DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date March 12, 2019

From Jerrell Little
IRB Administrator
Human Research Protection Office

Subject IRB Approval of Amendment #5 to CDC Protocol #6881.0, "Collections Related to Synthetic Turf Fields with Crumb Rubber Infill" (Expedited)

To Elizabeth Irvin-Barnwell, PhD
NCEH/ATSDR

CDC's IRB Committee 1 has reviewed and approved your request to amend protocol #6881.0, "Collections Related to Synthetic Turf Fields with Crumb Rubber Infill".

This approval is for amendment #5 of protocol 6881.

Amendment #5 approval is for:

- ***(1) The researchers are requesting a waiver of documentation of informed consent as the consent form is the only document collecting any personally identifiable information that will link the subject's identity to the data or biospecimens.***
- ***(2) The proposed changes to the consent forms indicate the reduced scope of work for the supplemental exposure measurements study. For the reduction in scope, researchers will only collect pre- and post-activity urine samples and do not proposed to collect personal air samples, dermal wipe samples, or pre- and post-activity blood samples.***
- ***(3) The proposal to recruit and enroll a subset of participants at a natural grass field as a comparison group is another change.***
- ***(4) Researchers also propose an increase in sample sizes (n=150 synthetic turf field users and 50 natural grass field users).***

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(2) categories 3 and 7, minor changes to previously approved research during the period of one year for which approval is authorized.

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for CDC IRB approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail:

cc:
NCEH/ATSDR Human Subjects (CDC)