



Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) • 2800 Plymouth Rd., Building 520, Room 1170, Ann Arbor, MI 48109-2800 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

To: Matt Reed

From:

Riann Palmieri-Smith
Thad Polk

Cc:

Larry	Salzmann
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Sheila	Ebert
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Laura	De Marzi
Kristina	Rowden
Miranda	St Amour
Matt	Reed
Shinhae	Yeo
Monica	Jones
Rose	Beechboard

Subject: Amendment [Ame00141701] Approved for [HUM00158177]

SUBMISSION INFORMATION:

Study Title: Child Strength Measurement

Full Study Title (if applicable):

Study eResearch ID: [HUM00158177](#)

Amendment eResearch ID: [Ame00141701](#)

Amendment Title: HUM00158177_Amendment - Mon Oct 23 11:44:02 EDT 2023 Add Staff, Add New Head & Hand Scanner to Protocol

Date of this Notification from IRB: 11/27/2023

Date of Approval for this Amendment: 11/27/2023

Review: Expedited

Current IRB Approval Date: 2/25/2019

UM Federalwide Assurance (FWA): FWA00004969 (For the current FWA expiration date, please visit the [UM HRPP Webpage](#))

OHRP IRB Registration Number(s): IRB00000245

Approved Risk Level(s) as of this Amendment:

Name	Risk Level
HUM00158177	No more than minimal risk

Continuing Review Required: No

NOTICE OF IRB APPROVAL AND CONDITIONS:

The IRB HSBS has reviewed and approved the amendment to the study referenced above. The IRB determined that the proposed research continues to conform with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

RENEWAL/TERMINATION:

The IRB has determined, consistent with 45 CFR 46.109(f), that annual continuing review is no longer required for this research.

You will receive an annual message reminding you of your responsibilities to manage this research application. Submit a Termination Report once you only hold or are analyzing deidentified data, or the research has ended.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:

You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

FUTURE AMENDMENTS:

All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:

You must inform the IRB of adverse events (AEs) and other reportable information and occurrences (ORIOs) according to your IRB's required reporting timetable ([IRBMED](#) and [IRB-HSBS/Flint/Dearborn](#)).

UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS (UPIRSOs or UaPs): Investigators must inform the IRB promptly of any potential Unanticipated Problems (UaPs or UPIRSOs) that come to the attention of the study team. Unanticipated Problems meet **all of the following criteria:**

1. **Unexpected** (in terms of nature, severity, or frequency);
 2. **Related or possibly related to participation in the research;** and
 3. Suggests that the research places subjects or others at **a greater risk of harm** than was previously known or recognized.
- See [U-M HRPP Operations Manual Part 12](#).III.B.1.a.

SUBMITTING VIA eRESEARCH:

You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study, referenced above.

MORE INFORMATION:

You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: <http://research-compliance.umich.edu/human-subjects>.



Riann Palmieri-Smith
Co-chair, IRB HSBS



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