UNIVERSITY OF MICHIGAN
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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: Dr. Matthew Reed

From:

Thad Polk

Cc:

Darya Dabiri
Sheila Ebert-Hamilton
Prachi Shah
Matthew Reed
Monica Jones

Subject: Initial Study Approval for [HUM00158177]

SUBMISSION INFORMATION:
Study Title: Child Strength Measurement
Full Study Title (if applicable):
Study eResearch ID: HUM00158177
Date of this Notification from IRB:3/19/2019
Review:Expedited
Initial 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):

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 study referenced above. The IRB determined that the proposed research conforms 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.

The research meets the following regulatory criteria for expedited research:
HHS Category 7: Research on individual or group characteristics or behavior

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.

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).

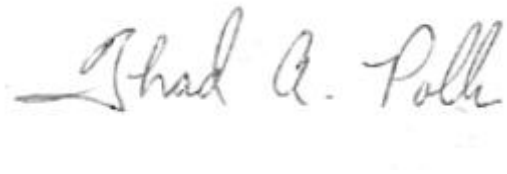
UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS (UPIRSOs or UaPs) :
Investigators must inform the IRB promptly of any potential Unanticipated Problems (UaPs or UPIRSOs) that come to the attention of the study team. Unanticipated Problems meet **all of the following criteria:**

1. **Unexpected** (in terms of nature, severity, 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.



Thad Polk
Chair, IRB HSBS