



Memorandum

Date July 29, 2016

From Jason Abel
IRB Administrator, Human Research Protection Office

Subject IRB Approval of Amendment #1 to CDC Protocol #6881.0, "Collections Related to Synthetic Turf Fields with Crumb Rubber Infill" (Expedited)

To ANGELA RAGIN, PhD
NCEH/ATSDR

CDC's IRB A 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 #1 of protocol 6881.

Amendment #1 approval is for:

- Modification 1: We have replaced the phrase "tire recycling/rubber manufacturing facility" to "tire recycling/rubber manufacturing plant" and "synthetic turf facility" to "synthetic turf field facility" throughout the document and attachments.
- Modification 2. We have removed the synthetic turf field age criteria which restricted eligible synthetic turf fields to those at least two years old. The change is indicated on page 25.
- Modification 3. We have revised the incentive amounts per the request of OMB. New incentive amounts are \$15 pre-activity collection, \$25 post-activity collection, and \$10 video activity collection. The incentive amount for the synthetic turf field users who complete the questionnaire is unchanged (\$25). The changes can be found on page 84 (also changed in the consent forms).
- Modification 4. Insertion of Appendix M - fact sheets for the three respondent groups (tire recycling/rubber manufacturing plants, synthetic turf field facility owners, and synthetic turf field facility users). There were minimal changes to the fact sheets, eligibility screenings, and consent forms as indicated above. Additionally, the questionnaires for the synthetic turf fields and the field users had minor edits based on comments from OMB. The changes are in Appendix F and Appendix I.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(2), 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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)