THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF UNIVERSITY COUNSEL

110 BYNUM HALL
CAMPUS BOX 9105
222 EAST CAMERON AVENUE
CHAPEL HILL, NC 27599-9105

T 919.962.1219
F 919.843.1617

May 15, 2014

Tyler Dukes
Reporter/Researcher
WRAL.com
(919) 821-8949
tdukes@wral.com

VIA ELECTRONIC MAIL

Dear Mr. Dukes:

I write in response to your correspondence dated January 21, 2014 (sent to Daniel Nelson and David Borasky), in which you wrote seeking access to and copies of University records. Specifically, you wrote:

> "I request access to and copies of all institutional review board documents related to research by Mary Willingham, including but not limited to research proposals, protocols, amendments and notices of suspension, through Jan. 21, 2014."

The enclosed documents are being provided to you in accordance with the North Carolina Public Records Act. This request has been fully processed and is now closed-out. The University's Public Records Policy is available on-line at http://policies.unc.edu/policies/public-records/.

Sincerely,

Regina Stabile

Regina J. Stabile, J.D.
Director, Institutional Records and Reporting Compliance

RJS/dqa

Enclosure

OFFICE OF HUMAN RESEARCH ETHICS
Institutional Review Board

DETERMINATION WHETHER RESEARCH OR SIMILAR ACTIVITIES REQUIRE IRB APPROVAL

Version 19-Feb-2008

08-0883

Part 1. Contact Information, Agreements, and Signatures

Title of Study: Screening for ADD/LD in student athletes

Date: 5/14/08

Name and degrees of Applicant: Mary Willingham
Department: Athletic Mailing address/CB #: Academic Support # 8550
UNC-CH PID: 7099-85125 Pager:
Phone #: 843-6029 Fax #: 962-8247 Email Address: mwillingham@oncaa.unc.edu

For trainee-led projects: __ undergraduate __ graduate __ postdoc __ resident __ other
Name of faculty advisor:
Department: Mailing address/CB #:
Phone #: Fax #: Email Address:

Name of funding source or sponsor (*please do not abbreviate*):
X not funded __ Federal __ State __ industry __ foundation __ UNC-CH
__ other (specify):
For industry sponsored research (if applicable):
Sponsor's master protocol version #: Version date:
Investigator Brochure version #: Version date:
Any other details you need documented on IRB approval:

RAMSeS proposal number (from Office of Sponsored Research):

Applicant: I will notify the IRB if the scope of the activity changes in such a way that the answers on this form are no longer valid. I will ensure that all collaborators, students and employees assisting in this project are informed about these obligations. All information given in this form is accurate and complete.

Mary C. Willingham
Signature of Applicant

5-14-2008
Date

Faculty Advisor if Applicant is a Student or Trainee: I accept ultimate responsibility for ensuring that this project complies with all the obligations listed above for the Applicant.

Signature of Faculty Advisor

Date

Part 2. Description of Research or Similar Activities

2.1. **Brief Summary of Purpose and Rationale.** Provide a *brief* non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. *Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content.*

Purpose: see attached abstract
Participants:
Procedures (methods):

2.2. **Which of the following describes your proposed activity?**

	Yes	No
2.2.1. Secondary analysis of existing data or specimens, deidentified or coded?	X	___
2.2.2. Program evaluation?	X	___
2.2.3. Class projects for educational purposes only?	___	___
2.2.4. QI/QA for internal purposes?	___	___
2.2.5. Center or core grants (to establish infrastructure)?	___	___
2.2.6. Training grants?	___	___
2.2.7. Demonstration projects?	___	___
2.2.8. Case study (publication of clinical scenario that has already occurred)?	___	___
2.2.9. Other? Explain _____	___	___

2.3. **Generalizable Knowledge.** Generalizable knowledge might include information presented to a broader audience or published with the intent of drawing scientific conclusions or increasing the body of scientific knowledge. This would not typically describe projects that are intended solely for internal assessment purposes, such as quality improvement/assurance, and program evaluations. Will the proposed activity result in the development of or contribution to generalizable knowledge?

X yes ____ no If no, please explain.

2.4. **Living Individuals.** Are you planning to obtain data from or about living individuals?

___ yes X no Please explain.

2.5. **Direct Interaction with Individuals.** Will you be collecting data via direct interaction with individuals (any contact with subjects including questionnaires, interviews, focus groups, observation, treatment interventions, etc.)?

___ yes X no

2.6. **Description of Existing Records, Data, Human Biological Specimens.** What existing records, data or human biological specimens will you be using? *(indicate all that apply)*:

	Yes	No
2.6.1. a. Data already collected from another research study? b. If yes, was applicant involved in the original collection? If yes, please explain role:	___ ___	___ ___
2.6.2. a. Patient specimens (tissues, blood, serum, surgical discards, etc.)? b. If yes, has the purpose for which they were collected been met before removal of any excess?	___ ___	___ ___
2.6.3. Data already collected for administrative purposes?	___	___
2.6.4. Medical records data?	X	___
2.6.5. Electronic data from a clinical (i.e., not a research) database?	___	___
2.6.6. Publicly available data?	X	___
2.6.7. Other? Explain:	___	___

If you have answered "yes" to any of the items 2.6.1 through 2.6.7, provide a description of the data you propose to use, describing the type of data, how they were collected (including consent procedures), and where they currently reside.

2.7. **Private Information.** Private information includes information about behavior that occurs in a context that an individual can reasonably expect will not be made public (e.g., a medical or school record). Public information might include information that is publicly available or from observation of public behavior (e.g., seatbelt use, use of bicycle lanes, etc.). Are the data for your project private?

X yes ___ no If no, explain:

2.8. **HIPAA.** Do any of these data come directly from a health plan, health care clearinghouse, or health care provider? (See http://www.unc.edu/hipaa/index.htm for more about HIPAA.)

X yes ___ no

2.9. **Identifiers in Existing Data.** Do the data you will receive have any of the following identifiers?

__ No __ Yes *If yes, check all that apply*:

a. X Names
b. __ Telephone numbers
c. X Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
d. __ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code
e. __ Fax numbers
f. __ Electronic mail addresses
g. __ Social security numbers
h. __ Medical record numbers
i. __ Health plan beneficiary numbers
j. __ Account numbers
k. __ Certificate/license numbers
l. __ Vehicle identifiers and serial numbers (VIN), including license plate numbers
m. __ Device identifiers and serial numbers (e.g., implanted medical device)
n. __ Web universal resource locators (URLs)
o. __ Internet protocol (IP) address numbers
p. __ Biometric identifiers, including finger and voice prints
q. __ Full face photographic images and any comparable images
r. __ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

► **If you have answered "no" regarding all items in 2.9, stop and submit this form.**

2.10. **Coded Data.** Coded data are those for which identifying information (see the list in 2.9) that would enable the investigator to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code) that cannot be linked to the original individual.

2.10.1 Are the data coded? X yes ___ no

2.10.2. Will you have access to a key that deciphers the code, enabling linkage of identifying information to private information or samples? ___ yes X no

► **If you have answered "yes" to 2.10.2 you must apply for IRB approval. Please complete the form "Application for IRB Approval of Human Subjects Research" available from the Office of Human Research Ethics website.**

If you have answered "no" to 2.10.2, identify the mechanism which precludes your access to the codes and include a copy of any agreements or documents that explain these protections:

	Yes	No
2.10.2.1. Data use agreement with data and code custodian (agreement prohibiting the release of the key to decipher the code to the applicant under any circumstances)?	X	___
2.10.2.2. Data are publicly available?	___	___
2.10.2.3. Honest broker (centralized custodian who controls data and will not release codes or IDs)?	___	___
2.10.2.4. Other. Explain _____	___	___

► **If the answers to the questions above do not direct you to apply for IRB approval using the form "Application for IRB Approval of Human Subjects Research," submit this completed form to the IRB for determination if your activity requires further IRB review and approval.**

CNS Vital Signs (CNSVS) as a tool to screen for ADHD/LD in Student Athletes

Objective: To estimate the incidence of ADHD and learning disabilities in freshmen student athletes. The prevalence of ADHD and learning disabilities is frequently reported to be higher in athletes than in the general population. **Methods:** Forty-six entering student athletes were screened in groups (6-10 per group) using a computerized cognitive battery (CNS Vital Signs), the screening subtests of the Scholastic Abilities Test for Adults, and rating scales (Brown ADD Scale, Wender-Utah Rating Scale). The testing took approximately 90 minutes per group. **Results:** Twenty-eight (61%) were identified as having ADHD and/or a learning disability on the basis of the screening. Their diagnoses were subsequently confirmed by formal neuropsychological evaluations and steps were taken to provide appropriate treatment services. Only four of the 28 (approximately 15%) had been previously evaluated. All of the 46 students were successful during their first few semesters in college. With the addition of Supplemental Instruction, a systematic educational approach used in core academic subjects, the LD/ADHD students did almost as well as the non-disabled students.
Conclusion: A brief, group administered battery can be used to screen for ADHD and learning disabilities in at-risk college students. The incidence of these disorders appears to be higher in student athletes.

IRB – 5/16/2008

Title : Screening for ADD/LD in Student Athletes

Enclosed, please find the data use agreement that the students signed

Mary Willingham

Mary W.

IRB CB# 7097

CHAPEL HILL
1829 East Franklin Street
400 Franklin Square
Chapel Hill, NC 27514
Telephone: (919) 933-2800
Fax: (919) 933-2830

CHARLOTTE
5208 Park Road
Charlotte, NC 28209
Telephone: (704) 529-4101
Fax: (704) 529-6655

North Carolina Neuropsychiatry, PA

ADULT FACE SHEET

Name: _____ DOB: _____

Address: _____

Town/City: _____ State: _____ Zip Code _____

Phone #: _____ Social Security #: _____

Who referred you to our clinic? _____

Occupation: _____ Business Phone _____

Employer Name & Address: _____

Spouse's Name: _____ Occupation _____

Employer: _____ Business Phone: _____

Insurance Company: _____ Group #: _____

Address: _____

Group Name: _____ Policy Holder: _____

CONSENT TO THE USE AND DISCLOSURE OF PATIENT HEALTH INFORMATION FOR TREATMENT, PAYMENT, RESEARCH AND HEALTHCARE OPERATIONS

I understand that my health information may be used and disclosed by NC Neuropsychiatry to carry out treatment, to obtain payment, and to conduct healthcare operations. I understand that NC Neuropsychiatry has a Privacy Policy, which gives a more complete description of uses and disclosures of health information, and which is freely available for me to read. I hereby grant medical personnel of NC Neuropsychiatry permission to release health information acquired in the course of my examination and treatment to the appropriate parties, with all due discretion, when necessary for treatment, payment, healthcare operations and emergency purposes. Examples of my health information that may be released include clinical findings, diagnosis, assessment, laboratory results, progress notes, psychotherapy notes, treatment recommendations, names of health care personnel, dates of hospitalizations, charges, visits, and any other information that may be related to medical and psychiatric conditions, including drug and alcohol related problems and sexually transmitted diseases. I understand that medical personnel at NC Neuropsychiatry will communicate, on a regular basis, with other treating health care providers. All records are kept confidential and shared only with pertinent personnel involved.

I understand that I may fill out rating scales and take psychological tests, including computerized tests, as part of a routine or special evaluation. I have been informed that the data from these instruments may be used for the purpose of research; for example, to evaluate the reliability of a test, or to assess the cognitive effects of different medications. My identity, however, is detached from these data before they are ever used, and can never be discovered or revealed.

I understand that I have the right to request restrictions on how health information may be used or disclosed, but that the provider designated is not required to agree to the restrictions requested. I understand that I have the right to revoke this consent in writing, except to the extent that the provider has taken action in reliance on the consent. I agree that this consent shall be valid for the duration of my treatment at NC Neuropsychiatry or until rescinded in writing.

Remarks, Stipulations: _____

_____

Signature: _____ Date: _____

Witness Signature: _____ Date: _____

North Carolina Neuropsychiatry, P.A.
1829 East Franklin Street, 400 Franklin Square, Chapel Hill, NC 27514
Phone: 919-933-2000 Fax: 919-933-2830

Release for Normative Research Database

I agree to take a computerized cognitive test called "©CNS Vital Signs".

CNS Vital Signs is an internet-based neurocognitive test battery that is scientifically sophisticated and easy to administer. It is designed to be used as a routine part of clinical practice, as a research instrument, and in schools or workplaces where health and safety are at issue. The test is currently used in physicians' offices to screen for mild cognitive dysfunction and may serve as a tool to evaluate whether medications are having an effect on mental function.

This new test system is called "©CNS Vital Signs" because it measures parameters that are indicative of the health of the brain, just as pulse, blood pressure, temperature, and respiratory rate measure the health of the body. The Vital Signs battery addresses the following cognitive areas: Attention, Memory, Psychomotor Speed, Reaction Time, and Cognitive Flexibility.

The test takes approximately 30 minutes and most people taking it find it challenging, but interesting. It is not an arduous test, but it does require concentration and mental effort. I have been informed that the test does not measure intelligence, personality, or mental illness. It is not a diagnostic test. A psychological or cognitive diagnosis requires a full evaluation by a trained clinician.

The only risk of participating in developing the data normatives is that I may discover that I have a cognitive impairment that needs to be evaluated by a physician or a psychologist. The doctors at North Carolina Neuropsychiatry will consult with me on this matter, at no cost. If I choose not to hear results from this test, whether there is impairment or not, then I should not take this test.

I have been informed that my participation is strictly voluntary. No special inducement has been offered to me for my data. I understand that I may stop taking the test and withdraw consent for my data to be used at any time and without penalty. I have been told that my test results will be used to develop normative data for this test. The results of the data may be presented at scientific meetings and published in medical journals. However, the results from my test will not be identifiable by name to anyone other than North Carolina Neuropsychiatry staff. After which time my data is stored in the database, it will not be retrievable by name. My personal demographic data; specifically age, gender, race, native language, years of education, and occupation level will be stored along with the test results.

By signing below, I agree to take ©CNS Vital Signs and allow my data to be included in the research database at North Carolina Neuropsychiatry. I understand that I may rescind this consent at any time, as put forth in writing.

Printed Name: _____ Date: _____

Address: _____

Participant Signature: _____ Date: _____

Witness Signature: _____ Date: _____

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
https://my.research.unc.edu for IRB status
Federalwide Assurance (FWA) #4801

To: Mary Willingham
Academic Services
CB: 8550 Kenan Field House

From: Behavioral IRB

Date: 5/19/2008

RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 08-0883

Study Title: Screening for ADD/LD in Student Athletes

This submission was reviewed by the above-referenced IRB. The IRB has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f)] and does not require IRB approval.

Study Description:

Purpose: To estimate the incidence of ADHD and learning disabilities in freshman student athletes.

Participants: 46 entering student athletes at UNC-Chapel Hill.

Procedures: Secondary data analysis.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

****

Lawrence B. Rosenfeld, Ph.D.
Office of Human Research Ethics
Co-Chair, Behavioral Institutional Review Board
CB# 7097, Medical School, Bldg 52
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7097
aa-irb-chair@unc.edu
phone 919-966-3113; fax 919-966-7879

****

First Review of IRB Submission
Initial

Training Not Met (Mary Willingham)

Receipt Date : 5/16/2008 **Expiration Date :** **Previous Review Type:**

IRB: Behavioral **PI:** Mary Willingham **IRB ID :** 08-0883 **IRB Coordinator :**

Title: Screening for ADD/LD in Student Athletes

☒ Not-HSR ☐ Exempt (Category:) ☐ Not Full IRB (Category:) ☐ Full IRB

Agenda Date Reviewer 1: Reviewer 2:

Entered by: Laura O Curry

Study Description:

Submission Description:

PROCESSING STEPS (OFFICE USE ONLY):
- ☐ Reviewer Checklist completed
- ☐ Minor Stipulation letter:
  - ☐ Draft letter prepared
  - ☐ Approved by chair as attached (Initials/Date:)
  - ☐ Approved by chair, see edits (Initials/Date:)
  - ☐ Email copy sent
  - ☐ Hard copy sent
- ☐ Approval letter:
  - ☑ Draft letter prepared DT
  - ☑ Approved by chair as attached (Initials/Date: TBL 5/21/08)
  - ☐ Approved by chair, see edits (Initials/Date:)
  - ☑ Email copy sent
  - ☑ Hard copy sent ✓
- Consent forms attached: Ø
- Other attachments: Ø

FINAL ACTIONS:
- ☑ Approved
- ☐ Approved with Minor Stipulations
- ☑ NHSR
- ☐ Return to sender
- ☐ Termination

Post Approval Submissions

Modification Information

ALERT: During the transition to online IRB applications, we are offering the following choices as a convenience between now and your next renewal. THIS APPLIES TO MODIFICATIONS ONLY.

If the application for this study was created ONLINE, you should proceed as directed below.

If the application for this study is currently on PAPER, you have two options to submit a modification:
1) You can continue to submit on paper until your next renewal is due. You may access the paper-based modification form here.
2) You can proceed with your online modification as directed below. This requires the conversion of your full application to the online format. Basic information about your study from the existing IRB database has been carried forward; however, the majority of information from your paper application will need to be entered at this time.

To modify an approved study, edit the individual answers that make up the application. The questions below are intended solely for the IRB to have a summary statement of your requested action. The modifications cannot be processed until the actual changes have been made throughout the application.

1.Provide a brief non-technical summary of any changes you will be making to the study. The text you enter here will be reproduced in the IRB approval document, and should contain the details that you and/or your sponsor find relevant (e.g., master protocol/amendment version number and date). Typical summaries are 50-100 words. Include a list of any documents that have been modified or added. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

This study now has screening information on 138 additional entering student athletes.

2.Is this modification being submitted in response to an unanticipated problem/adverse event or new findings?

No

3.Do any of the proposed changes increase risk?

No

4.Does this modification involve new information that requires reconsent of CURRENT subjects?

No Answer Provided

5.Is this study permanently closed to enrollment of subjects, all interventions and follow-up complete, and open for DATA ANALYSIS ONLY?

No

Continuing with Modifications

If the application for this study was created ONLINE, you will have access to your existing application. Click "save and continue."

If the application for this study is currently on PAPER, you have two options to submit a modification:

- *You can continue to submit on paper until your next renewal is due.*
- *You can submit the modification online. This requires the conversion of your full application to the online format. Basic information about your study from the existing IRB database has been carried forward; however, the majority of information from your paper application will need to be entered at this time. You may make any changes to the application that you are requesting at this time. Consent forms that currently exist on paper can be cut and pasted into the consent form editor. More details will be provided in the "Consent Forms" section.*

For additional guidance in converting your paper application, click here.

General Information

1. General Information

1.Project Title

Screening for ADD/LD in Student Athletes

2.**Brief Summary**. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Purpose: To estimate the incidence of ADHD and learning disabilities in freshman student athletes.

Participants: 184 entering student athletes at UNC-Chapel Hill.

Procedures: Secondary data analysis.

2. Project Personnel

1.Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

No

2.List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name	First Name	Department Name	Role	Detail
Willingham	Mary	Academic Services	Principal Investigator	view

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3.If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Academic Services

3. Funding Sources

1.Is this project funded (or proposed to be funded) by a contract or grant from an organization external to UNC-Chapel Hill?

No

2.Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

No

3.Is this research classified (e.g. requires governmental security clearance)?

No

4.Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- ✘ Grant Application
- ✘ Industry Sponsor Master Protocol
- ✘ Student Dissertation or Thesis Proposal
- ✘ Investigator Initiated Master Protocol
- ✘ Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH

1.Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

Yes

The next questions will determine if there are HUMAN SUBJECTS

2.Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

No

3.Will you be using identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

No

The following questions will help build the remainder of your application.

4.Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? If yes, this application will be reviewed by the CTRC and additional data will be collected.)

No Answer Provided

5.Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

No Answer Provided

6.Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)?

No Answer Provided

Part A. Questions Common to All Studies

A.9. Identifiers

1.Check all of the following identifiers you will be receiving. This does not apply to information on consent forms.

- ✘ Names
- ✘ Telephone numbers
- ✘ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- ✘ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- ✘ Fax numbers
- ✘ Electronic mail addresses
- ✘ Social security numbers
- ✘ Medical record numbers
- ✘ Health plan beneficiary numbers
- ✘ Account numbers
- ✘ Certificate/license numbers
- ✘ Vehicle identifiers and serial numbers (VIN), including license plate numbers
- ✘ Device identifiers and serial numbers (e.g., implanted medical device)
- ✘ Web universal resource locators (URLs)
- ✘ Internet protocol (IP) address numbers
- ✘ Biometric identifiers, including finger and voice prints
- ✘ Full face photographic images and any comparable images
- ✘ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

2.For any identifiers checked, how will these identifiers be stored in relationship to the research data?

- ✘ with the research data (i.e., in the same data set and/or physical location)
- ✘ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

3.Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

NHSR

NHSR Activities

Based on your responses, it appears that you are proposing a project that does not constitute research involving human subjects, and therefore does not require IRB approval. Please select the activities from the following list that best describe your project. The IRB will review this submission and you will be notified of the outcome.

1.Check all the following that describe your project.

- ✘ Program Evaluation
- ✘ Class projects for educational purposes only
- ✘ QI/QA for internal purposes
- ✘ Center or core grants (to establish infrastructure)
- ✘ Training grants
- ✘ Demonstration projects
- ✘ Case report (publication of clinical scenario that has already occurred)
- ✔ Secondary analysis of existing data or specimens, deidentified or coded
- ✘ Key informant interviews (e.g., interviewing officials about their organizations or policies)
- ✘ Other

2.Briefly describe your reason for checking the box(es) above:

Objective: To estimate the incidence of ADHD and LD in student athletes. The prevalence is frequently reported to be higher in athletes than the general population. Methods: One Hundred and Eighty Four student athletes were screened usuing a computerized congitive battery (CNS & Impace) and the subsets of the SATA and rating scales Brown, Wender-Utah). The testing took approximately 90 minutes. Results: 25% were identified as having ADHD or LD on the basis of the screening. Thier diagnosis were subsequently confirmed by fomal neuropschological evaluations and steps were taken to provide appropriate treatment. This is a significant finding over the general population 6-7%. Conclusion: A brief, group administered battery can be used to screen for ADHD and LD in at-risk college students. The incidence of these disorders appears to be higher in student athletes.

Attachments

File Name	Document Type
IRB 08_0883.pdf	Other

view attachments

By certifying below, the Principal Investigator affirms the following:

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 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.

This study proposes research that has been determined to include Security Level 1 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

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

Certifying Signatures:

Signature: Electronic Signature Received **Date:** 1/04/2013 03:15:49 PM

Mary Willingham

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Mary Willingham
Academic Services

From: Non-Biomedical IRB

Date: 1/07/2013

RE: Contingencies to be addressed following IRB Review
Submission Type: Modification
Study #: 08-0883

Study Title: Screening for ADD/LD in Student Athletes

This submission has been reviewed by the IRB. This is not an IRB approval. You may not implement the research activities described in your submission until you have received a memo indicating final IRB approval. The IRB determined that this submission MAY BE APPROVED, pending stipulated change(s) and/or clarification(s).

Your review will be found online at the link below. You will be able to respond to each stipulation using the online system.
http://apps.research.unc.edu/irb/eform_routing.cfm?masterid=117100&Section=attachments

[This page was blank.]

View Stipulations from this review

Number of Stipulations: 2

General Information

1. General Information

Brief Summary. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Created by Kristi Laan on 01/07/2013 01:46 PM

Please use the "go to question" button and revise the number of participants as you are adding 138.

Updated by Mary Willingham on 01/08/2013 03:07 PM

changes made using go to button

Updated by Kristi Laan on 01/09/2013 09:22 AM

Resolved

NHSR

NHSR Activities

Briefly describe your reason for checking the box(es) above:

Created by Kristi Laan on 01/07/2013 01:50 PM

Will you only be obtaining de-identified existing data? If a code exists that links the existing data to private identifiable data, who holds the link?

Updated by Mary Willingham on 01/08/2013 03:05 PM

It is only de-identified data. All links to identifiable information will be destroyed before importation into SPSS.

Updated by Kristi Laan on 01/09/2013 09:22 AM

Resolved

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Mary Willingham
Academic Services

From: Office of Human Research Ethics

Date: 1/09/2013

RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 08-0883

Study Title: Screening for ADD/LD in Student Athletes

This submission was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:

Purpose: To estimate the incidence of ADHD and learning disabilities in freshman student athletes.

Participants: 184 entering student athletes at UNC-Chapel Hill.

Procedures: Secondary data analysis.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

Post Approval Submissions

Modification Information

ALERT: During the transition to online IRB applications, we are offering the following choices as a convenience between now and your next renewal. THIS APPLIES TO MODIFICATIONS ONLY.

If the application for this study was created ONLINE, you should proceed as directed below.

If the application for this study is currently on PAPER, you have two options to submit a modification:
1) You can continue to submit on paper until your next renewal is due. You may access the paper-based modification form here.
2) You can proceed with your online modification as directed below. This requires the conversion of your full application to the online format. Basic information about your study from the existing IRB database has been carried forward; however, the majority of information from your paper application will need to be entered at this time.

To modify an approved study, edit the individual answers that make up the application. The questions below are intended solely for the IRB to have a summary statement of your requested action. The modifications cannot be processed until the actual changes have been made throughout the application.

1.Provide a brief non-technical summary of any changes you will be making to the study. The text you enter here will be reproduced in the IRB approval document, and should contain the details that you and/or your sponsor find relevant (e.g., master protocol/amendment version number and date). Typical summaries are 50-100 words. Include a list of any documents that have been modified or added. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Added Richard Southall to project personnel.

2.Is this modification being submitted in response to an unanticipated problem/adverse event or new findings?

No

3.Do any of the proposed changes increase risk?

No

4.Does this modification involve new information that requires reconsent of CURRENT subjects?

No

5.Is this study permanently closed to enrollment of subjects, all interventions and follow-up complete, and open for DATA ANALYSIS ONLY?

No

Continuing with Modifications

If the application for this study was created ONLINE, you will have access to your existing application. Click "save and continue."

If the application for this study is currently on PAPER, you have two options to submit a modification:

- *You can continue to submit on paper until your next renewal is due.*
- *You can submit the modification online. This requires the conversion of your full application to the online format. Basic information about your study from the existing IRB database has been carried forward; however, the majority of information from your paper application will need to be entered at this time. You may make any changes to the application that you are requesting at this time. Consent forms that currently exist on paper can be cut and pasted into the consent form editor. More details will be provided in the "Consent Forms" section.*

For additional guidance in converting your paper application, click here.

General Information

1. General Information

1.Project Title

Screening for ADD/LD in Student Athletes

2.**Brief Summary**. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Purpose: To estimate the incidence of ADHD and learning disabilities in freshman student athletes.

Participants: 184 entering student athletes at UNC-Chapel Hill.

Procedures: Secondary data analysis.

2. Project Personnel

1.Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

No

2.List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name	First Name	Department Name	Role	Detail
Willingham	Mary	Academic Services	Principal Investigator	view
Southall	Richard	Exercise and Sport Science	Co-investigator	view

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3.If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Academic Services

3. Funding Sources

1.Is this project funded (or proposed to be funded) by a contract or grant from an organization external to UNC-Chapel Hill?

No

2.Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

No

3.Is this research classified (e.g. requires governmental security clearance)?

No

4.Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- [x] Grant Application
- [x] Industry Sponsor Master Protocol
- [x] Student Dissertation or Thesis Proposal
- [x] Investigator Initiated Master Protocol
- [x] Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH

1.Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

Yes

The next questions will determine if there are HUMAN SUBJECTS

2.Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

No

3.Will you be using identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

No

The following questions will help build the remainder of your application.

4.Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? If yes, this application will be reviewed by the CTRC and additional data will be collected.)

No Answer Provided

5.Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

No Answer Provided

6.Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)?

No Answer Provided

Part A. Questions Common to All Studies

A.9. Identifiers

1.Check all of the following identifiers you will be receiving. This does not apply to information on consent forms.

- ✘ Names
- ✘ Telephone numbers
- ✘ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- ✘ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- ✘ Fax numbers
- ✘ Electronic mail addresses
- ✘ Social security numbers
- ✘ Medical record numbers
- ✘ Health plan beneficiary numbers
- ✘ Account numbers
- ✘ Certificate/license numbers
- ✘ Vehicle identifiers and serial numbers (VIN), including license plate numbers
- ✘ Device identifiers and serial numbers (e.g., implanted medical device)
- ✘ Web universal resource locators (URLs)
- ✘ Internet protocol (IP) address numbers
- ✘ Biometric identifiers, including finger and voice prints
- ✘ Full face photographic images and any comparable images
- ✘ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

2.For any identifiers checked, how will these identifiers be stored in relationship to the research data?

- ☒ with the research data (i.e., in the same data set and/or physical location)
- ☒ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

3.Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

NHSR

NHSR Activities

Based on your responses, it appears that you are proposing a project that does not constitute research involving human subjects, and therefore does not require IRB approval. Please select the activities from the following list that best describe your project. The IRB will review this submission and you will be notified of the outcome.

1.Check all the following that describe your project.

- ☒ Program Evaluation
- ☒ Class projects for educational purposes only
- ☒ QI/QA for internal purposes
- ☒ Center or core grants (to establish infrastructure)
- ☒ Training grants
- ☒ Demonstration projects
- ☒ Case report (publication of clinical scenario that has already occurred)
- ☑ Secondary analysis of existing data or specimens, deidentified or coded
- ☒ Key informant interviews (e.g., interviewing officials about their organizations or policies)
- ☒ Other

2.Briefly describe your reason for checking the box(es) above:

Objective: To estimate the incidence of ADHD and LD in student athletes. The prevalence is frequently reported to be higher in athletes than the general population. Methods: One Hundred and Eighty Four student athletes were screened usuing a computerized congitive battery (CNS & Impace) and the subsets of the SATA and rating scales Brown, Wender-Utah). The testing took approximately 90 minutes. Results: 25% were identified as having ADHD or LD on the basis of the screening. Thier diagnosis were subsequently confirmed by fomal neuropschological evaluations and steps were taken to provide appropriate treatment. This is a significant finding over the general population 6-7%. Conclusion: A brief, group administered battery can be used to screen for ADHD and LD in at-risk college students. The incidence of these disorders appears to be higher in student athletes.

Attachments

This submission requires the following attachments

Document Type

This submission includes the following attachments

File Name	Document Type
IRB 08_0883.pdf	Other

view attachments

By certifying below, the Principal Investigator affirms the following:

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 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.

This study proposes research that has been determined to include Security Level 1 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

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

Certifying Signatures:

Signature: Electronic Signature Received **Date:** 4/08/2013 08:52:07 PM

Mary Willingham

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Mary Willingham
Academic Services

From: Office of Human Research Ethics

Date: 4/09/2013

RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 08-0883

Study Title: Screening for ADD/LD in Student Athletes

This submission was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:

Purpose: To estimate the incidence of ADHD and learning disabilities in freshman student athletes.

Participants: 184 entering student athletes at UNC-Chapel Hill.

Procedures: Secondary data analysis.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

CC:
Richard Southall, Exercise and Sport Science

Post Approval Submissions

Modification Information

To modify an approved study, edit the individual answers that make up the application. The questions below are intended solely for the IRB to have a summary statement of your requested action. The modifications cannot be processed until the actual changes have been made throughout the application.

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Add Dr. Jay Smith as a secondary investigator

2.Is this modification being submitted in response to an unanticipated problem/adverse event or new findings?

No

3.Do any of the proposed changes increase risk?

No

4.Does this modification involve new information that requires reconsent of CURRENT subjects?

No

5.Is this study permanently closed to enrollment of subjects, all interventions and follow-up complete, and open for DATA ANALYSIS ONLY?

No

Continuing with Modifications

Click the "save and continue" button to access your existing application.
You may make any changes to the application that you are requesting at this time.

General Information

1. General Information

1.Project Title

Screening for ADD/LD in Student Athletes

2.**Brief Summary**. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

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Participants: 184 entering student athletes at UNC-Chapel Hill.

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2. Project Personnel

1.Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

No

2.List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
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Last Name	First Name	Department Name	Role	Detail
Willingham	Mary	Academic Services	Principal Investigator	view
Southall	Richard	Exercise and Sport Science	Co-investigator	view
Smith	Jay	History	Co-investigator	view

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3.If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Academic Services

3. Funding Sources

1.Is this project funded (or proposed to be funded) by a contract or grant from an organization external to UNC-Chapel Hill?

No

2.Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

No

3.Is this research classified (e.g. requires governmental security clearance)?

No

4.Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- [x] Grant Application
- [x] Industry Sponsor Master Protocol
- [x] Student Dissertation or Thesis Proposal
- [x] Investigator Initiated Master Protocol
- [x] Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH

1.Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

Yes

The next questions will determine if there are HUMAN SUBJECTS

2.Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

No

3.Will you be using identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

No

The following questions will help build the remainder of your application.

4.Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? If yes, this application will be reviewed by the CTRC and additional data will be collected.)

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5.Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

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No Answer Provided

Part A. Questions Common to All Studies

A.9. Identifiers

1.Check all of the following identifiers you already have or will be receiving. This does not apply to information on consent forms.

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- [x] Telephone numbers

- [x] Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older
- [x] Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code
- [x] Fax numbers
- [x] Electronic mail addresses
- [x] Social Security numbers
- [x] Medical record numbers
- [x] Health plan beneficiary numbers
- [x] Account numbers
- [x] Certificate/license numbers
- [x] Vehicle identifiers and serial numbers (VIN), including license plate numbers
- [x] Device identifiers and serial numbers (e.g., implanted medical device)
- [x] Web universal resource locators (URLs)
- [x] Internet protocol (IP) address numbers
- [x] Biometric identifiers, including finger and voice prints
- [x] Full face photographic images and any comparable images
- [x] Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

2.For any identifiers checked, how will these identifiers be stored in relationship to the research data?

- [x] with the research data (i.e., in the same data set and/or physical location)
- [x] separate from the research data (i.e., coded with a linkage file stored in a different physical location)

3.Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

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NHSR

NHSR Activities

Based on your responses, it appears that you are proposing a project that does not constitute research involving human subjects, and therefore does not require IRB approval. Please select the activities from the following list that best describe your project. The IRB will review this submission and you will be notified of the outcome.

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- [x] Class projects for educational purposes only

- ✘ QI/QA for internal purposes
- ✘ Center or core grants (to establish infrastructure)
- ✘ Training grants
- ✘ Demonstration projects
- ✘ Case report (publication of clinical scenario that has already occurred)
- ✔ Secondary analysis of existing data or specimens, deidentified or coded
- ✘ Key informant interviews (e.g., interviewing officials about their organizations or policies)
- ✘ Other

2.Briefly describe your reason for checking the box(es) above:

Objective: To estimate the incidence of ADHD and LD in student athletes. The prevalence is frequently reported to be higher in athletes than the general population. Methods: One Hundred and Eighty Four student athletes were screened usuing a computerized congitive battery (CNS & Impace) and the subsets of the SATA and rating scales Brown, Wender-Utah). The testing took approximately 90 minutes. Results: 25% were identified as having ADHD or LD on the basis of the screening. Thier diagnosis were subsequently confirmed by fomal neuropschological evaluations and steps were taken to provide appropriate treatment. This is a significant finding over the general population 6-7%. Conclusion: A brief, group administered battery can be used to screen for ADHD and LD in at-risk college students. The incidence of these disorders appears to be higher in student athletes.

Attachments

This submission requires the following attachments

Document Type

This submission includes the following attachments

File Name	Document Type
IRB 08_0883.pdf	Other

view attachments

By certifying below, the Principal Investigator affirms the following:

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 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.

This study proposes research that has been determined to include Security Level 1 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

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

Certifying Signatures:

Signature: Electronic Signature Received **Date:** 6/24/2013 03:23:54 PM
Mary Willingham

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Mary Willingham
Academic Services

From: Office of Human Research Ethics

Date: 6/24/2013

RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 08-0883

Study Title: Screening for ADD/LD in Student Athletes

This submission was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:
Purpose: To estimate the incidence of ADHD and learning disabilities in freshman student athletes.
Participants: 184 entering student athletes at UNC-Chapel Hill.
Procedures: Secondary data analysis.

Submission Description:
Add Dr. Jay Smith as a secondary investigator.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

CC:
Richard Southall, Exercise and Sport Science
Jay Smith, History

Post Approval Submissions

Modification Information

To modify an approved study, edit the individual answers that make up the application. The questions below are intended solely for the IRB to have a summary statement of your requested action. The modifications cannot be processed until the actual changes have been made throughout the application.

1.Provide a brief non-technical summary of any changes you will be making to the study. The text you enter here will be reproduced in the IRB approval document, and should contain the details that you and/or your sponsor find relevant (e.g., master protocol/amendment version number and date). Typical summaries are 50-100 words. Include a list of any documents that have been modified or added. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Compare this (deidentified) cohort with previous cohorts and include graduation trends.

2.Is this modification being submitted in response to an unanticipated problem/adverse event or new findings?

No

3.Do any of the proposed changes increase risk?

No

4.Does this modification involve new information that requires reconsent of CURRENT subjects?

No

5.Is this study permanently closed to enrollment of subjects, all interventions and follow-up complete, and open for DATA ANALYSIS ONLY?

No

Continuing with Modifications

Click the "save and continue" button to access your existing application.
You may make any changes to the application that you are requesting at this time.

General Information

1. General Information

1.Project Title

Screening for ADD/LD in Student Athletes

2.**Brief Summary**. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

Purpose: To estimate the incidence of ADHD and learning disabilities in freshman student athletes.

Participants: 184 entering student athletes at UNC-Chapel Hill.

Procedures: Secondary data analysis.

2. Project Personnel

1.Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

No

2.List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name	First Name	Department Name	Role	Detail
Willingham	Mary	Academic Services	Principal Investigator	view
Southall	Richard	Exercise and Sport Science	Co-investigator	view
Smith	Jay	History	Co-investigator	view

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3.If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Academic Services

3. Funding Sources

1.Is this project funded (or proposed to be funded) by a contract or grant from an organization EXTERNAL to UNC-Chapel Hill?

No

2.Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

No

3.Is this research classified (e.g. requires governmental security clearance)?

No

4.Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- ✘ Grant Application
- ✘ Industry Sponsor Master Protocol
- ✘ Student Dissertation or Thesis Proposal
- ✘ Investigator Initiated Master Protocol
- ✘ Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH

1.Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

Yes

The next questions will determine if there are HUMAN SUBJECTS

2.Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

No

3.Will you be using identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

No

The following questions will help build the remainder of your application.

4.Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? If yes, this application will be reviewed by the CTRC and additional data will be collected.)

No Answer Provided

5.Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

No Answer Provided

6.Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. See guidance.

No Answer Provided

Part A. Questions Common to All Studies

A.9. Identifiers

1.Check which of the following identifiers you already have or will be receiving, or select "None of the above." This does not apply to information on consent forms.

- ✘ Names
- ✘ Telephone numbers

☒ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older

☒ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code

☒ Fax numbers

☒ Electronic mail addresses

☒ Social Security numbers

☒ Medical record numbers

☒ Health plan beneficiary numbers

☒ Account numbers

☒ Certificate/license numbers

☒ Vehicle identifiers and serial numbers (VIN), including license plate numbers

☒ Device identifiers and serial numbers (e.g., implanted medical device)

☒ Web universal resource locators (URLs)

☒ Internet protocol (IP) address numbers

☒ Biometric identifiers, including finger and voice prints

☒ Full face photographic images and any comparable images

☒ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

☒ None of the above

2.For any identifiers checked, how will these identifiers be stored in relationship to the research data?

☒ with the research data (i.e., in the same data set and/or physical location)

☒ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

3.Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

NHSR

NHSR Activities

Based on your responses, it appears that you are proposing a project that does not constitute research involving human subjects, and therefore does not require IRB approval. Please select the activities from the following list that best describe your project. The IRB will review this submission and you will be notified of the outcome.

1.Check all the following that describe your project.

☒ Program Evaluation

- ✗ Class projects for educational purposes only
- ✗ QI/QA for internal purposes
- ✗ Center or core grants (to establish infrastructure)
- ✗ Training grants
- ✗ Demonstration projects
- ✗ Case report (publication of clinical scenario that has already occurred)
- ✓ Secondary analysis of existing data or specimens, deidentified or coded
- ✗ Key informant interviews (e.g., interviewing officials about their organizations or policies)
- ✗ Emergency use of investigational test article (without prior IRB approval)
- ✗ Research involving records or specimens from deceased individuals
- ✗ Other

2.Briefly describe your reason for checking the box(es) above:

Objective: To estimate the incidence of ADHD and LD in student athletes. The prevalence is frequently reported to be higher in athletes than the general population. Methods: One Hundred and Eighty Four student athletes were screened usuing a computerized congitive battery (CNS & Impace) and the subsets of the SATA and rating scales Brown, Wender-Utah). The testing took approximately 90 minutes. Results: 25% were identified as having ADHD or LD on the basis of the screening. Thier diagnosis were subsequently confirmed by fomal neuropschological evaluations and steps were taken to provide appropriate treatment. This is a significant finding over the general population 6-7%. Conclusion: A brief, group administered battery can be used to screen for ADHD and LD in at-risk college students. The incidence of these disorders appears to be higher in student athletes.

Attachments

This submission requires the following attachments

Document Type

This submission includes the following attachments

File Name	Document Type
IRB 08_0883.pdf	Other

view attachments

By certifying below, the Principal Investigator affirms the following:

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 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.

This study proposes research that has been determined to include Security Level 1 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

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

Certifying Signatures:

Signature: Electronic Signature Received **Date:** 11/12/2013 04:06:26 PM
Mary Willingham

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
Medical School Building 52
Mason Farm Road
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Mary Willingham
Academic Services

From: Office of Human Research Ethics

Date: 11/13/2013
RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 08-0883

Study Title: Screening for ADD/LD in Student Athletes

This submission was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (d or f) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:

Purpose: To estimate the incidence of ADHD and learning disabilities in freshman student athletes.

Participants: 184 entering student athletes at UNC-Chapel Hill.

Procedures: Secondary data analysis.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

CC:
Jay Smith, History
Richard Southall, Exercise and Sport Science

IRBIS

Logged in as Joy Bryde on apps0

HOME COMMITTEE REVIEWS ADMIN HELP LOGOUT

Study History Back to previous page

Timestamp Log IRB Number: 13 - (05-9999) Search Screening for ADD/LD in Student Athletes.

IRB No:	08-0883	**Study Status:**	NHSR
IRB:	Non-Biomedical	**Expiration Date:**	
PI:	Mary Willingham	**Last Approved:**	
Study Notes:	None found		

Submissions for 08-0883

Submission Type	Approval State	Date Submitted	Approval Date	Expiration Date	Review Type
Modification	NHSR	11/12/2013			Not Full Board
Modification	NHSR	06/24/2013			Not Full Board
Modification	NHSR	04/09/2013			Not Full Board
Modification	NHSR	01/04/2013			Not Full Board
>> Initial *	NHSR	05/16/2008			Not Full Board

* paper submissions

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

This application is supported by UNC-CH Research Information Technology
Please contact us if you have any questions

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
MEDICAL SCHOOL BUILDING 52
CAMPUS BOX 7097
CHAPEL HILL, NC 27599-7097
T: 919 843-8806
F: 919 966-7879
URL: HTTP://OHRE.UNC.EDU/

January 16, 2014

Mary Willingham
Learning Specialist
Center for Student Success and Academic Counseling
2206 SASB North Suite # 2203, Campus Box 3106
Chapel Hill, NC 27599-3106

RE: IRB Study #08-0883, "Screening for ADD/LD in Student Athletes"

As you know, our office made the determination in 2008 (and reaffirmed in 2013) that the project referenced above did not constitute research involving human subjects, as defined by federal guidance. Because it was understood to not involve human subjects, it did not require IRB approval. As a point of clarification, please note that this determination (i.e., that your project was not human subjects research) did not constitute an IRB approval, as it has been characterized in some recent communications.

This determination was based on information provided in your application(s), which led us to conclude that (a) you were conducting a secondary analysis using data collected by others for non-research purposes; and (b) you and other investigators would not be able to identify individual student athletes, i.e., the data were de-identified. If there are codes that might allow linkage to identifiers, these must reside in the custody of others who are outside of the research team, and are not to be shared with the researchers conducting the secondary analysis. This permanent "firewall" that separates research data from identifiers is what allows the determination that such projects do not involve human subjects.

It has now come to our attention that the dataset currently in your possession contains identifiers, which contradicts your earlier claims. Therefore, we must rescind our prior determination, effective immediately. If you wish to continue with research using these data, please submit a full application for review by the IRB. Any continued use of these data in the absence of IRB approval constitutes a violation of University and federal policies for protection of human subjects. Because it appears that your data are identifiable, it is even more imperative that you continue to protect the identities of individual subjects in your dataset. Please be sure to communicate this to others involved in your project.

Sincerely,

Jeanne Lovmo, MA
OHRE Compliance Coordinator

cc: Daniel Nelson, Director, Office of Human Research Ethics
Barbara Entwisle, Vice Chancellor for Research
Bobbi Owen, Senior Associate Dean for Undergraduate Education

From: Lovmo, Jeanne
To: Nelson, Daniel K
Subject: FW: FINAL Letter for Mary Willingham from UNC IRB 1-16-2014 -on Letterhead.pdf
Date: Thursday, January 16, 2014 5:25:00 PM

This email from Richard Southall was forwarded to me form Mary Willingham.
Jeanne

-----Original Message-----
From: Willingham, Mary C.
Sent: Thursday, January 16, 2014 5:12 PM
To: Lovmo, Jeanne
Subject: FW: FINAL Letter for Mary Willingham from UNC IRB 1-16-2014 -on Letterhead.pdf

_____

From: SOUTHALL, RICHARD [Southall@hrsm.sc.edu]
Sent: Thursday, January 16, 2014 5:07 PM
To: Willingham, Mary C.
Subject: Re: FINAL Letter for Mary Willingham from UNC IRB 1-16-2014 -on Letterhead.pdf

Mary,

Thank you for forwarding me the letter from the UNC OHRE.

If you want, as co-investigator on the referenced project, I would be happy to assist you in completing a full application for review with the UNC-CH Office of Human Research Ethics via the IRBIS system.

Before we begin this process, could you please forward several questions I have to the proper individual, perhaps Ms. Jeanne Lovmo - OHRE Compliance Coordinator. You may simply want to forward this email to her.

Please find out whether this full application for review should be completed as a modification to the current referenced study or whether this should a a new study submission. This will affect how the IRBIS application process is completed.

Also, there are several questions that are pertinent and on which I would appreciate clarification:

1) Are the individuals to whom you forwarded the the original non-research data (I think this is the data Dr. Lyn Johnson and you collected) precluded from utilizing the data and conducting any analyses? In other words, is Provost Dean or any other UNC staff member currently conducting any analysis on the original data set (with identifiers) forwarded to them? Is Dr. Dean and/or his staff subject to the restrictions noted in the attached letter. I ask this to insure no one is currently utilizing this data for analysis, since it would constitute a violation of University and federal policies.

2) The data you forwarded to me as I have previously noted was immediately de-identified (names were removed and subject #s assigned). There are no names on the data set I possess. However, can you ask Ms. Lovmo if, I am precluded from conducting a secondary analysis on the dataset, as was my understanding could be conducted under the assigned IRB 08-0883 study protocol. This data set does contain independent variables of race, gender, major, and sport. Are these considered ³identifiers?"

3) On this new application, are we restricted to the co-investigators listed on IRB Number 08-0883? The investigators I would like to add are Dr. Mark Nagel - University of South Carolina and Dr. E. Woodrow Eckard - University of Colorado-Denver.

Thanks in advance, for your assistance with this matter. I look forward to hearing back from you and conducting the

independent secondary analysis you have requested.

Sincerely,

Dr. Richard M. Southall

Dr. Richard M. Southall
Associate Professor
Director - College Sport Research Institute http://csri-sc.org/ Department of Sport and Entertainment Management
University of South Carolina Carolina Coliseum, Room 2024 Columbia, SC 29208

Office: 803.777-5550
Cell: 901.240-7197
Email: southall@hrsm.sc.edu

7th Annual CSRI Conference on College Sport April 22-26, 2014 csriconference.org <http://csriconference.org/>

On 1/16/14, 4:08 PM, "Willingham, Mary C." <mwillingham@unc.edu> wrote:

>
>

From: Tegnell, David G
Sent: Tuesday, January 21, 2014 12:53 PM
To: Borasky, David
Subject: Mary's UNC-G thesis

Dave, Mary Willingham's UNC-G thesis is available online via the UNC-G Libraries catalog. This thesis has little if anything to do with Mary's UNC-CH research. Jeanne has already reviewed the thesis, and says it constitutes essentially a review of other researchers' studies. Mary includes data tables in an appendix; these data were not gathered from UNC-CH. Jeanne points out that Mary lists in her bibliography her UNC-CH study on ADHD, which we determined to be NHSR—but that's the only connection between the thesis and Mary's UNC-CH research. Jeanne also says that Mary did not receive IRB approval for her thesis from UNC-G's IRB. In other words, we can't assume that Mary's UNC-CH research was covered by UNC-G's IRB or subsumed under Mary's UNC-G thesis work. The CNN story connecting the two appears to be inaccurate.

David Tegnell
IRB Coordinator / Help Desk
Office of Human Research Ethics
Direct line: 919-966-3685
OHRE: 919-966-3113
tegnell@email.unc.edu

For the past two weeks, there has been intense media coverage of research conducted by a UNC employee on literacy rates among student-athletes. These reports contained numerous errors and misrepresentations with regard to the IRB status of this research. The following statement was prepared by the Office of Human Research Ethics, which oversees the IRBs, to respond to media inquiries and address inaccuracies in prior reports:

January 21, 2014

We did not suspend approval for Mary Willingham's research. She has never had Institutional Review Board (IRB) approval, so there was no approval to suspend.

In 2008, Ms. Willingham requested a "Determination Whether Research or Similar Activities Require IRB Approval" (which is both the label and purpose of the form she submitted), and that is what she received. Based on the information provided, most importantly the certification that she and other researchers would be working solely with de-identified data, we determined that her proposed activity did not involve human subjects (as defined by federal regulations). "De-identified" does not mean that researchers will protect the identity of their subjects and not disclose them publicly (which is an obvious expectation for virtually all research)… but means that the researchers themselves do not have access to names or codes that would allow them to re-identify individual subjects. Many research projects are conducted in this manner and, because Ms. Willingham stipulated this was how her study would be done, it did not require IRB approval. This determination has been consistently misrepresented as an IRB or institutional approval, but this is not accurate.

On Jan 16, my office took action to correct the prior determination, as we would with any research project if/when it becomes clear that we were working with faulty or incomplete information. There should be no implication that Ms. Willingham was singled out, or that her provision of an identifiable dataset to the Provost was a violation that triggered our action. Rather, it was our realization that the researchers had, in fact, been in possession of named data all along; this was confirmed by multiple sources, including Ms. Willingham's own statements via the press. This constituted new information that contradicted her earlier statements to the IRB, and we acted accordingly.

There should also be no implication that my office was pressured to take this action. The IRB at UNC operates with a very high degree of independence and authority, as it was intended. As example, neither I nor my staff have ever heard from or communicated with Provost Dean on this (or any other) matter; I met him for the first time on Jan 17, for 30 seconds, when I attended the Faculty Council meeting in case questions arose that required my input.

In terms of the process going forward, Ms. Willingham has the same opportunity as any employee to apply for IRB approval of her research. This would be subject to the same review as any study, which will address issues of informed consent, access to records, and compliance with federal, state and university policies.

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Daniel K. Nelson, Director
Office of Human Research Ethics
Professor of Social Medicine
Adjunct Professor of Pediatrics
Faculty Associate, Center for Bioethics
University of North Carolina at Chapel Hill
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

From: Borasky, David
Sent: Thursday, January 23, 2014 10:37 PM
To: Nelson, Daniel K; Entwisle, Barbara
Subject: FW: additional information

Dan and Barbara,

Below is my most recent correspondence with Ms. Willingham. As I indicate in my email to her, I think her questions are a result of the meeting on Wednesday where we talked at several points about identified versus de-identified data, data ownership, and the approvals she would need to continue her work.

We've done our best to answer her questions completely and clearly, and have assured her that we would be happy to answer any additional questions about OHRE/IRB requirements, and navigating the IRBIS system should she decide to pursue IRB approval.

Dave

From: Borasky, David
Sent: Thursday, January 23, 2014 10:31 PM
To: Willingham, Mary C.
Subject: RE: additional information

Good evening Mary,

It's a fair question, since we spent time on Wednesday talking about the identifiability of data as a key factor in the IRB review process.

As we also discussed, any use of data going forward – including re-analysis or new analysis – would have to approved by the original owner/custodian of the data. That would be the case whether the analyses were performed entirely in-house or through an external research team, as you describe. We (OHRE, IRB) cannot speak for the University in this regard, but you might predict that they would have even greater concerns about sharing student data with external third parties, even if you de-identified them first.

On another note, we would typically use the phrase "primary data collection" to mean data obtained by researchers for research purposes. If that accurately describes data in your possession from 2004-2012, this would also raise the question of informed consent to support that collection and use.

As before, I am happy to try and answer any additional questions you have regarding IRB requirements or IRBIS.

Regards,

Dave

~~~~~~

David Borasky, MPH, CIP
Deputy Director, Office of Human Research Ethics
Medical School Bldg 52
CB# 7097
University of North Carolina at Chapel Hill
~~~~~~

Chapel Hill, NC 27599-7097
919.843.3186 (T)
919.966.7879 (F)
dborasky@email.unc.edu
http://ohre.unc.edu

From: Willingham, Mary C.
Sent: Thursday, January 23, 2014 4:35 PM
To: Borasky, David
Cc: Smith, Jay M
Subject: RE: additional information

David,
With regards to my data set, is it possible for me to de- identify it, destroy all other files and give it to a research team? This team would be comprised of content-area experts including (for example):

- Reading and literacy,
- Counseling psychology,
- Athlete academic support,
- Quantitative statistics, and
- College-sport organizational culture

The 'team' would be formed **at another institution** to conduct an analysis of the data obtained during the primary data collection from 2004 – 2012.
I believe that we discussed this possibility, and I just wanted clarification. Thanks again, Mary

---

From: Borasky, David
Sent: Wednesday, January 22, 2014 11:18 AM
To: Willingham, Mary C.; Smith, Jay M
Subject: additional information

Hi Mary and Jay,

It was nice to meet with you today.

For Mary's department, Student Success-Academic Counseling, the "approver" who will need to sign off on your IRB application before it comes through our electronic doorway is Harold Woodard.

If you have additional technical questions about the IRB online system, general IRB requirements, or questions specific to your application you are welcome to contact us. My direct line is listed below.

Regards,

Dave

~~~~~~

David Borasky, MPH, CIP
Deputy Director, Office of Human Research Ethics
Medical School Bldg 52
CB# 7097
University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7097
919.843.3186 (T)
919.966.7879 (F)
dborasky@email.unc.edu
http://ohre.unc.edu
~~~~~~

From: Tegnell, David G
Sent: Sunday, February 16, 2014 8:52 AM
To: Borasky, David
Subject: Fwd: Willingham_oped
Attachments: Willingham_oped.pdf; ATT00001.htm

Dave, I hope Mary separately sent you a copy of this. But if not, I want to be clear: I have had no contact with Mary since our meeting in the trailer.
David

Sent from my iPhone

Begin forwarded message:

> **From:** "Willingham, Mary C." <mwillingham@unc.edu>
> **Date:** February 16, 2014 at 7:19:37 AM EST
> **To:** "Tegnell, David G" <tegnell@email.unc.edu>
> **Subject: Willingham_oped**
>
> David,
> I've sent this letter along to the DTH, In in the event that they don't print it, I wanted to make sure that you received a copy. Thanks, Mary

Data that I collected while assessing the reading and writing abilities of a subset of UNC athletes between 2005 and 2012 have been the source of great controversy on our campus recently. Although I must refrain from talking about the data itself, there are a number of misconceptions that I would very much like to dispel.

Perhaps most important, I want to make clear that, in my opinion, the Institutional Review Board (IRB) acted in good faith when it put a halt to my research in January. I remain confused by the processes that led the IRB to determine in 2008 that my proposed study did not need the full review normally given to human research protocols, and I never intentionally misled anyone about the data I was collecting, but I understand that when someone brought to the attention of the IRB staff that I was in possession of an "identifiable" dataset, they did the only thing they could do; they complied with federal guidelines and stopped the study. I have never meant to impugn the professionalism of the IRB. I apologize for words uttered in frustration, and anger.

It bears emphasizing, however, that whatever procedural flaw may have marred my initial application to the IRB in 2008, the data I collected between 2005 and 2012 were in no way compromised by it. The data are objective scores earned on tests which I did not even administer; the fact that scores could theoretically be traced back to the individuals who earned them does not change the nature of the score earned or the level of the measured ability.

As for the provost's claim that I badly misinterpreted the scores in question, even confusing one kind of score for another, all I can say is that I, unlike the provost, have nearly twelve years of experience in interpreting reading scores. I have interpreted the scores of literally hundreds of students over the years, and for four years I worked closely with specialists in disability services here at UNC to correlate test scores with specific forms of learning disability.

This brings me to my last points. Everyone from Jim Dean to Roy Williams has scoffed at my claim that some UNC athletes were non-readers, and they dismiss as outlandish my suggestion that a significant percentage of profit-sport athletes read below the high school level. This continues a pattern, since I have tried without cease since the fall of 2010 to alert university leaders to problems with the education of our athletes; time and again I have seen my claims denied or ignored. Why the University would seek to dismiss and attack the literacy assessments of the learning specialist it hired to aid with academic assessments and accommodations for athletes is a mystery that may never be solved. In any case, neither the effort to dispute my data nor the reforms recently introduced in the academic support program and the admissions office help to address the structural inequalities built into the big-time college sport enterprise. I know from experience that too many UNC athletes have been forced to accept a watered down version of a college education. We owe current and future athletes an honest confrontation with this injustice.

Mary Willingham
CSSAC