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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

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
12/20/2016
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY
Former Professional Football Player 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.

This app is also a way to invite former players to be a part of other projects in the FPHS. We plan to collect health information through the app and combine it with information collected through other FPHS projects. We hope that this will help us to better understand health conditions that former players face. This understanding will help us in our mission to advance treatment, diagnosis, and prevention of injuries in former professional football players.

STUDY PARTICIPANTS

You have been asked to be in the study because you are a former professional football player who played any time during 1960 or later.

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. *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.

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- You will then be asked questions to see if you are eligible to be in the study as a former professional player. For example, you will be asked if you played professional football during or after 1960.
    - If you qualify, you will be asked for your ID # that was given to you from the Football Players Health Study at Harvard.
    - If you do not have a number, you will be directed by the app to the Football Players Health Study website to request your number.

- 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.

- 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:

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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 any of 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.
- 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, passwords, 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).

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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 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. Sage will connect your app collected data to your assigned Football Players Health Study ID number and will not have a way to connect it to your personal information (the data will be de-identified). Members of the Football Players Health Study will be the only ones who can connect your ID number and data to your personal information (name, email address).

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. If you have taken part in another study with the Football Players Health Study at Harvard - such as completing a questionnaire - the information that is collected in this study will be combined with that information. It will also be connected to any future information collected as a result of your continued participation in Football Players Health Study projects.

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

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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 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 or 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.

CERTIFICATE OF CONFIDENTIALITY

We have received a Certificate of Confidentiality for this study. The Certificate is issued by the National Institutes of Health of the U.S. Department of Health and Human Services. The Certificate says that we cannot be forced to give out information that identifies you as a research subject. This is true even if ordered to by a judge or court. The Certificate does not stop or protect us from sharing

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information about your participation in this study if you give us written permission to do so. You might give us permission to release your information if you are required to or want to give your information to another group. This could be an insurer, employer, or other third party, for example as a condition for filing a claim. However, there are times when even if you ask us to share information about you, we may need to refuse in order to protect the integrity of the study.

It is important to understand a few things about the Certificate. The Certificate only applies to protect the researchers from being forced to share information that would identify you as a participant in the study. The Certificate does not stop you from sharing your information, or protect you if you decide to share details about yourself or your participation in this study. **However, if you do publically identify yourself, or others publically identify you, as taking part in the study, we may lose the Certificate's protections. We welcome and encourage your support of the study. However, to protect your confidentiality, it may be better to state that you support the Players Health Study in general terms, rather than making specific statements like "I filled out the questionnaire."**

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

Is it possible that someone who is not part of the study will get access to my information?
The subject matter of the FPHS study has high public interest. Other parties who are not involved in the study may want to access information collected in the study. You or we may receive requests for information about your participation in this research. For example the research information may be relevant in legal proceedings that you are involved in, so we may receive requests in relation to pending lawsuits, or from the media. We will let you know if someone is requesting access to information that may identify you. We will take steps to avoid giving anyone information that identifies you as a research participant without your permission, including asserting the Certificate's protection. However, we cannot promise that these efforts will always work.

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.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: information collected in other FPHS initiatives) as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, and data managers), and may also be shared and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who

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provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The Department of Health and Human Services (DHHS), the National Institute of Health (NIH), the Office for Human Research Protections (OHRP), and other federal and state agencies that may have jurisdiction over the research.
- Sage Bionetworks: Sage Bionetworks will not be able to link your information collected in the study with your name.

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional, and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your

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withdrawal of your authorization to Dr. Alvaro Pascual-Leone at 330 Brookline Ave., KS 158, Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

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: _____