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.

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.

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)?

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.

- [x] Names
- [x] 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:** 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
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
****

DRAFT

OFFICE OF HUMAN RESEARCH ETHICS
Institutional Review Board

DETERMINATION WHETHER RESEARCH OR SIMILAR ACTIVITIES REQUIRE IRB APPROVAL
Version 19-Feb-2008

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
UNC-CH PID: 7099-85125 Pager: # 8550
Phone #: 843-6029 Fax #: 962-8243 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.

CHAPEL HILL
1308 East Franklin Street
200 Franklin Square
Chapel Hill, NC 27514
Telephone: (919) 933-2626
Fax: (919) 933-2628

CHARLOTTE
5200 Park Road
Charlotte, NC 28209
Telephone: (704) 529-4101
Fax: (704) 529-4655

North Carolina Neuropsychiatry, PA

ADULT FACE SHEET

Patient: _____ 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: _____

REVISED 09/01/04

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 computer based neuropsychological 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: _____