UNITED STATES SPORTS ACADEMY

Human Subjects Review Committee Policies and Procedures Manual

Institutional Review Board (IRB)

Revised: Nov 2019

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INSTITUTIONAL REVIEW BOARD (IRB)

PURPOSE

The Institutional Review Board (IRB) at the United States Sports Academy (Academy) will be responsible for the review of all research projects involving human subjects, which are carried out on the campus of the Academy, in the Academy Sports Medicine & Human Performance Labs, or any of its affiliated institutions, or by Academy students to meet Academy requirements. This review will determine the following.

Whether those subjects will be placed at risk; if so, whether the risk is outweighed by the benefit to the subject and the importance of the knowledge gained as to warrant a decision to allow the subject to accept those risks;

If the rights and welfare of such subjects are adequately protected by the informed consent to be obtained by appropriate methods;

If adequate steps are taken in the conduct of research activity to avoid involvement of children, minors, mentally incompetent, prisoners, the economically or educationally disadvantaged, and pregnant women so that such activity would not place the fetus at risk.

PROVISIONS TO PROTECT THE HEALTH AND SAFETY OF HUMAN SUBJECTS

It is the responsibility of the IRB Committee to insure that the setting and conditions of all projects and activities involving human subjects are such that any necessary resources of the Academy are available if required.

DEFINITIONS

Research - As defined by the Code of Federal Regulations TITLE 45 Public Welfare – Dept. of Health & Human Services, PART 46 Protection of Human Subjects (Appendix A), research means a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

Clinical Investigation - As defined by Code of Federal Regulations TITLE 45 Public Welfare – Dept. of Health & Human Services, PART 46 Protection of Human Subjects (Appendix A), "clinical investigation" means any experiment in which a drug is administered or dispensed to, or used, involving one or more human subjects. For the purpose of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

Human Subject - A living individual about whom an investigator (whether professional or student) conducting research obtains the following:

> Data through intervention or interaction with the individual. Intervention includes both physical procedures by which data are gathered (e.g., venipuncture, medical, or other treatment) and manipulation of the subject or the subject's environment that is performed for research purposes. Interaction also includes communication or interpersonal contact between investigator and subject
>
> Identifiable private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be individually identifiable (i.e., a medical record, questionnaire, etc.) Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Risk - The exposure of an individual to the possibility of injury (physical, psychological, sociological, or other) as a consequence of any activity which goes beyond the application of those established as accepted methods necessary to meet the person's needs or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

Minimal Risk - The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Investigator - A duly qualified faculty member (or a student sponsored by a faculty member) of the Academy.

Grant - A request for or an allocation of funds to support a project.

Project - A duly defined activity of academic inquiry.

Educational Activities - Those activities of a duly qualified faculty member of the Academy which are related to professional responsibilities in the areas of teaching, research and service.

IRB - Full Review - A Required IRB Review carried out by the full IRB Committee in accordance with the criteria set forth in this document.

IRB - Expedited Review - A Required IRB Review carried out by the IRB Committee Chair in accordance with the criteria set forth in this document.

COMPOSITION OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The IRB shall be appointed by the Dean of Academic Affairs, supported by the Academic Affairs Department. (Appendix B – USSA IRB Committee Members) The IRB Committee shall:

- consist of at least three (3) members of sufficiently diverse backgrounds, including consideration of racial and cultural backgrounds of members that are sensitive to issues such as the safety & protection of human rights and their physical/psychological welfare;

- include persons who are able to ascertain the acceptability of research applications in terms of institutional commitments, applicable laws/regulations and professional standards;

- include members of both sexes, when possible;

- include at least one member whose primary concerns are in behavioral disciplines;

- include at least one member whose primary concerns are in non-scientific areas;

- consist of members representing more than one profession. The Academy may invite individuals with competence in special areas to assist in the review of complex issues;

- include persons who are primarily concerned with the welfare of human subjects;

- not have a member participate in the initial or continuing review of any project in which the member has a conflicting interest;

- not have a member who is actively participating in any research project being reviewed. In such case, those involved will be excused from the review with the remaining members to administer the review protocol. If other members are needed to successfully review and vote, temporary members can be called upon within the Academic Affairs Department.

RESPONSIBILITIES OF THE IRB

A. The IRB will:

- Conduct initial and continuing review of research and report their findings and actions to the investigator and the institution.

- Determine which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

- Review proposed changes in research activities to ensure that changes in approved research, during the period for which IRB approval has been given, has not been initiated without IRB review and approval.

- Follow procedures to ensure that the IRB and the Dept. of Health & Human Services (HHS) receive reports (if applicable) of unanticipated problems involving risks to subjects and others.

- Conduct its review of research, except when an approved Expedited Review procedure is used, at convened meetings at which a majority of the members of the IRB are present.

- Approve research only with the concurrence of a majority of those members in attendance.

- Report to the Academic Committee and HHS (if applicable) any continuing or serious matters of non-compliance by investigators with the requirements and determinations by the IRB.

B. The IRB will maintain:

- Copies of all research proposals reviewed, scientific evaluations, approved sample consent documents, progress reports, and injuries to subjects.
- Minutes of meetings.
- Files, records and documentation of all reviews and review activities.
- Copies of all correspondence between the IRB and investigators.
- A list of all members.
- A copy of all written procedures.
- Statements of the significance of the study provided to subjects.
- Records required by HHS regulations, which shall be retained for at least three years after completion of the research. The records shall be accessible for review, inspection and copying by authorized representatives of the HHS.

REQUIREMENTS FOR IRB REVIEW AND APPROVAL OF RESEARCH

A. The IRB shall:

- Review and have authority to approve, require modification and/or disapprove all human research activities.

- Require that information given to subjects as a part of informed consent be in accordance with the requirements for informed consent and that additional information be provided the subject, as deemed necessary by the IRB, to add to the protection of the rights and welfare of the subjects.

- Require or waive documentation of informed consent.

- Notify in writing the investigator and the Academic Committee of its decision to approve or disapprove the proposed research or of modifications required to secure IRB approval of the research activity.

- Conduct continuing review of research involving human subjects at intervals appropriate to the degree of risk, but at least once a year.

- Have authority to suspend or terminate approval of research that is not in compliance with the IRB's determinations or has been associated with unexpected serious harm to subjects.

B. The IRB shall ensure that:

- Risks to subjects are minimized by ensuring the safest procedures consistent with sound research design.

- Risks to subjects are reasonable in relationship to anticipated benefits to subjects and importance of the knowledge that may be expected to result.

- Selection of subjects is equitable, taking into account the purpose of the research.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

- Informed consent will be appropriately documented.

- The research plan makes adequate provision for monitoring the data collected, where appropriate, to ensure the safety of the subjects.

- There are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.

- Additional safeguards are taken when vulnerable subjects (minors, mentally incompetent,

prisoners, economically and educationally disadvantaged, etc.) are involved in the research in order to protect against coercion or undue influence.

POLICIES & PROCEDURES OF THE INSTITUTIONAL REVIEW BOARD

A. Ethical Policies Statement

All members of the Academy will conduct all research involving human subjects under the ethical provisions of The Nuremberg Code" (1949); "Declaration of Helsinki" (1962) and revisions thereto by the World Medical Assembly (1975); "Responsibility and Investigations on Human Subjects" (1964); "Ethical Guidelines for Clinical Investigation" (1966); "Statements on the Use of Human Subjects for Research" (1969); and the Code of Federal Regulations TITLE 45 Public Welfare – Dept. of Health & Human Services, PART 46 Protection of Human Subjects (2009) (Appendix A).

All principals concerned with the protection of human subjects will assist the Academy in the discharge of its responsibilities for protecting the rights and welfare of subjects participating in research, investigation and care activities.

B. Exemptions from IRB Review

The following types of Research Practices qualify for an exemption from IRB review, with the exception that research of any type involving vulnerable subjects, i.e., children, minors, mentally incompetent, prisoners, the economically or educationally disadvantaged, is **never** exempt:

- Research involving the use of most educational tests (cognitive, diagnostic research, aptitude, achievement) if information taken from these sources is recorded in such a manner that such subjects cannot be identified directly or through identifiers linked to the subjects.

- Research involving surveyor interview procedures EXCEPT when the subjects can be identified, the responses, if they become known outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability or when the research deals with sensitive aspects of the subject's behavior such as illegal conduct, drug use, sexual behavior or use of alcohol.

- Research involving the collection or study of existing data, records, pathological specimens or diagnostic specimens, if these documents are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or indirectly.

- An investigator is required to file a separate justification for exemption. The appropriateness of a claimed exemption will be verified with the IRB on the basis of information contained in a research application prior to the release of the application to conduct the research. The Thesis or Dissertation Chair will also verify that all research involving human subjects described in a thesis or dissertation has been conducted with prior approval of the IRB.

- Research of any type conducted by an Academy student as part of a thesis, dissertation, mentorship, internship, practicum, research paper, etc. is **never** exempt from review. A

review of such documentation is at the discretion of the Thesis or Dissertation Chair to advise that an IRB is appropriate. In most cases it will be an Expedited Review.

C. Required IRB Full Review

A Full Review will be conducted by the IRB Committee (3 members). In the event that the IRB Committee Chair is actively involved, or has a conflict of interest with the research, the remaining committee may conduct this review with the lead taken by the IRB Committee Co-Chair. If both the IRB Committee Chair & Co-Chair are actively involved, or have a conflict of interest with the research, the remaining committee may conduct this review with the lead taken by the Designated Alternative Lead Member of the committee. Upon issuance of an approval, the project may be initiated.

In the event the committee requires modification or revision in the research protocol or design at that time, the approval will be rescinded temporarily and the investigator shall cease work on that portion of the project involving humans. The approval may be reinstated upon the investigator's complying satisfactorily with the committee's modification requests.

The following types of Research Practices qualify for an IRB Full Review:

- Any type involving vulnerable subjects, i.e., children, minors, mentally incompetent, prisoners, the economically or educationally disadvantaged, and pregnant women are **never** exempt.

- When the subjects can be identified.

- If the information to be obtained is of a sensitive nature, whether or not the subjects can be identified.

- The requirement that such protocols be reviewed by the IRB will serve to protect the investigator.

- An investigator is required to file a separate justification for exemption. The appropriateness of a claimed exemption will be verified with the IRB on the basis of information contained in a research application prior to the release of the application to conduct the research. The Thesis or Dissertation Chair will also verify that all research involving human subjects described in a thesis or dissertation has been conducted with prior approval of the IRB.

- Research of any type conducted by an Academy student as part of a thesis, dissertation, mentorship, internship, practicum, research paper, etc. is **never exempt** from review. A review of such documentation is at the discretion of the Thesis or Dissertation Chair to advise that an IRB is appropriate. In most cases it will be an Expedited Review.

D. Required IRB Expedited Review

An Expedited Review will be conducted by the IRB Committee Chair. In the event that the IRB Committee Chair is actively involved, or has a conflict of interest with the research, IRB Committee Co-Chair may conduct this review. If both the IRB Committee Chair & Co-Chair are actively involved, or have a conflict of interest with the research, Designated Alternative Lead Member of the committee may conduct this review. Upon issuance of an approval, the project may be initiated.

The action will be presented to the full committee at its next regularly scheduled meeting. In the event the committee requires modification or revision in the protocol at that time, the approval will be rescinded temporarily and the investigator shall cease work on that portion of the project involving humans. The approval may be reinstated upon the investigator's complying satisfactorily with the committee's modification requests. Expedited review procedures may not be used to disapprove the proposed research

The IRB will permit Expedited Review under the following circumstances:

If the research involves no more than minimal risk and appears on the list of categories of research eligible for expedited review.

Categories of research eligible for Expedited Review:

- Recording of data from subjects, 19 years of age or older, using noninvasive procedures routinely employed in clinical practice. This includes use of physical sensors that are applied to the surface of the body and do not involve input of matter or significant amounts of energy or invasion of the subject's privacy, weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography and ultrasound. It does not include exposure to electromagnetic radiation (x-rays, microwaves);

- Collection of blood samples by venipuncture in amounts not exceeding 450 ml in an eight-week period and no more than two times per week from subjects 19 years of age or older who are in good health and are not pregnant;

- Voice recordings made for research purposes;

- Low-to-moderate exercise by healthy volunteers;

- The study of existing data, documents, records, pathologic specimens or diagnostic specimens;

- Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, gain theory or test development where the investigator does not manipulate the behavior and the research will not involve stress to the subjects;

E. Conflict of Interest

No member of the IRB Committee shall be involved in either the initial or continuing review of an activity in which the committee member has a professional responsibility except to provide information to the committee.

F. Use of Outside Experts

The IRB Committee, with advice from outside experts at its discretion, may determine if the proposed research involving human subjects may be conducted at the Academy. This determination may be made on the basis of ethical considerations, scientific merit, or other criteria.

G. IRB – Policy on Informed Consent

The IRB will not only review the submitted protocol from the standpoint of the involvement of human subjects in research, but will also review that portion of the protocol that deals with Informed Consent. The issue of the type of Informed Consent that is to be obtained is an important one when sensitive matters are being investigated. Precautions must be taken to protect subjects and prevent self-in-crimination. The IRB can approve or in very sensitive cases, require that Oral Consent rather than Written Consent be obtained.

Information conveyed in the consent procedure shall include:

- A reasonable opportunity for the subject to consider participation;

- Be expressed in understandable language;

- Exclude exculpatory language;

- Contain a reasonable explanation of the research, its purposes, procedures and duration of participation, to include discomfort and risk;

- Describe any benefits to the subject or mankind;

- Describe the alternative procedures, when appropriate;

- Describe the extent to which confidentiality of records will be maintained;

- Explain the availability of compensation and availability of treatment, if injury occurs;

- Contain instructions concerning who may be contacted for answers to pertinent questions;

- State the conditions of participation. The following elements shall also be provided:
    - State that the procedure may involve unforeseeable risks;
    - State circumstances for termination of a subject's participation by the investigator;
    - State possible additional cost to the subject;
    - Describe consequences of a subject's withdrawal from participation, specifically, if the subject is free to withdraw from the project at any time without prejudice;
    - State the significant new findings will be made available to the subject;
    - In studies to be submitted to the Food and Drug Administration, a
    - statement shall be included informing the subject that research records may be subject to inspection by the FDA.

H. IRB – HIPAA Concerns

The IRB will not only review the submitted protocol from the standpoint of the involvement of human subjects in research, but will also review that portion of the protocol that deals with HIPAA. The issue of HIPAA is an important one when personal health information is recorded and documented during the investigation. Precautions must be taken to protect subjects' medical information. The IRB can approve or in very sensitive cases, require that HIPAA Forms be part of the preliminary protocols and requirements for review approval.

I. IRB – Policy on Changing Research Protocol Procedures

Investigators who desire to change the procedures in a research protocol must report such details in writing to the IRB Committee. In most cases an Expedited Review procedure can be applied to such changes.

Notification

Investigators will be promptly notified in writing by the committee of the results of its review of any proposed project, renewal request, or change in protocol. Such notifications will clearly state approval, disapproval, or the provisions under which such proposals will be acceptable.

Records

The IRB will maintain records of its meetings and all reviews and decisions concerning projects and activities involving human subjects. Such records will include all of the written information submitted to the IRB Committee with any request for approval or review of a project or activity; any questions or requests for additional information made by the committee; the pertinent discussion and the reports of any other subcommittees that relate to the proposal. Such records will also include recommendations of the chair, other committees, and/or other consultants.

Monitoring

The committee may request reports from an investigator to periodically evaluate research that presents high risk to the human subjects or involving vulnerable subjects such as children, institutionalized or hospitalized persons at intervals determined by the IRB at the initial review

RIGHT OF APPEAL FOR PRINCIPAL INVESTIGATOR ON UNFAVORABLE DECISIONS BY THE COMMITTEE

An investigator who receives an unfavorable review by the IRB Committee has the right of appeal. This appeal is initiated by filing a notice of appeal in writing with the Dean of Academic Affairs within thirty (30) days from the date that the IRB Committee issued its unfavorable report. It shall be the duty of the appellant to include the notice of appeal copies of any and all documents and protocols submitted to the committee. The Dean of Academic Affairs can either affirm the unfavorable report of the committee, in which case the decision is final, or the Dean can request re-review of the proposal at the next scheduled meeting of the IRB Committee. An unfavorable report by the IRB Committee on the re-review shall be final. Neither the Dean, nor any other institutional officials may reverse an IRB decision of non-approval.

APPENDIX A

(Electronic & Hard Copy on File)

Code of Federal Regulations
TITLE 45
PUBLIC WELFARE
Department of Health and Human Services
PART 46
PROTECTION OF HUMAN SUBJECTS

* * *

Revised January 15, 2009
Effective July 14, 2009
Revised May 2015

SUBPART A—Basic HHS Policy for Protection of Human Research Subjects

Section 46.100

SUBPART B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Section 46.200
46.201 To what do these regulations apply?
46.202 Definitions.
46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.
46.204 Research involving pregnant women or fetuses.
46.205 Research involving neonates.
46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.
46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

SUBPART C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Section 46.300
46.301 Applicability.
46.302 Purpose.
46.303 Definitions.
46.304 Composition of Institutional Review Boards where prisoners are involved.
46.305 Additional duties of the Institutional Review Boards where prisoners are involved.
46.306 Permitted research involving prisoners.

SUBPART D—Additional Protections for Children Involved as Subjects in Research

Section 46.400
46.401 To what do these regulations apply?
46.402 Definitions.
46.403 IRB duties.
46.404 Research not involving greater than minimal risk.
46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
46.408 Requirements for permission by parents or guardians and for assent by children.
46.409 Wards.
Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).
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SUBPART E — Registration of Institutional Review Boards

Section 46.500
46.501 What IRBs must be registered?
46.502 What information must be provided when registering an IRB?
46.503 When must an IRB be registered?
46.504 How must an IRB be registered?
46.505 When must IRB registration information be renewed or updated?

Editorial Note: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in Part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

APPENDIX B

USSA Institute Review Board (IRB) Committee
Human Subject Review

Mission:
Review all research done by faculty, staff, and students, to ensure that there are no violations of human research protocols.

Meetings:
As called by Chair.

Members:

Dr. Roch King	Committee Chair	Chair of Sports Coaching
Dr. Brian Wallace	Member	Chair of Sports Exercise Science
Dr. Brandon Spradley	Member	Director of Sports Management
Dr. Fred Cromartie	Member	Director of Doctoral Studies

NOTES:

Most IRB committees contain an odd number of voting members to preclude a tied vote.

USSA IRB members include four; three permanent members plus one alternate member, due to in-house research.

There will always be an odd number of committee members (three) for the review and voting process.

APPENDIX C

USSA Institutional Review Board Application

Instructions: In MS Word, highlight the shaded underlined box and replace with your text. Double-click checkboxes to check/uncheck. Provide signatures where appropriate.

Principal Investigator/Study Director: _____

Status: Faculty ☐ Staff ☐ Student ☐

Department: _____

College/Research Center: _____

Telephone: _____

Email: _____

Supervising Faculty Information (if student)

a. **Name**: _____

b. **Campus Address**: _____

c. **Email** : _____

Title of Study: _____

Purpose of Study: _____

Hypotheses: _____

Description of Subjects: _____

How Subjects Will Be Selected: _____

Description of Procedure: _____

Instrumentation (if applicable): _____

Duration of Study

a. **Total amount of time with each subject**: _____

b. **Time to complete study**: _____

Benefit(s) of the Study: _____

Possible Risks to Subject(s) and Precautions Taken to Avoid Risks: _____

How You Will Ensure Confidentiality/Anonymity: _____

Documentation of Informed Consent by Subject(s) Attached? Yes ☐ No ☐

Signature: _____

Supervising Faculty Signature (if student):_____

Send Form To:

United States Sports Academy
USSA Research Dept.
IRB – Committee
1 Academy Drive
Daphne, Alabama 36526
If you have questions:
Call (251) 626-3303
Email research@ussa.edu

Important Note: Check with IRB Manual for various IRB forms needed in addition to this document. This is only an Application. Other forms may be needed.

APPENDIX D

USSA Application / Check List / Notification

Part A. Contact Information, Agreements, and Signatures

Title of Study:

_____

Print Name / Credentials of Principal Investigator

_____ _____

Principal Investigator Signature **Date**

Address:

Phone #: **Cell:**

Fax #: **Email:**

Name of Faculty Advisor or Dissertation/Thesis Committee Chair:

Institution:

Department: **Position:**

Tel #: **Fax #:**

Email:

List all other project personnel including co-investigators, and anyone else who has contact with subjects/participants or identifiable data from subjects/participants:

Name: **Email:**

Name: **Email:**

Part B. Checklist of Items to Include with Your Submission

Applications must provide all information requested, i.e., complete answers must be contained in the application, along with all signatures. Attach all referenced documents and support materials with application.

Include the following items with your submission, where applicable.
Check the relevant items below and include one copy of all checked items.

Check	Item	Initial
□	1. This application.	
□	2. Application must have original PI signatures.	
□	3. Informed Consent and Assent Forms, fact or information sheets; include phone and verbal consent scripts. HIPAA authorization addendum to consent form.	
□	4. All recruitment materials including scripts, flyers and advertising, letters, emails. Focus group guides, scripts used to guide phone or in-person interviews, etc.	
□	5. Complete copy of Methods with complete copy of List of Equipment utilized, Questionnaire & Survey.	
□	6. Documentation of reviews from any other committees (e.g., Research, Dissertation Committee or Thesis Committee, or local review committees in Academic Affairs).	
□	7. Complete copy of Research Design, Dissertation/Thesis Proposal. Chapters I, II, & III with all Appendices --- as it is applicable.	
□	8. Copy of the Approval Sheet with Committee Signatures & Comment	
□	9. Statement of Purpose & Significance of Study	

NOTE: Applications will be returned if these instructions are not followed.

Principal Investigator:
I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and Institution / University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

_____ _____

Principal Investigator Signature **Date**

<u>Faculty Advisor or Dissertation/Thesis Committee Chair if PI is a Student or Trainee Investigator</u>:

I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

_____

Faculty Advisor or Research/Dissertation/Thesis Committee Chair Signature

_____

Date

APPENDIX E
USSA Application for Expedited Review

Instructions: In MS Word, highlight the shaded underlined box and replace with your text. Double-click checkboxes to check/uncheck. Provide signatures where appropriate.

Name: _____ **Date**: _____
Address: _____
City, State, Zip: _____
Telephone: _____ **Email**: _____
Course Title & Number (if applicable): _____
Course Instructor (if applicable): _____
Signature **Date**

Research involving human subjects may receive expedited review by the USSA if the research involves no more than minimal risk and fully meets *at least one* of the following (please check all that apply):

☐ Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. [Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.] (b) Research on medical devices for which *either* (i) an investigational device exemption application (21 CFR Part 812) is not required, *or* (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture that meets at least one of the following conditions: (a) If the blood sample is collected from healthy, non-pregnant adults weighing at least 110 pounds, the amounts drawn will not exceed *550 ml in an 8 week period*, and collection occurs no more frequently than *twice per week*. (b) If the blood sample is collected from other adults and children, considering the subject's age, weight, and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected, the amount drawn will not exceed *the lesser of 50 ml or 3 ml per kg in an 8 week period* and collection occurs no more frequently than *twice per week*.

☐ Prospective collection of biological specimens for research purposes by noninvasive means.

☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). [NOTE: Some research in this category may be exempt from review. 45 CFR 46.101(b) (4). This listing refers only to research that is not exempt.]

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [NOTE: Some research in this category may be exempt from review. 45 CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.]

I hereby certify that my research fully meets the categories indicated above. If my research becomes ineligible for such expedited review, for any reason, I will re-apply for appropriate IRB approval.

_____

Signature **Date**

APPENDIX F
USSA Application for Exemption from Review

Instructions: In MS Word, highlight the shaded underlined box and replace with your text. Double-click checkboxes to check/uncheck. Provide signatures where appropriate.

Name: _____ **Date**: _____
Address: _____
City, State, Zip: _____
Telephone: _____ **Email**: _____
Course Title & Number (if applicable): _____
Course Instructor (if applicable): _____
Signature **Date**

Research involving human subjects may be exempted from USSA approval if the research fully meets *at least one* of the following (please check all that apply):†

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews, or observation of public behavior, in which information is obtained in a manner that human subjects cannot be identified directly or through identifiers linked to the subjects, and in which any disclosure of the human subjects' responses outside the research would NOT place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior in which *either* (a) the human subjects are elected or appointed public officials or candidates for public office *or* (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

†Surveys, interviews, or observation of public behavior involving minors (persons under 19 years of age) cannot be exempt.

I hereby certify that my research fully meets the categories indicated above. If my research becomes ineligible for such exemption review, for any reason, I will re-apply for appropriate IRB review.

_____
Signature **Date**

IF NOT APPLICABLE, INITIAL HERE_____

APPENDIX G
USSA Full Review Human Subjects Protocol

Instructions: In MS Word, highlight the shaded underlined box and replace with your text. Double-click checkboxes to check/uncheck. Provide signatures where appropriate.

1. **Title of Project**: _____
2. **Investigator Information**

a. Name of Principal Investigator: _____
Qualifications of Investigator: _____

I certify that the information/data/specimens collected for this research will be used and disclosed only as set forth in this protocol. Signature of Investigator: _____ Date: _____

Campus Address

Department _____ Bldg_____ Room _____
Phone _____ Fax _____ E-mail _____

b. Contact Person _____ Phone _____
E-mail _____ Fax _____

c. List the name, rank, and major departmental appointment of other investigators participating in this project, if any. Use a separate sheet of paper if necessary. All investigators who will be listed on the Food and Drug Administration's Form 1572 should be included. *Attach a copy of the FDA 1572 if applicable.*

None ☐ Others _____

In this research team, are there professionals credentialed for the techniques and/or procedures required by the study? Yes ☐ No ☐

d. Provide Faculty Advisor/Course Instructor's name _____, phone number _____, e-mail address _____ and Signature _____ as contact for student, fellowship, or resident research project.

e. If medical supervision is necessary, give the name of the physician who will be responsible for the supervision: Name _____ Phone _____

Provide verification of medical supervision in the form of a memo signed by the person providing the medical supervision and attach it to this application.

f. List all personnel, other than the investigator, who will be conducting the consent discussion and obtaining consent from participants, if any: _____

3. **Grant/Contract Information**

If this study is part of a grant or contract, provide one copy of the grant or contract and indicate the following:

Grant or Contract Title: _____
Principal Investigator of Grant or Contract: _____
Grant or Contract Tracking Number: _____

4. **Source of Funds**

State specific name of sponsor and/or funding source:

Governmental Agency or Agencies: _____
Foundation, Organization, or Corporation: _____
None ☐ USSA Departmental Funds ☐ Self-Funded ☐ NIH Coop. Group Trial ☐

**Please provide the IRB with the grant number upon receipt from the funding agency.*

5. **Number and Type of Participants and Controls**

a. Number of Participants and Controls anticipated to be enrolled by Academy investigator and the total for the trial if this is a multi-center trial: _____

b. Type of Participants and Controls (including age ranges and health status): _____

c. Population from which derived: _____

d. Describe the anticipated gender and racial/ethnic composition of the study population, as well as criteria for inclusion or exclusion of any subpopulation: _____

e. Will any of the below special populations groups be involved in the project: Yes ☐ No ☐

If yes, mark the appropriate box below. If using groups marked with an asterisk, complete the **"Special Populations Review Form."**

*Pregnant Women ☐ *Neonate/Nonviable Neonate ☐ *Fetuses ☐
*Prisoners ☐ *Minors under 19 years of age ☐ Students ☐
Intellectually Disabled (DSM-5, ICD-11) ☐ Impaired Mental Capacity ☐ Employees ☐

If populations mentioned above are involved, state reasons for using these populations: _____

List any subjects who will be at risk other than those directly involved in the study: _____

f. Will the study be conducted at or recruit participants from the Mobile/Baldwin County Department of Public Health or Public Schools? Yes ☐ No ☐

If yes, please provide notification that the protocol has been submitted for review.

g. Will participant recruitment materials (e.g., advertisements, flyers, or letters) be used? Yes ☐ No ☐

If yes, please attach.
If no, describe the source (e.g., databases, employees) from which you will obtain participants. _____

6. **Duration of Study**

a. Anticipated duration of entire study: _____

b. Total amount of time each subject will be involved: _____

c. Duration of each phase in which the subject will be involved: _____

7. **Location of Study**

Name of Institution: _____ Type of Room: _____

If the project is a field study, describe the community: _____

If the study is to be undertaken within a school, business, or other institution that does not have a review board, attach a statement of any contacts with the appropriate officials.

8. **HIPAA**

Does your research use health information that contains ANY of the following identifiers? (Check all that apply):

☐ Names
☐ Geographic subdivisions smaller than a State
☐ Elements of dates (except year) related to an individual
☐ Telephone numbers

- ☐ Fax numbers
- ☐ Email addresses
- ☐ Social security numbers
- ☐ Medical record numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers
- ☐ Device identifiers and serial numbers
- ☐ Biometric identifiers
- ☐ Web universal resource locators (URLs)
- ☐ Internet protocol address numbers
- ☐ Full-face photographic images
- ☐ Any other unique identifying number (codes are not identifying as long as the researcher cannot link the data to an individual)
- ☐ None

9. **Purpose, Background, and Study Methodology**

   a. Purpose of Project or Activity in LAY LANGUAGE: _____

   b. Background: _____

      Describe past experimental and/or clinical findings leading to the formulation of this study. Include any past or current research by the Principal Investigator.

   c. Study Methodology:

      i. Describe the study methodology that will affect the participants, particularly in regard to any inconvenience, danger, or discomfort. _____

      ii. List the procedures (including screening procedures), the length of time each will take, and the frequency of repetition. _____

      iii. Attach a copy of any interview or questionnaire that will be used. _____

      iv. Specify the amount, if any, the subject will be paid for participating in the research protocol. (**Note**: Payments should be made throughout the study.) _____

      v. Will biological samples be stored for future use? ☐ Yes ☐ No

         If yes, will they be used for the disease under study in this trial or other research? _____

10. **Risks and Precautions**

a. Possible Risks—Physical, Psychological, and Social: _____

   i. Estimate their frequency, severity, and reversibility. _____

   ii. Describe any alternative treatments. _____

   iii. Describe any withholding of normal treatment. _____

   iv. What is the risk-benefit ratio? _____

b. Special Precautions:

   i. Describe precautions that will be taken to avoid hazards and the means for monitoring to detect hazards. _____

   ii. State the point at which the experiment will be terminated if hazards materialize. Differentiate between the point for termination of an individual subject's involvement and for the termination of the entire study. _____

   iii. Describe the method of screening potential Participants and Controls, and the factors that will be the basis for excluding potential participants from the study. Attach all patient/subject recruitment materials and/or advertisements. _____

   iv. If an agent or therapy is being assessed, indicate the point at which the differences in outcomes between Participants and Controls will be considered sufficiently significant to eliminate the need for additional participants, or to require modification of the disclosure made to continuing and prospective participants because of greater information concerning relative risks. _____

   v. State any differences in the serious adverse event reporting from this particular clinical trial and 45 CFR 46, Subpart A or 21 CFR 312. _____ (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/ShowCFR.cfm?FR=312.32)

   vi. State whether the potential subject will be, or will have been, in a stressful, painful, or drugged condition. If yes, describe the proposed precautions to overcome the effect of the condition on the consent process. _____

11. Consent Form Process

a. Describe how participants will be "recruited." Attach a copy of any recruitment materials such as brochures, advertisements, etc. _____

b. Please explain how consent will be obtained. _____

c. Will more project-specific instruments be used in the consenting process? ☐ Yes ☐ No

If yes, attach patient information sheets or other such instruments.

12. Procedures to Maintain Confidentiality

a. Will any information derived from this study be given to any person or group, including the subject? Yes ☐ No ☐

If yes, describe to whom the information will be given and the nature of the information. _____

b. Describe the manner and method in which research data will be stored and how confidentiality will be maintained. Identify the department and all computer systems on which data is stored and how access to the stored data will be limited to those with a need to know. _____

13. Other Information

_____

Send Form To:

United States Sports Academy
USSA Research Dept.
IRB – Committee
1 Academy Drive
Daphne, Alabama 36526
If you have questions:
Call (251) 626-3303
Email research@ussa.edu

APPENDIX H
USSA Special Population Review (Children/Minors)

Instructions: In MS Word, highlight the shaded underlined box and replace with your text. Double-click checkboxes to check/uncheck.

Definition: In Alabama, a child/minor is any person under 19 years of age.

A. State the reasons for including this population in your project: _____

B. Check the category into which you would recommend the proposed research be placed and respond to the relevant questions:

☐ Children's Risk Level (CRL) #1 (45 CFR 46.404) Research not involving greater than minimal risk. Research in this category requires both assent of the child and permission of at least one parent or guardian.

Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

☐ CRL #2 (45 CFR 46.405) Research involving greater than minimal risk but of possible direct benefit to the child, in which the risk is at least as favorable to the subject as that presented by available alternative approaches. This requires both the assent of the child and permission of at least one parent or guardian.

a) Is the risk justified by the anticipated benefit to the subjects? ☐Yes ☐No
b) Is the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches? ☐Yes ☐No
c) Are adequate provisions being made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408? ☐Yes ☐No

☐ CRL #3 (45CFR 46.406) Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the disorder or condition, in which the risk is minor relative to the potential improvement in knowledge to be applied to general understanding. Permission must be obtained from both parents unless there is only one reasonable available parent. Guardian consent should be substituted for parental consent under appropriate legal constraints.

a) Does the risk represent a minor increase over minimal risk? ☐Yes ☐No
b) Does the intervention or procedure present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations? ☐Yes ☐No
c) Is the intervention or procedure likely to yield generalizable knowledge about the subjects' disorder or condition? ☐Yes ☐No
d) Are adequate provisions being made for soliciting assent of the children and permission of their parents or guardians, as set for in § 46.408.? ☐Yes ☐No

☐ CRL #4 (45 CFR 46.407) Research not meeting any of the above the specifications, but which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health and welfare of children. This category is considered so serious that it must be submitted to a ruling by the Secretary of DHHS following consultation with an appropriate panel of experts.

APPENDIX I
USSA Request to Waive Informed Consent

Instructions: In MS Word, highlight the shaded underlined box and replace with your text. Double-click checkboxes to check/uncheck.

If you need to waive the requirement for informed consent for reasons other than exemption, please check the condition that applies to you, and provide a brief explanation justifying your choice. (If you are providing informed consent, you may skip this section.)

☐ The research is (a) conducted by or approved by state or local government officials with the purpose of studying and evaluating public benefits or service programs, procedures for obtaining benefits or services under those programs, possible changes in, or alternatives to those programs or procedures, possible changes in those programs, or possible changes in levels of pay for benefits under those services; *and* (b) the research could not be carried out without the waiver of consent or alteration of consent requirements.

☐ Research involves no more than minimal risk to subject and could not be carried out without the waiver of consent. In this case, waiver of consent cannot adversely affect the rights or welfare of subjects, and subjects should be provided with additional pertinent information after participation.

Justification

_____

APPENDIX J

USSA Informed Consent to Participate in Research Study

Project Title:
Principal Investigator:
Department:

You are being asked to volunteer for this research study. This study is being conducted at (enter the study site). You were selected as a possible participant because (explain how the participant was selected).

Please read this form and ask any questions that you may have before agreeing to take part in this study.

Purpose of the Research Study

The purpose of this study is:

(Briefly explain the research question and its purpose in lay language.)

Number of Participants

About (insert number of study participants) people will take part in this study.

Procedures

If you agree to be in this study, you will be asked to do the following:

(Explain the tasks/procedures involved in the study. Identify assignments to study groups, frequency of procedures, etc. Describe any procedures that are experimental. If there are none, this may be omitted.)

Length of Participation

(Indicate the length of time of participation such as 30 minutes, 1 hour, 4 visits for a total of 2 weeks. If applicable, also include anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.)

This study has the following risks:

(In order of severity, list any possible risks--physical, psychological, economical, etc. Include the likelihood of each and under what conditions the researcher will terminate the study.)

Benefits of being in the study are

(If no benefits, enter "None." Do not include compensation as a benefit)

Alternate Procedures

(If the study involves participation in a student research pool where students have the option of a non-research assignment, this should be disclosed. If there are no alternative procedures, this section may be omitted.)

Injury

(Delete this section if not applicable.)
In case of injury or illness resulting from this study, emergency medical treatment is available. However, you or your insurance company may be expected to pay the usual charge for this treatment. The United States Sports Academy has set aside no funds to compensate you in the event of injury.

Confidentiality

In published reports, there will be no information included that will make it possible to identify you without your permission. Research records will be stored securely and only approved researchers will have access to the records.

There are organizations that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the (Insert the name of the study Sponsor) and the USSA Institutional Review Board.

Compensation

You (will/will not) be reimbursed for you time and participation in this study. (Include payment, reimbursement, class credit, etc. Explain when disbursement will occur and conditions of payment (e.g., if compensation will be reduced for early withdrawal).

Voluntary Nature of the Study

Participation in this study is voluntary. If you withdraw or decline participation, you will not be penalized or lose benefits or services unrelated to the study. If you decide to participate, you may decline to answer any question and may choose to withdraw at any time.

Waivers of Elements of Confidentiality (Delete this section if not applicable.)

Your name will not be linked with your responses unless you specifically agree to be identified. Please select one of the following options

_____ I consent to being quoted directly.

_____ I do not consent to being quoted directly.

_____ I consent to having my name reported with quoted material.

_____ I do not consent to having my name reported with quoted material

Request for record information (Delete this section if not applicable; or modify as appropriate.)

If you approve, your confidential records will be used as data for this study. The records that will be used include (list specific confidential data that will be collected). These records will be used for the following purpose(s): (describe how data will be used in the study).

_____ I agree for my (type of record, i.e., school) records to be accessed and used for the purposes described above.

_____ I do not agree for my (type of record, i.e., school) records to be accessed for use as research data.

Audio Recording of Study Activities (Delete this section if not applicable.)

To assist with accurate recording of participant responses, interviews may be recorded on an audio recording device. You have the right to refuse to allow such recording without penalty. Please select one of the following options.

I consent to audio recording. ___ Yes ___ No.

Video Recording of Study Activities (Delete this section if not applicable.)

To assist with accurate recording of your responses, interviews may be recorded on a video recording device. You have the right to refuse to allow such recording. Please select one of the following options:

I consent to video recording. ___ Yes ___ No.

Photographing of Study Participants/Activities (Delete this section if not applicable.)

In order to preserve an image related to the research, photographs may be taken of participants. You have the right to refuse to allow photographs to be taken without penalty. Please select one of the following options.

I consent to photographs. ___ Yes ___ No.

Contacts and Questions

If you have concerns or complaints about the research, the researcher(s) conducting this study can be contacted at
(Provide phone number and email address. If the researcher is a student, include the advisor's name, telephone number, and email address here.)

Contact the researcher(s) if you have questions or if you have experienced a research-related injury.

If you have any questions about your rights as a research participant, concerns, or complaints about the research and wish to talk to someone other than individuals on the research team or if you cannot reach the research team, you may contact the United States Sports Academy – Research Dept. - Institutional Review Board (USSA IRB) at 251-626-3303, research@ussa.edu.

You will be given a copy of this information to keep for your records. If you are not given a copy of this consent form, please request one.

Statement of Consent

I have read the above information. I have asked questions and have received satisfactory answers. I consent to participate in the study.

_____

Signature Date

_____

Parent or Guardian Signature Date

Contact Information:

United States Sports Academy
USSA Research Dept.
IRB Committee
1 Academy Drive
Daphne, Alabama 36526
If you have questions:
Call (251) 626-3303
Email research@ussa.edu

APPENDIX K

USSA Assent to Participate in Research Study

Project Title:
Principal Investigator:
Department:

For children 7-12 years old

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when researchers collect a lot of information to learn more about something. Researchers will ask you a lot of questions. After we tell you more about it, we will ask if you'd like to be in this study or not.

Why are we doing this study? (Modify the wording in red to fit your study)

This study is being done to try and understand why people……

In the whole study, there will be about 300 children who have ……...

What will happen to you if you are in this study? (Modify the wording in red to fit your study)

If you agree to be in this study, two things will happen:

1. You will answer a lot of questions. These questions will ask about how you…….
2. We will ask you to play with…….

How long will you be in the study? (Modify the wording in red to fit your study)

You will be in the study for about 3 weeks.

What bad things might happen to you if you are in the study? (Modify the wording in red to fit your study)

No bad things will happen to you. The questions might take a long time to answer.

What good things might happen to you if you are in the study? (Modify the wording in red to fit your study)

You will get a gift card for being in the study. You may have fun playing with the……

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in this study?

No, you don't. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. Or if you do want to be in the study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you.

Your Mom or Dad will also have to give permission for you to be in this study.

If you don't want to be in this study, just tell us.

If you want to be in this study, just tell us.

The person who talks to you will give you a copy of this form to keep.

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION

I have explained the study to _____(*print name of child here*) in language he/she can understand, and the child has agreed to be in the study.

_____ _____
Signature of Child Date

_____ _____
Signature of Person Conducting Assent Discussion Date

_____
Name of Person Conducting Assent Discussion (*print)*

Contact Information:

United States Sports Academy
USSA Research Dept.
IRB Committee
1 Academy Drive
Daphne, Alabama 36526
If you have questions:
Call (251) 626-3303
Email research@ussa.edu

IF NOT APPLICABLE, INITIAL HERE_____

APPENDIX L

USSA HIPAA – Authorization to Use or Disclose Protected Health Information for Research

An additional Informed Consent Document
For Research Participation may also be required.

Title for Research project:

Principal Investigator:

IRB Number:

Address:

Phone Number:

If you decide to join this research project, United States Sports Academy (USSA) researchers may use or share (disclose) information about you that is considered to be protected health information for their research. Protected health information will be called private information in this Authorization.

Private information To be Used or Shared. Federal law requires that researchers get your permission (authorization) to use or share your private information. If you give permission, the researchers may use or share with the people identified in this Authorization any private information related to this research from your medical records and from any test results. Information, used or shared, may include all information relating to any tests, procedures, surveys, or interviews as outlined in the consent form, medical records and charts, name, address, telephone number, date of birth, race and government-issued identification number.

Purposes for Using or Sharing Private Information. If you give permission, the researchers may use your private information to .

Other Use and Sharing of Private Information. If you give permission, the researchers may also use your private information to develop new procedures or commercial products. They may share your private information with the research sponsor, the USSA - Institutional Review Board, auditors, and inspectors who check the research, and government agencies such as the Department of Health and Human Services (HHS). The researchers may also share your private information with .

Confidentiality. Although the researchers may report their findings in scientific journals or meetings, they will not identify you in their reports. The researchers will keep your information confidential, but confidentiality is not guaranteed. Any person or organization receiving the information based on this authorization could re-release the information to others and federal law would no longer protect it.

YOU MUST UNDERSTAND THAT YOUR PROTECTED HEALTH INFORMATION MAY INCLUDE INFORMATION REGARDING ANY CONDITIONS CONSIDERED AS A COMMUNICABLE OR VENEREAL DISEASE WHICH MY INCLUDE, BUT ARE NOT LIMITED TO, DISEASES SUCH AS HEPATITIS, SYPHILIS, GONORRHEA, AND HUMAN IMMUNODEFICIENCY VIRUS (HIV).

Voluntary Choice. The choice to give USSA researchers permission to use or share your private information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for USSA researchers to use or share your private health information if you want to participate in the research and if you revoke your authorization, you can no longer participate in this study.

Refusing to give permission will not affect your ability to get routine treatment or health care from USSA.

Revoking Permission. If you give USSA researchers permission to use or share your private information, you have a right to revoke your permission whenever you want. However, revoking your permission will not apply to information that the researchers have already used, relied on, or shared.

End of Permission. Unless you revoke it, permission for USSA researchers to use or share your private information for their research will end in . You may revoke your permission at any time by writing to:

United States Sports Academy
USSA Research Dept.
IRB – Committee
1 Academy Drive
Daphne, Alabama 36526
If you have questions:
Call (251) 626-3303
Email research@ussa.edu

Giving Permission. By signing this form, you give USSA and USSA's researchers led by , permission to share your private information for the research project called .

Subject Name:

_____ _____
Signature of Subject Date
Or parent if Subject is a Child

Or

_____ _____
Signature of Legal Representative** Date

**If signed by a legal Representative of the subject, provide a description of the relationship to the subject and the authority to act as a legal representative:

_____

USSA may ask you to produce evidence of your relationship.

A signed copy of this form must be given to the subject or the legal representative at the time this signed form is provided to the researcher or his representative.

APPENDIX M
Member Review Approval Process Form

a. Are the proper IRB Application Forms complete? Yes ☐ No ☐

If NO – What is needed? _____

b. Are the proper IRB Review Forms complete? Yes ☐ No ☐

If NO – What is needed? _____

c. Do Documents have proper Signatures and Contact Information? Yes ☐ No ☐

d. Are Consent / Assent Forms applicable to Research? Yes ☐ No ☐ N/A ☐

If YES – Are they completed? Yes ☐ No ☐
If NO – What is needed? _____

e. Are HIPAA Forms applicable to Research? Yes ☐ No ☐ N/A ☐

If YES – Are they completed? Yes ☐ No ☐
If NO – What is needed? _____

f. Are ALL necessary recruitment materials including scripts, flyers and advertising, letters, emails, focus group guides, scripts used to guide phone or in-person interviews, etc. provided? Yes ☐ No ☐

If NO – What is needed? _____

g. Are ALL Complete copies of Methods with complete copies of the List of Equipment utilized, and Questionnaires & Surveys used provided? Yes ☐ No ☐

If NO – What is needed? _____

h. Benefit(s) of Study Statement / Statement of Purpose / Significance of Study Completed? Yes ☐ No ☐

If NO – What is needed? _____

g. Has this study been rejected by another IRB, similar review board, departmental committee(s), thesis/dissertation committee? Yes ☐ No ☐

If YES – Give the reasons: _____

Note: If the protocol has/is subsequently rejected or disapproved by another review board, the USSA IRB Committee must be notified promptly.

Check the relevant review items below and check for included copies, as part of the application.

Check	Item	Dates
□	1. This application.	
□	2. Application must have original PI signatures.	
□	3. Informed Consent and Assent Forms, fact or information sheets; include phone and verbal consent scripts. HIPAA authorization addendum to consent form.	
□	4. All recruitment materials including scripts, flyers and advertising, letters, emails. Focus group guides, scripts used to guide phone or in-person interviews, etc.	
□	5. Complete copy of Methods with complete copy of List of Equipment utilized, Questionnaire & Survey.	
□	6. Documentation of reviews from any other committees (e.g., Research, Dissertation Committee or Thesis Committee, or local review committees in Academic Affairs).	
□	7. Complete copy of Research Design, Dissertation/Thesis Proposal. Chapters I, II, & III with all Appendices --- as it is applicable.	
□	8. Copy of the Approval Sheet with Committee Signatures & Comment	
□	9. Benefits of Study Statement / Statement of Purpose / Significance of Study	

Decision based upon Review: ACCEPTED ☐ NOT ACCEPTED ☐

IRB Committee Member Name: _____
(Print)

IRB Committee Member Signature: _____

IF NOT APPLICABLE, INITIAL HERE_____