Official Title:	Sub-Threshold Exercise Treatment for Adolescents with Sport-related Concussion
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Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Title of research study: A Randomized Controlled Trial of Exercise Treatment for Concussion

Version Date: October 9, 2015

Investigator: John Leddy MD FASCM FACP

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you have a concussion and you are 18 years of age or older.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at one of the UB Concussion Management Clinic (716-829-5501; leddy@buffalo.edu).You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu

if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

We don't know if low level exercise or rest helps people recover from concussion. The purpose of the research is to find better ways of speeding recovery from concussion.

How long will the research last?

We expect that you will be in this research study for 3-5 weeks, depending on how fast you recover.

Permission to Take Part in a Human Research Study

How many people will be studied?

We expect about 120 people will be in the entire study locally.

What happens if I say yes, I want to be in this research?

- At your first visit you will have a physical examination by a doctor and if you are interested in being in the study, you will read and sign this consent form and have the chance to ask questions about the study. Then you will complete a computer test and a few brief paper-pencil tests to measure reaction time and memory. You will fill out a Quality of Life survey. If you are attending school, you will be asked to provide the contact information of a teacher who knows you well to complete two online surveys. You will be asked to mail a copy of your New York State Achievement Test results to the clinic. You will then have a treadmill test to see how much exercise you can do. During the test you will wear a hat that uses sound waves to measure the blood flowing in your head and a heart rate monitor to measure your pulse. You will then receive a written prescription for exercise. You will exercise for 30 minutes per day with a monitor to record your heart rate (chest strap and a watch). You will receive a text message to remind you to exercise and to record your symptoms, maximum heart rate, minutes of exercise, and number of hours in school or at work on a website after dinner each evening. You will return to the clinic every week to fill out a Quality of Life survey and have repeat computer and treadmill testing and to be checked by the doctor to see if you have recovered. You will be allowed to return to your sport or work once you have recovered. You may only need to return one or two more weeks after the first visit. The most you will have to come back is 4 weeks more after your first visit. If appropriate, regarding school issues, you will fill out a follow-up survey at the third visit and a telephone Quality of Life survey at six weeks from your last visit. All visits will require one hour of time. You will be guided and monitored by experienced research assistants and examined by the doctor. The research will be done at University Sports Medicine clinics in Buffalo and Niagara Falls, NY, during normal business hours or by special appointment if you need to come at a different time.

  Experimental procedures and therapies: exercise for 30 minutes per day (for example, on a stationary cycle or by walking on a treadmill) at a level below which you had symptoms on the treadmill test or stretching exercises near your resting heart rate during this time. You should not do any other forms of exercise or sports. Otherwise, you may do usual daily activities but not structured exercise.

  Procedures part of regular medical care that will be done even if you do not take part in the research: history and physical examination by the doctor.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment. You will be told which treatment you are getting; however your study doctor will not know.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: come to all study visits, do the prescribed treatment 30 minutes per day, avoid all other forms of exercise during the study, and record your symptoms, heart rate, etc., on the website each evening.

Permission to Take Part in a Human Research Study

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you.

Instead of being in this research study, your choices may include: Standard care.

The important risks and possible benefits of these alternatives include: you may or may not recover faster from your concussion.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

Data collected to the point of withdrawal will be used in our analyses.

Is there any way being in this study could be bad for me?

- Physical risk: There is a possibility of some symptoms re-occurring during the cognitive testing or during exercise, such as fatigue or headache. Should this occur during exercise or during cognitive testing, the test session will be stopped immediately if you cannot continue. During the exercise test there is a small risk of injury but you will perform the treadmill test under supervision of two people to minimize this risk. You may also become tired and experience muscle soreness and breathlessness common to exercising on a treadmill, although the exercise intensity is very low to start with and will be increased in a gradual manner. You may stop the treadmill test at any time you feel the need to. There is no pain or risk from the test that measures brain blood flow during exercise. You may experience some muscle soreness from stretching.
- Psychological risks: none known.
- Privacy risks: the chance of any information about your health being disclosed inappropriately is very small since all of your information is coded and not associated with your name.
- Legal risks: By signing this consent document you are not waiving any of your legal rights.
- Social risks: none known.
- Economic risks: You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

  For this study, your doctor visits are charged to you and your insurance company but any study-related tests like the treadmill test or computer tests are free.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include that you will be confident that you have recovered from the concussion and it is safe for you to return to play or work.

Permission to Take Part in a Human Research Study

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include failure to complete at least 80% of your online questionnaires or failure to attend all of your follow up visits.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the Program for Understanding Childhood Concussion and Stroke and the Ralph C. Wilson Foundation.

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

If you agree to take part in this research study, we will pay you $150 for your time and effort: $25 after the first day, $25 after the second visit, and $100 when you complete the study. Military personnel should check with their supervisor before accepting payment for participation in this research.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

Permission to Take Part in a Human Research Study

__X___ Information from your full medical records:

__X___ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

Provide a general description of information that will be collected: history of concussions, age, height, weight, concussion symptoms, heart rate and blood pressure, exercise performance, cognitive performance on a computer, number of hours of school, symptoms or problems during school, hours of work and minutes of exercise.

B. Who is authorized to provide or collect this information?

__√_ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__X___ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

___X__ b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you.

Permission to Take Part in a Human Research Study

___X__ d. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

John Leddy MD
University at Buffalo
160 Farber Hall
Buffalo, NY 14214

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date

IRB Approval Period

Permission to Take Part in a Human Research Study

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203

Title of research study: A Randomized Controlled Trial of Exercise Treatment for Concussion

Version Date: October 9, 2015

Investigator: John Leddy MD FASCM FACP

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you have a concussion and you are between the ages of 13 and 17 years.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at one of the UB Concussion Management Clinic (716-829-5501; leddy@buffalo.edu).You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu

if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

We don't know if low level exercise or rest helps people recover from concussion. The purpose of the research is to find better ways of speeding recovery from concussion.

How long will the research last?

We expect that you will be in this research study for 3-5 weeks, depending on how fast you recover.

How many people will be studied?

We expect about 120 people will be in the study locally.

What happens if I say yes, I want to be in this research?

- At your first visit you will have a physical examination by a doctor and if you are interested in being in the study, you will read and sign this consent form and have the chance to ask questions about the study. Then you will complete a computer test and a few brief paper-pencil tests to measure reaction time and memory**.** You will fill out a Quality of Life survey. You will be asked to provide the contact information of a teacher who knows you well to complete two online surveys. You will be asked to mail a copy of your New York State Achievement Test results to the clinic. You will then have a treadmill test to see how much exercise you can do. During the test you will wear a hat that uses sound waves to measure the blood flowing in your head and a heart rate monitor to measure your pulse. You will then receive a written prescription for exercise. You will exercise for 30 minutes per day with a monitor to record your heart rate (chest strap and a watch). You will receive a text message to remind you to exercise and to record your symptoms, maximum heart rate, minutes of exercise, and number of hours in school or at work on a website after dinner each evening. You will return to the clinic every week to have repeat computer and treadmill testing and to be checked by the doctor to see if you have recovered. You will be allowed to return to your sport or work once you have recovered. You may only need to return one or two more weeks after the first visit. The most you will have to come back is 4 weeks more after your first visit. Regarding school issues, you will fill out a follow-up survey at the third visit and a telephone Quality of Life survey at six weeks from your last visit. All visits will require one hour of time. You will be guided and monitored by experienced research assistants and examined by the doctor. The research will be done at University Sports Medicine clinics in Buffalo and Niagara Falls, NY, during normal business hours or by special appointment if you need to come at a different time.

  Experimental procedures and therapies: exercise for 30 minutes per day (for example, on a stationary cycle or by walking on a treadmill) at a level below which you had symptoms on the treadmill test or stretching exercises near your resting heart rate during this time. You should not do any other forms of exercise or sports. Otherwise, you may do usual daily activities but not structured exercise.

  Procedures part of regular medical care that will be done even if you do not take part in the research: history and physical examination by the doctor.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment. You will be told which treatment you are getting; however your study doctor will not know.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: come to all study visits, do the prescribed treatment 30 minutes per day, avoid all other forms of exercise during the study, and record your symptoms, heart rate, etc., on the website each evening.

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you.

Instead of being in this research study, your choices may include: Standard care.

The important risks and possible benefits of these alternatives include: you may or may not recover faster from your concussion.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

Data collected to the point of withdrawal will be used in our analyses.

Is there any way being in this study could be bad for me?

- Physical risk: There is a possibility of some symptoms re-occurring during the cognitive testing or during exercise, such as fatigue or headache. Should this occur during exercise or during cognitive testing, the test session will be stopped immediately if you cannot continue. During the exercise test there is a small risk of injury but you will perform the treadmill test under supervision of two people to minimize this risk. You may also become tired and experience muscle soreness and breathlessness common to exercising on a treadmill, although the exercise intensity is very low to start with and will be increased in a gradual manner. You may stop the treadmill test at any time you feel the need to. There is no pain or risk from the test that measures brain blood flow during exercise. You may experience some muscle soreness from stretching.
- Psychological risks: none known.
- Privacy risks: the chance of any information about your health being disclosed inappropriately is very small since all of your information is coded and not associated with your name.
- Legal risks: By signing this consent document you are not waiving any of your legal rights.
- Social risks: none known.
- Economic risks: none known

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include that you will be confident that you have recovered from the concussion and it is safe for you to return to play or work.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include failure to complete at least 80% of your online questionnaires or failure to attend all of your follow up visits.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the Program for Understanding Childhood Concussion and Stroke and the Ralph C. Wilson Foundation.

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

If you agree to take part in this research study, we will pay you $150 for your time and effort: $25 after the first day, $25 after the second visit, and $100 when you complete the study. Military personnel should check with their supervisor before accepting payment for participation in this research.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

__X___ Information from your full medical records:

__X___ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

Provide a general description of information that will be collected: history of concussions, age, height, weight, concussion symptoms, heart rate and blood pressure, exercise performance, cognitive performance on a computer, number of hours of school, symptoms or problems during school, hours of work and minutes of exercise.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__X___ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

___X__ b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you.

___X__ d. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your

authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

John Leddy MD
University at Buffalo
160 Farber Hall
Buffalo, NY 14214

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Signature Block for Assent of Child

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	

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 copy of this document will be given to the subject.

Signature of person obtaining assent	Date
Printed name of person obtaining assent	

IRB Approval Period

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203

A Randomized Controlled Trial of Exercise Treatment for Concussion
Assent to be in a Research Study - (for Children at least 12 but not yet 13 years of age)

Who are we?
My name is *Dr. Leddy* and I am a *Professor* at the University of Buffalo. I work in the Department of *Orthopaedics*.

Why are we meeting with you?
We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

Why are we doing this study?
We want to see if light exercise or rest makes you feel better after a concussion.

What will happen to you if you are in the study?

You will be examined by a doctor. Then you will complete a computer test and a few brief paper-pencil tests to measure your memory**.** You will fill out a Quality of Life survey. You will be asked to tell us the name of a teacher who knows you well. Your parent will be asked to mail a copy of your New York State Achievement Test results to the clinic. Then you will walk on a treadmill to see how you feel when you exercise. During exercise you will wear a hat to measure how much blood is going to your brain and a chest strap to measure your heart beat. Then when you go back home, you will be asked to exercise for 30 minutes a day by either riding a bike, walking or doing stretches. You will receive a text message to remind you to answer some questions on a website after dinner each evening. You will return to the doctor's office every week to have repeat computer and treadmill testing, to fill out a Quality of Life survey, and to be checked by the doctor to see if you have recovered. You will be allowed to return to your sport once you have recovered. You may only need to return one or two more weeks after the first visit. The most you will have to come back is 4 weeks more after your first visit. You will fill out a survey after the third visit and we will call you on the phone 6 weeks after your final visit to ask you about school and to complete a Quality of Life survey. All visits will require one hour of time.

What are the good things and bad things that may happen to you if you are in the study?

You may or may not recover faster from your concussion. You might learn more about how to feel better after a concussion. You may feel tired or out of breath on the treadmill and your concussion symptoms may increase. The test will be stopped if this happens or whenever you want to stop it. You may also have sore muscles from walking on the treadmill or from stretching.

Do you have to be in the study?

No you don't. No one will get angry or upset with you if you don't want to do this. Just tell us if you don't want to be in the study. And remember, you can change your mind later if you decide you don't want to be in the study anymore.

Do you have any questions?

You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Name of contact person on the study: *Dr. Andrea Hinds*

Phone Number: *716-829-5501*

* *

Signature Block for Assent of Child

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	

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 copy of this document will be given to the subject.

Signature of person obtaining assent	Date
Printed name of person obtaining assent	

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Parental Permission Form

Title of research study: A Randomized Controlled Trial of Exercise Treatment for Concussion

Version Date: October 9, 2015

Investigator: John Leddy MD FASCM FACP

Why is your child being invited to take part in a research study?

Your son/daughter is being invited to take part in a research study because your son/daughter has a concussion.

What should I know about a research study?

- Someone will explain this research study to you and your son/daughter.
- Whether or not you take part is up to you and your son/daughter.
- Your son/daughter can choose not to take part.
- Your son/daughter can agree to take part and later change his/her mind.
- Your son/daughter's decision will not be held against your son/daughter.
- Your son/daughter can ask all the questions s/he wants before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at one of the UB Concussion Management Clinic (716-829-5501; leddy@buffalo.edu).You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu

if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

We don't know if low level exercise or rest helps people recover from concussion. The purpose of the research is to find better ways of speeding recovery from concussion.

How long will the research last?

We expect that your son/daughter will be in this research study for 3-5 weeks, depending on how fast your son/daughter recovers.

How many people will be studied?

We expect about 120 people will be in this research study locally.

What happens if your son/daughter says yes, s/he wants to be in this research?

- At the first visit your son/daughter will have a physical examination by a doctor and if interested in being in the study, your son/daughter will read and sign an assent form and have the chance to ask questions about the study. Then your son/daughter will complete a computer test and a few brief paper-pencil tests to measure reaction time and memory. You and your son/daughter will fill out a Quality of Life survey. You will be asked to provide the contact information of a teacher who knows your son/daughter well to complete two online surveys. You will be asked to mail a copy of your son/daughter's New York State Achievement Test results to the clinic. Your son/daughter will then have a treadmill test to see how much exercise s/he can do. During the test your son/daughter will wear a hat that uses sound waves to measure the blood flowing in the head and a heart rate monitor to measure the pulse. Your son/daughter will then randomly receive a written prescription for a type of exercise. Your son/daughter will exercise for 30 minutes per day with a monitor to record heart rate (chest strap and a watch). Your son/daughter will receive a text message to remind your son/daughter to exercise and to record symptoms, maximum heart rate, minutes of exercise, and number of hours in school or at work on a website after dinner each evening. Your son/daughter will return to the clinic every week to have repeat computer and treadmill testing, to fill out a Quality of Life survey, and to be checked by the doctor to see if your son/daughter has recovered. Your son/daughter will be allowed to return to sport or work once s/he has recovered. Your son/daughter may only need to return one or two more weeks after the first visit. The most your son/daughter will have to come back is 4 weeks more after the first visit. Regarding school issues, your son/daughter will fill out a follow-up survey at the third visit and a telephonic survey (with a Quality of Life survey) at six weeks from the last visit. All visits will require one hour of time. Your son/daughter will be guided and monitored by experienced research assistants and examined by the doctor. The research will be done at University Sports Medicine clinics in Buffalo and Niagara Falls, NY, during normal business hours or by special appointment if your son/daughter needs to come at a different time.
- ***Experimental procedures and therapies:*** exercise for 30 minutes per day (for example, on a stationary cycle or by walking on a treadmill) at a level below which your

son/daughter had symptoms on the treadmill test or stretching exercises near your son or daughter's resting heart rate during this time. Your son or daughter should not do any other forms of exercise or sports. Otherwise, s/he may do usual daily activities but not structured exercise.

Procedures part of regular medical care that will be done even if you do not take part in the research: history and physical examination by the doctor.

The treatment your son/daughter gets will be chosen by chance, like flipping a coin. Neither your son/daughter nor the study doctor will choose what treatment your son/daughter gets. Your son/daughter will have an equal chance of being given each treatment. Your son/daughter will be told which treatment s/he is getting; however the study doctor will not know.

What are your son/daughter's responsibilities if s/he takes part in this research?

If your son/daughter takes part in this research, your son/daughter will be responsible to: come to all study visits, do the prescribed treatment 30 minutes per day, avoid all other forms of exercise during the study, and record symptoms, heart rate, etc., on the website each evening.

What happens if your son/daughter does not want to be in this research?

Your son/daughter can leave the research at any time and it will not be held against your son/daughter.

Instead of being in this research study, your son/daughter's choices may include: Standard care.

The important risks and possible benefits of these alternatives include: you may or may not recover faster from your concussion.

What happens if you or your son/daughter says yes, but changes his/her mind later?

Your son/daughter can leave the research at any time it will not be held against your son/daughter.

Data collected to the point of withdrawal will be used in our analyses.

Is there any way being in this study could be bad for your SON/DAUGHTER?

- Physical risk: There is a possibility of some symptoms re-occurring during the cognitive testing or during exercise, such as fatigue or headache. Should this occur during exercise or during cognitive testing, the test session will be stopped immediately if your son/daughter cannot continue. During the exercise test there is a small risk of injury but your son/daughter will perform the treadmill test under supervision of two people to minimize this risk. Your son/daughter may also become tired and experience muscle soreness and breathlessness common to exercising on a

treadmill, although the exercise intensity is very low to start with and will be increased in a gradual manner. Your son/daughter may stop the treadmill test at any time s/he feels the need to. There is no pain or risk from the test that measures brain blood flow during exercise.

- Psychological risks: none known.
- Privacy risks: the chance of any information about your son/daughter's health being disclosed inappropriately is very small since all of the information is coded and not associated with your son/daughter's name.
- Legal risks: By signing this consent document you are not waiving any of your or your son/daughter's legal rights.
- Social risks: none known.
- Economic risks: You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

  For this study, your doctor visits are charged to you and your insurance company but any study-related tests like the treadmill test or computer tests are free.

Will being in this study help your son/daughter in any way?

We cannot promise any benefits to your son/daughter or others from taking part in this research. However, possible benefits include that you and your son/daughter will be confident that your son/daughter has recovered from the concussion and it is safe for your son/daughter to return to play or work.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your son/daughter your son/daughter's medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Can your son/daughter be removed from the research without my OK?

The principal investigator of the study can remove your son/daughter from the research study without your approval. Possible reasons for removal include failure to complete at least 80% of the online questionnaires or failure to attend all follow up visits.

We will tell you about any new information that may affect your son/daughter's health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the Program for Understanding Childhood Concussion and Stroke and the Ralph C. Wilson Foundation.

If your son/daughter needs medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

If your son/daughter agrees to take part in this research study, we will pay your son/daughter $150 for his/her time and effort: $25 after the first day, $25 after the second visit, and $100 at study completion.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about your son/daughter and about your son/daughter's health that will be obtained by the researchers when s/he participates in the research study. Health information is considered "protected health information" when it may directly identify your son/daughter as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about your son/daughter as part of this research study?

__X___ Information from your son/daughter's full medical records:

__X___ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

Provide a general description of information that will be collected: history of concussions, age, height, weight, concussion symptoms, heart rate and blood pressure, exercise performance, cognitive performance on a computer, number of hours of school, symptoms or problems during school, hours of work and minutes of exercise.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your son/daughter's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__X___ Clinical staff not involved in this research study who may become involved in your son/daughter's care if it is potentially relevant to their treatment

Your son/daughter's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your son/daughter's information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your son/daughter's individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your son/daughter's protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

___X__ b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about your son/daughter.

___X__ d. Your son/daughter's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information

about your son/daughter will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

John Leddy MD
University at Buffalo
160 Farber Hall
Buffalo, NY 14214

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your son/daughter's individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your son/daughter receives at this institution and will not cause any penalty or loss of benefits to which your son/daughter is otherwise entitled. If you decide not to sign this authorization, your son/daughter will not be able to participate in the research study.

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research.

Printed name of child	
Signature of parent or individual legally authorized to consent to the child's general medical care	Date
Printed name of parent or individual legally authorized to consent to the child's general medical care	❑ Parent ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

IRB Approval Period

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 copy of this document will be given to the subject.

Signature of person obtaining permission	Date
Printed name of person obtaining permission	

IRB Approval Period