating that he or she is legally authorized to consent to the child’s general medical care. Attach the documentation to the signed document.

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A signed and dated copy of this consent will be given to the participant.

Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

I certify that the “Person Obtaining Consent” is an authorized “Designee.”

(Print) Investigator

Signature of Investigator Date

**ASSENT FORM FOR MINOR STUDY SUBJECTS**

9-17 years of age

**Why is this research being done?**

We are trying to figure out how playing football affects your brain. People don’t know a lot about the hits to your head that aren’t hard enough to cause a concussion. We want to track those smaller hits to see if they have an effect over time.

**What will I need to do if I participate?**

When you play football, you will wear a helmet that measures how hard your head gets hit. The helmet will feel the same as a regular helmet and look the same from the outside. You will also come to our office before and after each football season to see the doctor and do a few brain tests. They will not hurt. You will be showing your strength and body control, answering questions, playing a card game on the computer, solving puzzles, and showing how well you can balance. During one of the tests, you will wear a special hat that doesn’t hurt but measures your brain waves while you listen to headphones and look at a computer.

**What happens if my helmet senses a big hit?**

If your helmet shows that you took a big hit, an athletic trainer or coach will check to see if you have a concussion, just like they would do if they saw you take a big hit. If they think you might have a concussion, you will be checked by the doctor at our office. If they don’t think you have a concussion, you can keep on playing.

**What happens if I get a concussion?**

A doctor at our office will help you get better from the concussion, just like they would for any person with a concussion. You will see the doctor in the clinic about once per week until you get better. You will also repeat some of the brain tests each time you come to our clinic.

**What happens if I don’t want to participate?**

It will not affect you playing on the football team, and you will wear a regular helmet. If you get a concussion, you can still see a doctor at our office, or go to another doctor.

**Do I have to pay anything, and do I get paid for participating?**

You will not have to pay for the office visits before and after the football season. You will get a $37.50 gift card for each of those visits. If you get a concussion, we will ask your insurance to pay for your clinic visits while you’re getting better; if they don’t, then your family may have to.

**Are there any risks to participating?**

Participating in the study will not change whether you get a concussion or not. Other people could see your personal information, but we will keep your information in a computer with a password or in a locked filing cabinet.

**Are there any benefits to participating?**

You will see a concussion doctor twice per year and very quickly if you get a concussion. The things we learn in this study might help children who play sports in the future.

**I have been given an information sheet that describes this study. I understand that I do not have to take part in this study and I can stop anytime without getting in trouble. By writing my name below, I agree to be in this study.**

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Signature of Minor Study Subject Date

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Printed name of Minor Study Subject

This minor appears to understand the research to the best of their ability and has agreed to participate.

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A signed and dated copy of this consent will be given to the participant.

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Signature of person obtaining assent Date

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Printed name of person obtaining assent

I certify that the “Person Obtaining Assent” is an authorized “Designee.”

(Print) Investigator

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Signature of Investigator Date