Supplemental Measurements for Exploratory Research regarding Exposure during Activities Conducted on Synthetic Turf Fields with Tire Crumb Rubber Infill

OMB Control No. 0923-xxxx

New Information Collection Request

Supporting Statement Part A –

Justification

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Part A. Justification

Goals of the research study: The research protocol, *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*, has been conducted previously under two information collection requests (ICRs): Activity 1 under OMB Control No. 0923-0054 (expiration date 01/31/2017) and Activities 2 and 3 under OMB Control No. 0923-0058 (expiration date 08/13/2018), which were limited to collections from August to October, 2017. Activities 2 and 3 aim to evaluate and characterize the human exposure potential to constituents in crumb rubber infill among a convenience sample of 60 field users (Activity 2) and to collect biological specimens (blood and urine) from 45 participants (Activity 3). Due to the limited enrollment and collection period, the target Activity 2 and Activity 3 samples sizes were not met in 2017.

The current request seeks to conduct supplemental measurements to expand the exploratory analysis conducted under OMB 0923-0058. The current request allows for further investigation of patterns observed in the preliminary data from the 2017 pilot-scale exposure measurements of individuals playing on synthetic turf fields with crumb rubber infill and collecting data from a small number of individuals who are playing on grass fields.

Intended use of the resulting data: The intended uses are to conduct exploratory analyses to inform the need for additional research that may be needed to inform future public health decisions. The research activities are anticipated to add important knowledge on the topic and improve exposure characterization capabilities needed to inform further evaluation.

Methods to be used to collect:

For this request, the investigators are proposing to use a design similar to OMB 0923-0058, but will only collect questionnaires and pre-activity and post-activity urine samples. Researchers will not collect personal air samples, dermal wipe samples, or blood samples.

Respondents: A convenience sample of field users (e.g., athletes) who are persons with potential for high exposures to contaminants in synthetic turf. For this request, the investigators are requesting approval to recruit a convenience sample of 200 respondents, including 150 synthetic turf field users and 50 natural grass users.

How data will be analyzed: To the extent possible, data will be analyzed using non-parametric and parametric statistical methods. If possible, the data will be used for exposure modeling and to perform screening level exposure evaluations.

A.1. Circumstances Making the Collection of Information Necessary

Synthetic turf fields are used across the United States with more than 12,000 fields currently in use (Synthetic Turf Council, 2015). These fields are often made with rubber granules from recycled tire waste used as infill (referred to as crumb rubber). There are differences in the types of crumb rubber, including differences due to processing and coating (Gomes et al, 2010). In recent years, the public has raised concerns about the use and safety of synthetic turf with crumb rubber infill. To date, there has been no comprehensive evaluation of crumb rubber material as previous studies are limited, often due to small sample size.

In November 2015, the White House Council on Environmental Quality (CEQ), requested that 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]

US EPA and ATSDR collaborated on the exploratory research study from 2016-2018. The research goals for three activities in the protocol were 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).

The ATSDR and US EPA completed Activity 1 by consenting and sampling nine recycling plants and 40 synthetic turf fields with crumb rubber infill across the United States by December, 2016, under the six-month emergency request for “Collections Related to Synthetic Turf Fields with Crumb Rubber Infill” (OMB Control No. 0923-0054, expiration date 01/31/2017). These activities 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] The results of this work were publicly disseminated on July 25, 2019 and

[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.

are available at: https://www.epa.gov/chemical-research/july-2019-report-tire-crumb-rubber-characterization-0.

In 2017-2018, ATSDR and US EPA conducted additional research activities under OMB Control No. 0923-0058 (expiration date 08/31/2018) "Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill". The target Activity 2 and Activity 3 samples sizes of 60 and 45, respectively, were not met; only 11 pre-post blood sample pairs, 14 pre-post urine sample pairs, 25 wipe samples, and 32 questionnaires were collected.

This is a new two-year information collection request (ICR) to supplement the data already collected in 2017-2018. The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting to conduct this supplemental exposure characterization and measurements study to follow up on preliminary data that showed an unexplained pattern in urinary levels of a class of chemicals among a small subset of synthetic turf field users. Additionally, in order to provide insight into the biomonitoring results, the investigators will enroll a convenience sample of natural grass field users. This new collection is being referred to as the "supplemental measurements study" to distinguish it from the original collection. To speed the data collection and alleviate unnecessary burden on the respondents, ATSDR will reduce the scope of the collection to questionnaires and urine collections only. Specifically, measurements that were not readily obtained in the initial study or for which laboratory analysis was not informative will not be continued. US EPA will not be participating in the supplemental data collection.

ATSDR is authorized by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(i)(1)(E), (7), (9), (15) and 9626(a)] to collect this study data (**Attachment 1**).

A.2. Purpose and Use of the Information Collection

The original research study protocol (**Attachment 5**) has been amended to include the supplemental exposure characterization and measurements study (**Protocol Section 9**) to collect only questionnaire data and pre- and post-activity urine samples from users of tire crumb rubber synthetic turf fields and natural grass fields. The calculated sample size is designed to allow identification of statistically significant differences pre- and post-activity when the samples from all locations are pooled. Consistent with the limitation of the data collected under OMB Control No. 0923-0058, the sample will not be nationally representative due to the convenience sampling methods employed. Completing the activities set forth in this package should help improve the exploratory characterization of exposure that we began in the original protocol.

While the sample design will not allow for generalization of results to the universe of field users with exposures to tire crumb rubber in synthetic turf fields in the United States, the research will provide valuable information to better understand and identify the potential chemical exposures. Though this will not be a representative sample of children and adults in the US, we will be able to compare the urinary levels for the respondents in this study to values in the general US population (NHANES comparison values). Additionally, we will be able to compare differences in urinary levels of select compounds in synthetic turf field users pre- and post-activity to those levels in natural grass field users. It is important to communicate to the public and other stakeholders that the study activities are not designed to and will not be sufficient by themselves to directly answer the public's question about safety but will contribute to the more extensive research portfolio necessary to achieve that goal in the longer term.

A.2.1. Scope of the Exposure Characterization and Measurements Study

In 2019, we aim to initiate participant recruitment at nine of the synthetic turf fields that previously participated in the tire crumb characterization portion of the research (OMB Control No. 0923-0054) and to include a small number of natural grass fields. Our target sample size is 200 completed questionnaires and pre- and post-activity urine collections. Approximately 50 participants will use natural grass fields and 150 will use synthetic turf fields as described in **Table B.2.1**. For the supplemental exposure characterization and measurement study, there will be a decrease in scope of the activities as outlined below.

A majority of the supplemental collection will be the same as previously defined in the original Research Protocol (US EPA and CDC/ATSDR, 2016). The recruitment strategy for this additional sampling effort will also remain largely the same as participant recruitment will occur on-site at the field location. During the previous data collection, the indoor field practice schedule did not allow for participant recruitment; for the new ICR, we will attempt to recruit from at least two indoor fields, in addition to the outdoor fields. Additionally, previously, time did not permit inclusion of grass fields; however, this ICR permits including natural grass field users to generate hypotheses about patterns observed. This change is anticipated to significantly strengthen the results of the overall study.

The fact sheets and the eligibility screening form has been modified for the reduced scope of the new data collection (**Attachments 3a, 3b, 3c**). The eligibility screening form has been modified for inclusion of natural grass field users (**Attachment 3c**). The exposure characterization and measurements study consent, assent, and permission forms have been revised to reflect the reduction in scope for the data collection and signatures will be required of all participants and parents/guardians for youth/child participants (**Attachment 3d**). Questionnaires will be administered to adult and adolescent participants or parents/guardians for youth and child participants. The questionnaires were modified to include natural grass field

users **(Attachments 3e&3f**). Pre- and post-activity urine samples will be collected using the same protocol as in the previous exposure measurement pilot-scale effort (**Protocol Appendix J**). No blood, dermal wipes, or personal air monitoring samples will be collected. Additionally, there will not be a video activity component of the study. The exposure measurement form will be used to log the pre- and post-activity urine collection and urine volume (**Attachment 3g**).

A.3. Use of Improved Information Technology and Burden Reduction

ATSDR plan to continue to use electronic reporting in the form of computer-assisted interviews (CAIs) for data collection; the eligibility screening form and questionnaire were developed using Epi Info. The eligibility screening will continue to occur prior to the questionnaires for the field users. The questionnaires incorporate computer-generated skip patterns thus alleviating respondent burden for inapplicable questions. The questionnaires will be administered by trained study interviewers.

A.4. Efforts to Identify Duplication and Use of Similar Information

Several studies have performed measurements at synthetic turf fields for selected metal or organic chemical analytes (Schiliro et al., 2013; Menchini et al., 2011; Shalat, 2011; Cal-OEHHA, 2010; Simcox et al., 2011; Van Rooij and Jongeneelen, 2010; Highsmith et al., 2009; NYDEC, 2009; Vetrano and Ritter, 2009; Castellano et al., 2008; Dye et al., 2006). Most of these measurements have been for particles, metals, or organics in air while only a few studies measured chemicals present on field surfaces using wipe samples (NYDEC, 2009; Highsmith et al., 2009; CPSC, 2008; Cal-OEHHA, 2007). Concentrations of chemicals in the air of indoor fields have generally been found to be higher than those at outdoor fields. There is limited information on biomonitoring of individuals who play on synthetic turf fields as very few studies have reported biomonitoring data (Van Rooij and Jongeneelen, 2010; Castellano et al., 2008). For the two identified studies, 1-hydroxypyrene was measured as a marker of exposure to pyrene, and no elevated levels were found following synthetic field sports use. However, the sample sizes and number of fields included were very small.

There are other studies currently being conducted, primarily by the California Office of Environmental Health and Hazard Assessment (OEHHA). However, California OEHHA is not conducting a biomonitoring study at this time. In the event that California OEHHA initiates a

biomonitoring study, the data collection described in this ICR will have minimal duplication as we will target field users across the US and will not focus on one state alone.

Consultation between the federal research team and Cal-OEHHA researchers will be used to identify and implement methods and approaches that will, where feasible, produce comparable data. There as a recent study by the Washington State Department of Health; however, there is no duplication of efforts as the study focused on cancer incidence among soccer players residing in the state at the time of diagnosis.

Other attempts at identifying activities that could results in duplication of efforts, including literature searches, attendance at national meetings, and consultations with other federal and state agencies, did not reveal any other ongoing activities related to crumb rubber infill in synthetic turf.

A.5. Impact on Small Businesses or Other Small Entities

The activities will involve field users, which will likely not involve small businesses or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

The activity will be a one-time collection, and the respondents will respond once per form.

However, the biological specimen collection will occur two times in a 24-hour period (immediately pre-activity and post-activity), but no additional information will be collected (e.g. no additional exposure measurement questionnaire). If the specimen collections are not obtained, the lack of knowledge regarding exposure potential to chemicals in crumb rubber infill will persist. Responsive and actionable public health recommendations cannot be implemented.

There are no technical or legal obstacles to reducing burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The following special circumstance applies to this information collection. The respondents for research activity will be drawn from a convenience sample; therefore, the results are not intended to be generalized to the universe of field users.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the Federal Register on December 26, 2018, Vol. 83 No. 246, pgs 66265-66266.

B. During the 60-day public comment period, one non-substantive comment from the public was received (**Attachment 2a**).

C. For the research study, ATSDR and US EPA have consulted directly with the White House CEQ and CPSC to obtain their views on the public health issue/concern surrounding crumb rubber infill in synthetic turf. These federal partners initiated the *Federal Research Action Plan for the Use of Recycled Tires in Synthetic Turf Playing Fields and Playgrounds*. This activity is a result of the pilot-scale exposure measurements sub-study data collection.

Table A.8.1. 2016 ATSDR External Consultations

Name	Title	Affiliation	Phone	Email
FEDERAL CONSULTANTS				
Annette Guiseppi-Elie, PhD	Associate Director for Exposure Science	US EPA	*(919) 541-4651*	*TireCrumbs@epa.gov*
Kent Thomas, BSPH	Research Physical Scientist	US EPA	*(919) 541-4651*	*TireCrumbs@epa.gov*

Table A.8.2. 2016 Consultations with CDC NCEH Laboratories

Name	Title	Affiliation	Phone	Email
Antonia Calafat	Branch Chief	CDC/NCEH/DLS	*(770) 488-7891*	*ACalafat@cdc.gov*

A.9. Explanation of Any Payment or Gift to Respondents

A.9.1. Supplemental Exposure Measurements Study

ATSDR is requesting approval to screen 220 potential participants with the respondent goal of 150 synthetic turf field users and 50 natural grass users for this data collection.

As in the prior data collection, incremental tokens of appreciation in the form of gift cards are described below.

- Eligible respondents who provide informed consent and who complete the activity questionnaire will receive a gift card ($25).
- Respondents who complete the urine collection component, will receive additional gift cards ($10 pre-activity and $15 post-activity).

This will be at a total monetary level that is less than originally approved by OMB for the full exposure characterization study ($75).

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act does not apply. For the exposure characterization and measurements study, investigators have received IRB approval for a waiver of documentation of informed consent (**Attachment 6**); therefore, no information in Identifiable Form (IIF) will be linkable to the participants' data or specimens, which will be labeled with an assigned study ID.

The NCEH/ATSDR Information Systems Security Officer (ISSO) has approved a Data Privacy & Security Plan to ensure measures are in place to protect participant data while using Epi Info™ software. The system's Security Plan defines the process for handling security incidents. The system's team and the Office of the Chief Information Security Officer (OCISO) share the responsibilities for event monitoring and incident response. The team will direct reports of suspicious security or adverse privacy-related events to the NCEH/ATSDR ISSO, CDC Helpdesk, or to the CDC Incident Response team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

The Privacy Impact Assessment (PIA) is found in **Attachment 4**.

The records will follow the required disposition schedules under: 1) CDC/ATSDR Records Control Schedule.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

ATSDR intends to collect the minimum amount of information necessary to meet the objectives of research activity. Some of the information could be viewed as sensitive by the respondents, specifically related to field procedures.

The amended study protocol (**Attachment 5**) has been approved by CDC IRB (**Attachment 6**), with a waiver of documentation of informed consent. All respondents will be consented as indicated by a check box on the consent, assent, and permission forms (**Attachment 3d**); each

form will be labeled with a participant ID label the indication of informed consent. All respondents will be informed that their participation is voluntary and that they can choose to not answer any question.

A.12. Estimates of Annualized Burden Hours and Costs

The time burden requested for the exposure characterization and measurements study is 184 hours. Estimated annualized burden hours are presented and justified below.

Assuming a 90 percent eligibility rate and a 50-to-50 ratio between adults and adolescents vs. children ages 7 to 12 for the supplemental sub-study, ATSDR estimates that 220 respondents would be screened for eligibility in 5 minutes resulting in a burden of 18 hours (**Attachment 3c**). For the activity questionnaires, we estimate the respondent burden would be 100 hours, based on 200 respondents (100 adults/adolescents vs. 100 children) at 30 minutes each (**Attachments 3e&3f**). Documenting the time required to collect pre- and post-activity urine samples would total 66 burden hours for the 200 respondents at 20 minutes each (**Attachment 3g**). Therefore, the total time burden requested for the supplemental sub-study is 184 hours.

Table A.12.a. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Adult/ Adolescent Field Users	Eligibility Screening Form	110	1	5/60	9
	Adult and Adolescent Questionnaire	100	1	30/60	50
	Exposure Measurement Form	100	1	20/60	33
Parents/ Guardians of Youth/Child Field Users	Eligibility Screening Form	110	1	5/60	9
	Youth and Child Questionnaire	100	1	30/60	50
Youth/Child Field Users	Exposure Measurement Form	100	1	20/60	33

Total					184

The adult and adolescent field users are assumed to be college student athletes with an earning potential, if employed, of $7.25/hour based on the federal minimum wage. See http://www.dol.gov/general/topic/wages/minimumwage. To maintain comparability of wages over time, we make the same assumptions about the hourly wage for parent/guardian respondents of youth or child field users as $24.34 for all occupations based on the Bureau of Labor Statistics *May 2017 National Occupational Employment and Wage Estimates* (see https://www.bls.gov/oes/current/oes_nat.htm#00-0000). We assume that the parents/guardians will wait while their youth or child, who is not a wage earner, to collect and donate two urine samples; therefore, by proxy, we again attribute $24.34 per hour for respondent cost burden for this activity.

Table A.12.b. Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adult/Adolescent Field Users	Eligibility Screening Form	9	$7.25	$65.25
	Adult and Adolescent Questionnaire	50	$7.25	$362.50
	Exposure Measurement Form	33	$7.25	$239.25
Parents/Guardians of Youth/Child Field Users	Eligibility Screening Form	9	$24.34	$219.06
	Youth and Child Questionnaire	50	$24.34	$1,217.00
Youth/Child Field Users	Exposure Measurement Form	33	$24.34	$803.22
Total				$2906.28

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no additional capital and maintenance costs for study described in this ICR for respondents or record keepers.

A.14. Annualized Cost to the Federal Government

In total, the estimated annual cost to the government is approximately $400,000.

- The estimated average annualized cost of the program is $325,000.
    - Personnel: $265,000 per year.
        - The annual personnel costs are based on a FTE at GS-13/1 with an estimated 3 full time staff.
    - Travel: $60,000. This amount is based on the number of site visits conducted.
- Other project requirements, including but not limited to, laboratory analysis and tokens of appreciation, are estimated to cost $85,000.

A.15. Explanation for Program Changes or Adjustments

The research protocol, *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*, has been conducted to date under two ICRs. Activity 1 was conducted under a six-month emergency request (OMB Control No. 0923-0054; expiration date 01/31/2017). Activities 2 and 3 were partially completed under OMB Control No. 0923-0058 (expiration date 08/13/2018)]; due to time constraints, collections were limited to approximately 3 months with a completion date of October 2017.

This is a new request to supplement the data collection for Activities 2 and 3 under the prior exposure characterization and measurements study. The investigators are proposing to continue data collection and achieve a sample size of 200 participants, including 150 synthetic turf field users and 50 natural grass field users. This will be a larger-scale assessment of exposure potential for individuals who use/play on synthetic turf fields with tire crumb rubber infill. The study will include persons who use synthetic turf with crumb rubber infill and who routinely perform activities that would result in a high level of contact to crumb rubber. The study will also include persons who use natural grass fields. This will allow generation of hypotheses about potential high-end exposures to constituents in synthetic turf among this group of users.

This supplemental measurements study will be reduced in scope. The investigators will collect only urines and will not collect the full suite of environmental exposure measures, such as personal air samples, dermal wipe samples, or blood samples.

Reducing the scope of the environmental measurement to urine collections required the use of data collection forms based closely on the original eligibility screening form, the consent forms,

and the exposure measurement form (**Attachments 3a, 3b, 3c, & 3f**). Including natural grass field users required modifications to the adult/adolescent and the youth/child questionnaires (**Attachments 3d & 3e**). Additionally, the questionnaire has been modified to include questions regarding potential lifestyle and dietary exposures to the specific chemicals of concern. Urine collection procedures remain the same as in the 2017-2018 collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Upon completion of data collection and laboratory analysis, ATSDR plans to report on the various activities to the respondents and to the public. The research will be described in a final report. The report will help answer some of the key questions that have been raised about tire crumb used in artificial turf fields, and will provide a better understanding of potential exposures that athletes and others may experience by using these fields.

As stated earlier in this Supporting Statement, as the sample design for this study will not allow for generalization of results to the universe of synthetic turf fields in the United States, this investigative pilot study is only intended to set the stage for designing and implementing future human exposure studies. For all publications, presentations, and materials disseminated to the public and other stakeholders of this study's findings, it will be clearly communicated that the study activities are not designed to and will not be sufficient by themselves to directly answer the public's questions about safety but will implement the preliminary research necessary to achieve that goal in the longer term.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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List of Attachments

Attachment 1. Authorizing Legislation

Attachment 2. 60-day Federal Register Notice

Attachment 3. Forms and Supporting Documents

- Attachment 3a. Field User Fact Sheet
- Attachment 3b. Field Owner/Manager Fact Sheet
- Attachment 3c. Field User Eligibility Screening Form
- Attachment 3d. Exposure Measurement Sub-study Consent, Assent, Permission Forms
- Attachment 3e. Field User Adult and Adolescent Questionnaire
- Attachment 3f. Field User Youth and Child Questionnaire
- Attachment 3g. Exposure Measurement Form
- Attachment 3h1. Exposure Measurement Form - Pre-activity Questionnaire Administration Notice
- Attachment 3h2. Exposure Measurement Form - Post-activity Questionnaire Administration Notice

Attachment 4. Privacy Impact Assessment

Attachment 5. Research Protocol

Attachment 6. CDC IRB Amendment Approval