The Children's Hospital of Philadelphia®
RESEARCH INSTITUTE
INSTITUTIONAL REVIEW BOARD

Date: March 18, 2022

To: Daniel Corwin
CC: Melissa Godfrey
From: The Committees for the Protection of Human Subjects (IRB)

Re: IRB 22-019755, **Protocol Title:** Mobile Health-Facilitated Specialist Management to Improve Outcomes in Pediatric Concussion Patients
Sponsor or Funder: National Institutes of Health (NIH)

IRB SUBMISSION: NOTICE OF IRB APPROVAL

Dear Dr. Corwin,

The study referenced above was reviewed and approved by the convened CHOP IRB on with modifications required. All requested modifications have now been addressed and all required ancillary committee approvals have been received.

IRB approval is effective as of 3/18/2022.

The approved enrollment limit for this study at CHOP is 160, with a total enrollment study wide of 160.

PLEASE NOTE: Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subjects research study. The Investigator is responsible for satisfying any additional institutional requirements that may apply (e.g. execution of the appropriate agreement with the Office of Collaborative and Corporate Research Contracts for sending or receiving data or samples, etc.).

Main Study Document(s):

- Protocol (dated 3-17-2022)
- Consent Form (dated 3-17-2022)
- Screening HIPAA Authorization (attached 3-17-2022)
- Pre-Screening Questionnaire (attached 3-17-2022)
- Screening Enrollment Questionnaires (attached 3-17-2022)
- Post-Enrollment Surveys (attached 3-17-2022)
- ReCoUPS Survey (attached 2-21-2022)
- Provider Recruitment Email (attached 3-14-2022)

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Website: https://irb.research.chop.edu/

- Qualitative Interview Guide (attached 3-14-2022)
- Apple End User License Agreement (dated 3-12-2022)
- Google Play Terms of Service (dated 10-12-2020; attached 3-14-2022)

Other Document(s):

- Request for Just-In-Time Information (dated 2-17-2022)

Subpart Determination(s):
Subpart D Determination: 45 CFR 46.404

Consent/Assent/HIPAA:
Consent Form: Written consent/parental permission, assent, and HIPAA authorization are required for study enrollment. Per 45 CFR 46.408(b), the IRB has determined that at least 1 parent (or legal guardian) must give permission for the inclusion of a child in this research. The approved, date-stamped informed consent document is available in the main study workspace under the Consent and IRB Correspondence tab.
Waiver of HIPAA Authorization: A waiver of HIPAA authorization has been approved per 45 CFR 164.512(i)(2)(ii) for reviewing medical records and recording PHI for recruitment purposes.

Please note the following conditions for conducting this study:

INVESTIGATOR RESPONSIBILITIES: Please refer to the following page on the IRB's website for information and guidance on the responsibilities of investigators who conduct human subjects research at CHOP: https://irb.research.chop.edu/investigator-responsibilities.

REPORTABLE EVENTS: On-site reportable events, such as serious adverse events, protocol deviations/violations, unanticipated problems involving risk to subjects or others, and non-compliance that occurs in relation to this study, must be reported to the IRB in a timely manner, as outlined in IRB SOP 408. Please refer to the following page on the IRB's website for information about reportable events: https://irb.research.chop.edu/reportable-events.

RENEWAL (Continuing Review/Progress Reports): Approval is valid until the expiration date for your protocol shown above. The IRB must review and approve all human subject research studies at intervals appropriate to the degree of risk. To avoid lapses in study approval and suspension of study procedures, please submit the application for continuing review at least 45 days before the expiration date for your protocol. This will provide the IRB will sufficient time to review your study. As a courtesy, the IRB will send you a reminder; however, it is your responsibility to ensure that you submit the continuing review application on time.

CHANGES/AMENDMENTS/MODIFICATIONS/REVISIONS: You must obtain IRB approval under 45 CFR 46 if you change any aspect of this study, including but not limited to study procedures, consent form(s), co-investigator(s), study staff,

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advertisements, protocol documents or procedures, Investigator's Brochure or accrual goals. Implementation of these changes cannot occur until you receive the IRB approval notice.

COMPLETION OF STUDY: Notify the IRB when your study is completed. Neither study closure by the sponsor nor the investigator removes your obligation for submitting a timely study closure via continuing review or a final report. Please refer to the following page on the IRB's website for information about study closures: https://irb.research.chop.edu/continuing-review.

If you have any questions, please click on the IRB# (above) and contact the IRB analyst listed in the study workspace.

DHHS Federal Wide Assurance Identifier: FWA00000459

IS_034

**** *This memorandum constitutes official CHOP IRB correspondence.* ****

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