

Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill

OMB Control No. 0923-New

New Information Collection Request

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

Program Official: Angela Ragin-Wilson
Title: Chief, Environmental Epidemiology Branch
Phone: 770-488-3807
Email: ARagin@cdc.gov
Fax: 770-488-1537

Date: April 27, 2017

Table of Contents

B.1. Respondent Universe and Sampling Methods.....	3
B.2. Procedures for the Collection of Information.....	4
B.3. Methods to Maximize Response Rates and Deal with Nonresponse.....	10
B.4. Test of Procedures or Methods to be Undertaken.....	10
B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	10
References.....	12
List of Attachments.....	13

Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

In recent years, the public has raised concerns about the use and safety of synthetic turf with crumb rubber infill. In November 2015, the White House Council on Environmental Quality (CEQ), requested that the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry (CDC/ATSDR) and the United States Environmental Protection Agency (US EPA), in collaboration with the Consumer Product Safety Commission (CPSC), develop a *Federal Research Action Plan* to address the issues surrounding synthetic turf with crumb rubber infill. On February 12, 2016, US EPA, ATSDR, and the CPSC, released the *Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds*.¹

As part of the work under the *Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds*, the Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (US EPA) were granted a six-month emergency OMB approval for the research protocol (Attachment 6) titled "Collections Related to Synthetic Turf Fields with Crumb Rubber Infill" (OMB Control No. 0923-0054, expiration date 01/31/2017) on July 22, 2016, to conduct a tire crumb rubber characterization study. The research goals for three activities in the protocol are pilot-level investigations to evaluate and characterize: the chemical composition and use of crumb rubber infill in synthetic turf using a convenience sample of nine tire recycling manufacturing plants and 40 facilities that use synthetic turf fields (Activity 1); the human exposure potential to constituents in crumb rubber infill among a convenience sample of 60 field users (Activity 2); and collection of biological specimens (blood and urine) from 45 participants from Activity 2 (Activity 3).

ATSDR and US EPA have completed Activity 1, by consenting and sampling 40 synthetic turf fields with crumb rubber infill across the United States. The activities, completed prior to December, 2016, are reported in the "Status Report on the Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds." The Status Report was released on December 30, 2016.²

¹ Accessed 6/21/2016 at <https://www.epa.gov/chemical-research/federal-research-recycled-tire-crumbs-used-playing-fields> and at <https://www.epa.gov/chemical-research/federal-research-action-plan-recycled-tire-crumb-used-playing-fields>.

² Accessed 1/24/2017 at <https://www.epa.gov/chemical-research/december-2016-status-report-federal-research-action-plan-recycled-tire-crumb>.

This new information collection request (ICR) proposes to use fields previously identified in Activity 1 to investigate the potential for human exposure to environmental constituents that may result from contact with crumb rubber infill. Due to the limited time constraints and field activity schedules, ATSDR and US EPA are requesting a new PRA clearance to complete Activities 2 and 3 for the human exposure characterization sub-study (Attachment 6).

Important study design constraints include the mandated timeline for research activity completion and reporting under the *Federal Research Action Plan*, and the resources available for implementing the research. Therefore, a convenience sample will be used for the exposure characterization study. Because the activity will not involve a statistically-based sampling design, the research will not provide data intended for nationwide generalizations. However, the research is anticipated to provide more information than is currently available, to fill key data gaps, and to improve exposure characterization capabilities needed to inform further evaluation. If successful, this sub-study will also include more fields and field users than any previous single study in the US.

B.1.1 Facility User Exposure Characterization

The respondents are adults and youth that routinely use synthetic turf fields with crumb rubber infill for athletics, recreation, and/or physical education or physical training purposes. No data are available regarding the numbers of such individuals in the US, however, given the large number of installed fields it can be reasonably anticipated that the number of users is in the millions. As described in the *Federal Research Action Plan*, this research is a pilot-scale effort aimed at providing information and data for exposure characterization purposes. Respondents will be recruited from among those thought to be in one or more higher-exposure scenarios based on the frequency and duration of synthetic turf field use, as well as specific activities that may be involved in higher levels of contact with crumb rubber material. We anticipate that up to 10 of the facilities participating in the tire crumb rubber characterization study, having already provided agreement for participation, will be the facilities participating in the human exposure characterization study.

B.2. Procedures for the Collection of Information

B.2.1. Facility User Exposure Characterization Research Aims

There are two primary aims of the facility user exposure characterization. The first aim is to collect human activity data for synthetic turf field users that will reduce the reliance of default exposure factor assumptions in exposure and risk assessment. This activity is intended to collect information using questionnaires from adults and youth who use synthetic turf fields

with crumb rubber infill for several types of active uses including athletics and possibly physical education or physical training. Information will be collected to provide data about relevant parameters for characterizing and modeling exposures associated with the use of synthetic turf fields. In addition, extant videography of users engaged in activities on synthetic fields will be acquired to provide objective assessment of contact rates and types that are difficult to capture consistently using questionnaires.

The second aim is to conduct a pilot-scale 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, particularly for the dermal and ingestion exposure pathways. The human exposure measurement data for synthetic turf field users are limited. Important data gaps exist, particularly for potential dermal and ingestion exposures to crumb rubber constituents. There are also important limitations in the types of methods that have been developed and used for human exposure measurements during activities on synthetic fields. There are challenges in collecting relevant surface, dust, and personal air samples. Few studies have performed measurements of dermal exposures. A limited number of studies have collected urine or blood samples that might be used for measuring biomarkers of exposures to chemicals in crumb rubber infill. The study will be aimed at further developing and deploying appropriate sample collection methods and generating data for field use scenarios anticipated to be among those resulting in the highest potential for exposures.

B.2.1.1 Facility User Information Collection

Up to 75 people who engage in physical activities at facilities with synthetic turf fields with tire crumb rubber infill will be recruited across several use-type categories (Table B.2.1). The categories will include activity types anticipated to be among those resulting in higher exposure scenarios either because of the intensity and frequency of field use or because of potentially inherent differences in activity factors (e.g., soccer goalkeepers expected to have repeated contact with turf materials or children younger than age 12 that are likely to have higher hand-to-mouth contact rates). Examples of user types and categories and number of respondents of interest for data collection are shown in Table B.2.1. We anticipate up to 60 people will agree to participate in providing questionnaire responses.

Participants will be recruited from users of a subset of non-military facilities recruited for participation in the tire crumb rubber characterization activity (Activity 1). Multiple outreach mechanisms will be used to identify and recruit facility users. As part of the contact with facility owners and managers (identified and contacted as part of the tire crumb rubber characterization activity), the respondents were asked whether they can assist in identifying potential participants of interest.

Table B.2.1. Number and Types of Facility Users to be Recruited for Questionnaire Data Collection

Example Activity Types ^a	Total Number Of Users Recruited	Total Number Of Users Participating ^b	Questionnaires		Total Number Of Facilities
			Indoor Facility	Outdoor Facility	
Professional athletics (Group A)	15	12	6	6	2
College athletics (Group B)	15	12	6	6	2
High school P.E. or athletics (Group C)	15	12	6	6	2
Youth ages 10 – 12 athletics (Group D)	15	12	6	6	2
Children ages 7 – 9 athletics (Group E)	15	12	6	6	2
Total Number of Users	75	60	30	30	10

^aThese are examples of activity types of potential interest; the final categories will depend on recruitment success. Different activity types of interest for higher exposure scenarios may be identified through the facility information gathering process.

^bIt is anticipated that up to 60 of the 75 people recruited will participate.

We anticipate recruiting respondents from only two different facilities for each type of activity to minimize the time and cost given the study constraints. Facility users will be contacted to determine eligibility (Attachment 4b) and request participation in the questionnaire and exposure measurement research activities (for a subset of questionnaire respondents, Table B.2.2). Based on *a priori* decisions regarding activities that may be among higher exposure scenarios, the recruitment may focus on specific types of users among a larger group. For example, more soccer goalies than field players may be recruited from a soccer team or league based on their likely higher contact rates with field materials. Adult and adolescent facility users who agree to participate will be administered a questionnaire (Attachment 4d) by trained research staff in person or over the phone using a Computer Assisted Interview (Epi Info™). For children 7-9 (Group E) and youth 10-12 (Group D), we will administer the questionnaire to the parent/guardian (Attachment 4e). The questionnaires will be used to collect Information about characteristics and activity parameters that may affect the magnitude of exposure to crumb rubber infill constituents, including:

- a) demographic characteristics,
- b) frequency of field use across a range of activity types,

- c) duration of field use across a range of activity types,
- d) levels of physical exertion that affect breathing rates,
- e) contact rates for different types of activities,
- f) different clothing types and uses, and,
- g) hygiene practices.

Two types of videography data collection are proposed for this activity. Publicly available videography of physical activities for adult and youth sports participating on synthetic turf fields will be identified. A range of activities, including those in team practices and in games, may be considered for video information collection and analysis. Information about types and frequencies of various contact rates, along with clothing and protective equipment usage, will be collected. A subset of participants in the exposure measurement sub-study will also have videography performed for a specific sports or training activity on a synthetic turf field with tire crumb rubber. We anticipate enrolling 24 participants in the videography component of the activity (Table B.2.2). Enrollment in the videography component will be co-initiated with the exposure measurement sub-study until the minimum sample size has been reached (Attachment 4c). Once the target sample size has been reached, the videography consent addendum will be removed from the consent form package. Video data collection will include simple counts of specific activity types, including but not limited to hand-to-mouth, diving on turf, falling on turf, laying on turf, sitting on turf, and hand contact with turf.

Questionnaire and videographic-based data will be organized into a database suitable for exposure characterization purposes, including exposure screening calculations and exposure modeling. Although a statistical design is not being implemented, differences among user groups will be explored to assess whether differences in activity types, durations, and frequencies occur that may affect exposure to crumb rubber constituents. No data sets have been identified that can be used to inform between-group difference power calculations for the exposure scenario parameters of interest (e.g. mean and standard deviation values for hours of field use per week, number of hand-to-field contacts per hour). There may be some autocorrelation in results because multiple people from a given facility and/or team will be included.

B.2.1.2 Facility User Exposure Measurement Collection

Up to 45 people who engage in physical activities at facilities with synthetic turf fields with tire crumb rubber infill will be recruited across one to three use categories for participation in the exposure measurement portion of the research study (Table B.2.2). These participants will be a subset of those who respond to the questionnaire administration. The category or categories will include activity types expected to be among those resulting in higher exposures either because of the intensity and frequency of field use or because of differences in activity factors

and likely contact rates. Examples of user types and categories and number of respondents of interest for data collection are shown in Table B.2.2. We will recruit facility users in a given activity type category from only two different facilities (ideally, one indoor and one outdoor facility, Table B.2.2) to minimize time and cost. Specifically, we will first recruit participants from Groups A, B, and E (Attachment 4c). If the participant sample size is not reached within those three groups, we will recruit in Groups C and D until the sample size requirement is met.

Table B.2.2. Number and Types of Facility Users to be Recruited for Exposure Measurements

Example Activity Types ^a	Exposure measurement Indoor Facility ^b	Exposure measurement Outdoor Facility ^b	Total Number of Users	Videography Indoor Facility ^c	Videography Outdoor Facility ^c	Total Number of Facilities
Professional athletics (Group A)	8	7	15	4	4	2
College athletics (Group B)	8	7	15	4	4	2
Children 7 – 9 athletics (Group E)	8	7	15	4	4	2
Total Number of Users			45	12	12	6

^aThese are examples of activity types of potential interest; the final categories will depend on recruitment success. Different activity types of interest for higher exposure scenarios may be identified through the facility information gathering process.

^bIt is assumed that all of the people recruited for questionnaire administration in selected activity categories will participate in the exposure measurement portion of the study. Up to two facilities for each type of activity; the facilities are likely to be different for each activity type.

^cVideography will be done for a subset of participants who complete the questionnaire and participate in the exposure measurements (see recruitment description below).

Several types of personal and facility samples will be collected (Table B.2.3). Specific sample collection and analysis methods have not been identified at this time. Some methods, including dust from synthetic turf fields, may require method development in advance of the conducting the exposure measurement sub-study. An exposure measurement sampling collection form is provided in Attachment 4f.

Table B.2.3. Number and Types of Samples for Exposure Characterization Measurements ^a

Sample Type	Number of Users	Number of Facilities ^c	Number of Locations or Samples	Analytes ^d	Total Samples or Analyses
<u>Personal Samples</u>					
Air	45		1	VOCs	45
Dermal	45		4	SVOCs, metals	270
Urine	45		2	VOCs, PAHs, metals ^e	270
Blood	45		2	Metals ^e	90
<u>Facility Samples^b</u>					
Air		6	3 ^e	VOCs, SVOCs, particulates	54
Surface wipe		6	3	SVOCs, metals	36
Surface drag sled		6	3	SVOCs	18
Dust		6	3	SVOCs, metals	54

^aThese are anticipated types and numbers of samples. Final decisions will be based on method availability, resources, respondent burden, and respondent safety considerations

^bSamples of crumb rubber infill analyzed for constituents as part of Activity 1.

^cIncludes one indoor and one outdoor facility for each activity type

^dEach analyte type will require a separate sample

^eIncludes one-off field background location for each field.

Exposure measurement data will be organized into a database suitable for exposure characterization purposes, including exposure screening calculations and exposure modeling. Although a statistical design is not being implemented, differences among user groups will be explored to assess whether differences in activity and/or facility types result in differences in exposure to crumb rubber constituents. Estimation of population distributions of exposures will not be possible using these data; however, if the scenarios do represent those leading to higher exposures then the data will inform exposure assessment of what is likely to be in the upper end of the distribution. The biological specimens will be archived and analyzed at a future date.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

Although this research does not rely on a statistically representative sample, a critical factor for the success of this study is identifying and recruiting a diverse range of facility and facility user respondents in a very short time frame. Immediately upon receiving approvals, we will contact numerous organizations and institutions to provide a fact sheet and information about the purpose and value of the research and to request participation (Attachment 4a). We will employ a number of strategies in an attempt to maximize response rates. These include having trained study representatives: 1) make multiple phone calls/visits at different times of day and on different days of the week; 2) leave detailed messages with a call-back number; and 3) calling “alternate contacts.”

B.4. Test of Procedures or Methods to be Undertaken

Few of the procedures and methods to be used in this study have been previously tested and evaluated. Exceptions may be air (metals and particulates), surface (metals), and material (metals) sample collection and analysis procedures used in the 2008-2009 US EPA Scoping Study (Highsmith et al., 2009).

Due to the very short timeline mandated for this research effort, any testing of survey instruments and measurement methods was limited. Any testing that occurred was among federal employees or among nine or fewer members of the public. ATSDR and US EPA completed testing and modifications prior to submitting the ICRs for PRA clearance.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Table B.5.1. Personnel Consulted on Statistical Design

Name	Title	Affiliation	Phone	Email
Paul Jones, PhD	Biostatistician	US EPA	(919) 541-4651	TireCrumbs@epa.gov

Table B.5.2. Personnel Responsible for Collection and Analysis of Information

Name	Title	Affiliation	Phone	Email
Annette Guiseppi-Elie, PhD	Associate Director for Exposure Science	US EPA	(919) 541-4651	TireCrumbs@epa.gov
Elizabeth Irvin-Barnwell, PhD	Team Lead, Environmental Epidemiology Branch	CDC/ATSDR	770-488-3684	Jcx0@cdc.gov
Angela Ragin-Wilson, PhD	Chief, Environmental Epidemiology Branch	CDC/ATSDR	770-488-3807	ARagin@cdc.gov
Kent Thomas, BSPH	Research Physical Scientist	US EPA	(919) 541-4651	TireCrumbs@epa.gov
<i>Contractors TBD</i>				

References

Highsmith R., Thomas K.W., Williams R.W. (2009). A Scoping-Level Field Monitoring Study of Synthetic Turf and Playgrounds; EPA/600/R-09/135. National Exposure Research Laboratory, US Environmental Protection Agency.

[http://cfpub.epa.gov/si/si_public_record_report.cfm?
dirEntryId=215113&simpleSearch=1&searchAll=EPA%2F600%2FR-09%2F135](http://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=215113&simpleSearch=1&searchAll=EPA%2F600%2FR-09%2F135)

Menichini et al. (2011). Artificial-turf Playing Fields: Contents of Metals, PAHs, PCBs, PCDDs and PCDFs, Inhalation Exposure to PAHs and Related Preliminary Risk Assessment. *Sci Total Environ.* 409(23):4950-7.

List of Attachments

Attachment 1. Authorizing Legislation

Attachment 2. 60-day Federal Register Notice

Attachment 2a. Public Comments and Agency Responses

Attachment 3. External Peer Review and Agency Responses

Attachment 4. Activity 2 and 3 Forms and Supporting Documents

Attachment 4a. Facility User Fact Sheet

Attachment 4b. Facility User Eligibility Screening Script

Attachment 4c. Consent, Assent, Permission Forms

Attachment 4d. Facility User Adult and Adolescent Questionnaire

Attachment 4e. Facility User Youth and Child Questionnaire

Attachment 4f. Exposure Measurement Form

Attachment 4g. Phlebotomist Safety Exclusion Questions Form

Attachment 5. Privacy Impact Assessment

Attachment 6. Research Protocol

Attachment 7. CDC IRB Approval

Attachment 8. US EPA Human Research Review Approval