UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF THE
SCIENCE ADVISOR

MEMORANDUM

SUBJECT:	Final Approval of Human Subjects Research
REQUEST No.:	HSR-000637
DATE:	Jul 07, 2016

FROM: Toby Schonfeld, PhD
EPA Human Subjects Research Review Official

TO: Kent Thomas
National Exposure Research Laboratory (RTP)/ORD

I have reviewed the application cited below according to the requirements of EPA Order 1000.17 Change A1 (**Policy and Procedures on Protection of Human Research Subjects**) and have determined that it complies with EPA Regulation 40 CFR 26 (**Protection of Human Subjects**).

The purpose of this study is to provide information needed to further characterize tire crumb rubber use in synthetic fields in the U.S. and to examine key factors that may affect human exposure to chemical and microbiological constituents. Human subjects will be involved in a) collection of human activity data for synthetic turf field users that will reduce the reliance of default exposure factor assumptions in exposure and risk assessment, and, b) an exposure measurement sub-study for people using synthetic turf fields with tire crumb rubber infill, in what are likely to be among the higher exposure scenarios, to improve understanding of potential exposures for field users. Several of the key gaps and limitations identified in previous research will be addressed through the research. Research end points include: (1) Identifying key constituents of concern in recycled tire crumb used in artificial turf fields; (2) Assessing potential exposures to potentially harmful constituents; (3) Conducting an initial evaluation of potential cancer and non-cancer toxicity of key chemical constituents; and (4) Identifying follow-up activities that could be conducted to provide additional insights about potential risks.

The research does not involve the intentional exposure, under any circumstances, of pregnant women, nursing women, fetuses, or children to any substance regulated by the EPA.

The IRB of record (CDC) has approved the research and deemed that the risks are minimized and reasonable

in relation to the expected benefits and that the consent form is adequate.

Accordingly, **approval** is granted for this study to proceed in accordance with 40 CFR 26.

Investigators are responsible for following all policies of the IRB of record for their project, including the reporting of problems, submitting changes before implementing them, and continuing review submissions. The EPA may ask to see any of this documentation at any time.

Resubmission of research for EPA approval is only necessary if (1) there is a significant change in approved research (defined as one that materially increases risk, or materially decreases benefit, or materially decreases scientific merit); (2) the IRB of record determines that an event represents a reportable "unanticipated problem involving risk to subjects or others" (UPIRSO); or (3) an event results in the removal of a subject from the study, even if the event is not reportable to the IRB of record. In these instances, information should be submitted through the "significant study modification" pathway.

Please refer to the HSR Request Number (HSR-000637) below in all future correspondence.

Study Title:	Collections Related to Synthetic Turf Fields with Crumb Rubber Infill
Principal Investigator:	Kent Thomas
EPA Contact:	Kent Thomas
Application/Grant/Award Number:	N/A