

Analysis and Publication Policy for the Football Players Health Study

Due to the nature of the Football Players Health Study (“FPHS” or “Study”) project as a collaborative research initiative performing a multi-site study, all collaborators must agree to follow the terms of this Analysis and Publications Policy. Compliance with this policy is necessary to ensure that, prior to commencement of new analyses or publication of research results from individual analyses, the following efforts—which are essential for appropriate coordination of the Study—have been taken:

- a. The FPHS PI and Study leaders have confirmed that planned analysis efforts are aligned with the Study’s scientific priorities and are not at cross-purposes with other planned analysis efforts;
- b. In cases where cohort data is utilized, necessary and sufficient data are available for analyses;
- c. The FPHS PI and Study leaders are made aware of the findings derived from the Study;
- d. Collaborating investigators are made aware of supporting data from other aspects of the Study that they could draw from to support their analysis;
- e. A plan is in place to notify our player community of important and relevant findings prior to publication.

The intent of the policy is not to restrict academic freedom or limit publications, but rather to ensure alliance of efforts across this large and complex research effort which has multiple active sub-studies occurring at any one time. In all cases, publication of results shall acknowledge authorship from appropriate researchers of all the contributing researchers and institutions, following the traditional system for determining authorship and authorship order as determined by the investigators.

The Analysis and Publication Committee

The Analysis and Publication Committee (“APC”) of the Football Players Health Study is made up of the PI of the FPHS, the Research Director and Co-Director, and investigators with expertise in other relevant fields (e.g., epidemiology, physiology, medicine and statistics.) Appointments of membership shall be made by the FPHS PI, are for three years, and can be extended or terminated at the discretion of the PI. The APC reviews and approves analysis proposals, and also reviews abstracts and publications. At their own discretion, for specific proposals the APC may seek additional expert input from members of the FPHS Research Advisor group, or other scientists within or outside of Harvard.

The Committee operates under a set of Guidelines as summarized below.

Reviewing Analysis Proposals

Before an analysis is done that uses FPHS data the investigator(s) must obtain approval from the APC. There are several purposes for this approval:

1. Ensure that the goals of the proposal are aligned with the scientific priorities of the FPHS and contributes to the scientific literature;
2. Avoid duplication and overlap of analyses and ensure that no one else is doing or is planning to do the same analyses;
3. Ensure that necessary and sufficient data are available for the analysis, particularly in cases where cohort data is utilized;
4. Ensure that the planned analyses are appropriate for the type of data available, and that the data requested is necessary and appropriate to support the research question/objective.

The analysis proposal must include all required information as outlined in the analysis proposal form (see attached template). All analysis proposals must be submitted to FPHS_proposals@hms.harvard.edu.

For accepted proposals from an outside investigator, the Committee may identify a FPHS investigator to collaborate with the outside investigator. In addition, the committee may also recommend including other investigators with expertise that is relevant to the analysis proposal.

Investigators must present analysis results to the APC when the data analyses for a study are complete, or earlier if feedback from the APC is needed. Any changes to the methods, analysis or timeline for an approved proposal need to be approved by the APC.

Reviewing abstracts

All abstracts to be submitted to conferences and meetings that use data from the FPHS require review by the APC, for the purpose of ensuring that no confidential FPHS data is disclosed. Abstracts should be submitted to the APC twenty-one (21) working days prior to submission to conference meetings. If the APC determines that an abstract contains confidential FPHS data, the author agrees to remove such confidential data. Email abstracts to FPHS_proposals@hms.harvard.edu. Include name and date of conference or meeting.

If abstract is accepted by the conference, authors must email the accepted version to FPHS_proposals@hms.harvard.edu. Include type of acceptance (presentation, poster) and date and location of the conference.

Reviewing publications

All publications that use data from the FPHS require review by the APC **before submitting** to a journal. The committee reserves the right to reach out to external advisors to get feedback on the manuscript to be submitted; external advisors shall be required to maintain manuscripts in confidence. Publications must be submitted to the APC at least thirty (30) days prior to journal submission. Email publication to FPHS_proposals@hms.harvard.edu. Include name of journal and proposed date of journal submission. Review of publications shall be primarily for the purpose of ensuring that no confidential FPHS data is disclosed, but may encompass other issues as well. If the APC determines that a publication contains confidential FPHS data, the author agrees to remove such confidential data. The author also agrees to consider any additional comments made by the APC in good faith, but is not required to make such changes.

If publication is accepted by the publisher, email a copy of the accepted manuscript with name of journal and anticipated date of publication to FPHS_proposals@hms.harvard.edu.

Manuscript preparation:

1. All publications based on data from the FPHS must have the following acknowledgement:

The authors would like to thank the study participants, advisors, and staff of the Football Players Health Study.

2. When acknowledging funding support from the FPHS, you must include the following:

The Football Players Health Study is funded by a grant from the National Football League Players Association. The content is solely the responsibility of the authors and does not necessarily represent the official views of Harvard Medical School, Harvard University or its affiliated

academic health care centers, the National Football League Players Association, or [HOME INSTITUTION].

3. Human subject approval can be stated as:

This investigation was approved by the Institutional Review Board of the Beth Israel Deaconess Medical Center and Harvard Medical School.

4. All publications must follow authorship guidelines set forth by Harvard Medical School (http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/authorship_guidelines.pdf).
5. Authors are required to share progress updates on manuscript preparation with the APC at 6-month intervals. The APC reserves the right to terminate projects that are not progressing at an acceptable pace or inhibiting the forward progress of other projects, if such delays are not cured within thirty (30) days of notification of intention to terminate.