FOR CCI USE ONLY
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Administrator: Astrid Joseph

Consent Approval Date: 1/6/16

Protocol Number: 2015P000378

Study Approval Expiration Date: 12/20/16

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12/20/2016
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY
General Public Consent

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: THE FOOTBALL PLAYERS HEALTH STUDY AT HARVARD UNIVERSITY – MOBILE PHONE APP
PRINCIPAL INVESTIGATOR: ALVARO PASCUAL-LEONE, MD, PHD
PROTOCOL NUMBER: 2015P000378

INTRODUCTION:

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Please read this consent form carefully and contact the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be emailed a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Alvaro Pascual-Leone, and is funded by the National Football League Players Association (NFLPA). The funding agency in this study, the NFLPA, is paying Beth Israel Deaconess Medical Center and Harvard Medical School to perform this research. The following study investigators and staff have additional interests in this research project or in the funding agency as follows: Associate Director of the Football Players Health Study, Dr. William P. Meehan III, serves as an unpaid consultant to the NFLPA on the Mackey-White Traumatic Brain Injury Foundation. Co-Director, Dr. Ross Zafonte, serves as the director of the MGH TRUST clinic funded by the NFLPA.

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WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Pascual-Leone, Principal Investigator, at (617) 432-5000 or Alixandra Nozzolillo, Player Relations Manager, at (617) 432-5000.

PURPOSE

The goal of this study is to help us better understand health issues that former professional football players face using a mobile app, *TeamStudy*. We will ask you to use a mobile app to collect health information over time. This app uses a mix of surveys, activities, and information from sensors in your phone to track your health, movement and symptoms. For example, we will use surveys to ask you questions about any pain that you are having. We will ask questions about your physical activity level. The phone sensors can collect information about the number of steps that you take in a day. These are ways that we can see different health patterns over time. Former professional football players can use this app as a way to confidentially share health information with the Football Players Health Study at Harvard University.

STUDY PARTICIPANTS

You are being asked to participate in this study as you are a member of the general public. You will be the “control Arm” of the study. This means that your information will be compared to information collected from former professional football players to look for differences.

DESCRIPTION OF STUDY DETAILS

If you decide to join the study you will need to download the free study application on your mobile device and register to the study. Currently, the app is only available for use on an iPhone. The *TeamStudy* is available in the Apple App Store. Once you have signed up for the study, we will ask you to periodically respond to surveys and/or perform tasks using your mobile phone.

Signing up for the study:

Once you download the app, you will answer some basic eligibility questions, for example, if you are comfortable reading and writing in English on your phone. If you qualify, you will:

- Review a series of phone screens that will describe the study including the risks and benefits of using the app (informed consent).
    - You will have to answer a few questions to show that you understand the study.

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- You will then create your account by entering your name and email address.
    - Your name and email will:
        - Be used to send you a copy of the informed consent.
        - Not be directly connected to any of the information collected from the app.

- You will have the chance to decide what sensors on your phone you will allow the app to use. For example, one of the activities asks you to count out loud and the microphone will record your voice. If you don't want your voice recorded, then you can shut off the microphone. You can change these preferences at any time.

- For your privacy, you will be required to create a password that you will use to access the app on your phone.

- You can cancel out of the registration process at any time.

What to Expect While Using *TeamStudy*

Health Surveys:
You will be asked to answer questions about yourself, your health history and medications, and your current health and symptoms. For example, you will be asked to answer questions about any pain that you may be having or questions about your activity level.

- The surveys will be sent to you about once a week.
- You may skip any questions that you do not wish to answer.

Tasks and Physical Activities:

You will be asked to perform physical activities while holding or using your mobile phone. These activities are not outside of the normal activity for most people. Your phone will use motion sensors, the microphone and your GPS to record the activity. Your GPS will only be used to report the distance you travelled, not your location. You will have the option of not allowing these features. Examples of activities include:

- Walking as quickly as possible for 6 minutes with your phone in your pocket.
- Counting backward out loud while walking.

You will be asked to do these activities every two weeks. Use your best judgment when you do these activities:

- Be careful where and when you do these activities.
- As with any new physical activity, you should check with your doctor before taking part.

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- Stop the activity at any time if you are feeling unwell or unsafe.

You will be asked to make a short written entry once a week.
- Typing speed and accuracy will be examined by the study team.
- The study team will not be looking at specific content.

Passive Measures:
Passive measures are measurements that happen automatically. For example, the phone will collect the number of steps that you take in a day.
- You will have the option to have your daily activity, such as steps walked, collected through the sensors on your mobile phone and possibly other personal devices, such as your iWatch.
- You can choose not to provide this data and still participate in the study.
- We will NOT access your personal contacts, other applications, personal photos, text or email messages.

TeamStudy will take approximately 20 minutes of your time per week.

Additional Features and Activities:
You will be able to keep track of the activities that you have completed on the main menu of the app. You will also be able to visualize your own data to learn more about trends in your own health.

As you complete different activities, you will receive badges, awards and points. This will allow you to track your study participation over time.

There will also be a weekly question feature. These questions may be about your health, preferences and general interest. The combined results of these daily questions will be shared the following week (for example, 20% of respondents sleep at least 8 hours a night).

The app will contain a newsfeed. The newsfeed will be used to provide brief study updates and current news about the Football Players Health Study.

You can choose to receive notifications on your phone asking you to complete these activities and surveys. These notifications are optional. You may choose to participate in all or only some parts of the study and can skip any question you do not wish to answer. This study should only take you about 5-10 minutes each day. At any time you can adjust the app settings to turn on or off sending data and/or receiving notifications.

App Data Processing, Protection and Storage:
All data collected by the TeamStudy app will be encrypted (data that is coded making it difficult to understand) and will be transferred from your phone to secure data servers. These data servers are

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maintained by Sage Bionetworks. Sage Bionetworks is a non-profit company that is dedicated to providing researchers secure ways for collecting and storing sensitive research data. Sage will separate any personal information such as your name, email, and consent form from any app data collected on your phone. We will use a random code instead of your name on all study data (the data will be de-identified). Information about the code will be kept in a separate, secure system.

Your encrypted study data will be securely transferred to the Football Players Health Study secure data repository from Sage Bionetworks. Only a limited number of people will have access to this database. Our team is trained to handle highly confidential data. The Football Players Health Study study staff will not have access to your name and email and will not have any way to connect your study data to you. The Football Players Health Study will have a copy of your consent form, but will not have a way of connecting it to your study data. Your data will only be identified using the random study code.

Sharing Your Study Data:
You can choose to share your de-identified study data with qualified researchers worldwide for use in this research and beyond. De-identified study data is data that does not include personal information such as your name or email. Qualified researchers are registered users of Synapse who have agreed to use the data in an ethical manner for research purposes, and have agreed to not attempt to re-identify you. If you choose to share your de-identified study data, the de-identified data will be added to a shared dataset available to qualified researchers on the Sage Bionetworks Synapse servers. (www.synapse.org). Sage Bionetworks will have no oversight of the future research that qualified researchers may conduct with the de-identified study data.

RISKS AND DISCOMFORTS

There are possible risks, discomforts, and inconveniences associated with any research study. This is not a treatment study involving any new drugs or therapies, so we do not expect any medical side effects from participating.

The primary concern associated with this study is privacy risk. For example, other people may see the study app or notifications on your phone screen and realize that you are enrolled in this study.

We take great care to protect your information, however there is a slight risk of loss of privacy. This is a low risk because we separate your personal information (information that can directly identify you, such as your name or phone number) from the research study data to respect your privacy. However, even with removal of this information, in the event of unauthorized access, it is sometimes possible to re-identify an individual. This risk, while low, should be considered before enrolling.

Some survey questions may make you feel uncomfortable. The information that you provide is

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entirely up to you and you are free to skip questions that you do not want to answer.

Wait until you are in a safe place before performing any app-related tasks activities. Do not interact with the app while driving or doing any other activities which could result in injury. Do not perform any tasks that make you feel unsafe. If you feel fatigued, light headed or uncomfortable while performing an app-related physical activity, please stop. It is possible that you could fall or experience muscle strain or soreness from participating in the physical activities.

Data collected in this study will count against your existing mobile data plan. You may configure the app to use only WiFi connections in the app settings to limit the impact this data collection has on your data usage and plan.

Study participation may involve risks that are not known at this time.

LOSS OF CONFIDENTIALITY

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. However, if your participation becomes known, it could create a problem or hardship for you depending upon the type of information disclosed.

CONFIDENTIALITY

Information learned from your participation in this study may be reviewed and photocopied by federal and state regulatory agencies, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study may be used for research purposes and may be published; however, you will never be identified by name in such publications.

POSSIBLE BENEFITS

There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research. The potential benefits are primarily the creation of insights to help current and future former professional football players to better detect, understand, and manage their health. It is possible that you may learn more about trends in your health.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the option of not

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participating in the study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this app study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. If you decide to leave this mobile app study, you can do this by accessing your profile within the app. There is a “leave the study” option there.

Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

COSTS AND/OR PAYMENTS TO YOU

There is no compensation or payment for taking part in this study. There is no cost to you to participate other than to your mobile data plan if applicable. You can configure the app to use only Wifi connections if you want to limit the impact on your data plan.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at (617) 667-0469 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator’s research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

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THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO) at [617]667-0469

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____