

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

OMB Control No. 0923-0062 (Expiration Date 10/31/2021)

Non-substantive Change Request

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

Program Official: Elizabeth Irvin-Barnwell

Title: Director, Office of Community Health and Hazard Assessment

Phone: 770-488-3684

Email: jcx0@cdc.gov

Fax: 770-488-1547

Date: December 18, 2020

Table of Contents

B.1. Respondent Universe and Sampling Methods.....	3
B.2. Procedures for the Collection of Information.....	5
B.3. Methods to Maximize Response Rates and Deal with Nonresponse.....	8
B.4. Test of Procedures or Methods to be Undertaken.....	8
B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	8
References.....	10
List of Attachments and Protocol Appendices.....	11
Attachment 1. Authorizing Legislation.....	11
Attachment 2. 60-day Federal Register Notice.....	11
Attachment 2a. Public Comments and Agency Responses.....	11
Attachment 3. Privacy Impact Assessment.....	11
Attachment 4. CDC IRB Amendment Approval.....	11
Research Protocol.....	11
Appendix N1a. Field User Fact Sheet.....	11
Appendix N1b. Field Owner/Manager Fact Sheet.....	11
Appendix N2. Field User Eligibility Screening Form.....	11
Appendix N3. Exposure Characterization and Measurement Study Consent, Assent, Permission Forms.....	11
Appendix N4a. Field User Adult and Adolescent Questionnaire.....	11
Appendix N4b. Field User Youth and Child Questionnaire.....	11
Appendix N5a. Exposure Measurement Form - Pre-activity Questionnaire Administration Notice.....	11
Appendix N5b. Exposure Measurement Form - Post-activity Questionnaire Administration Notice.....	11
Appendix N6. Exposure Measurement Form.....	11
Appendix N7. Site Health and Safety Plan.....	11
Appendix N8. Synthetic Turf COVID-19 Precaution Plan.....	11

Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

This is a request for a non-substantive change to a previously approved OMB package (OMB Control No. 0923-0062; expiration date 10/31/2021). Revisions include a health and safety plan to address COVID-19 and keep employees as well as study participants safe.

For this supplemental study, the recruitment strategy will remain largely unchanged from the previously approved study. We will be recruiting participants from the nine fields in the original study that agreed to allow for recruitment and field sampling for future studies; if we are unable to recruit at the fields, we will recontact community fields who participated in the tire crumb characterization study (OMB Control No. 0923-0054) and request agreement to allow for participant recruitment. We will not be sampling at any of the 19 fields at military installations. We will be using a convenience sampling approach to recruit and consent field users at the nine synthetic turf fields.

For the pilot-scale study, researchers recruited the same sample size for two different field activities (e.g. football and soccer). Based on prior experience, we do not anticipate oversampling for certain activities.

To generate hypotheses about patterns observed in the synthetic turf users, ATSDR plans to include natural grass field users at nearby fields when available. ATSDR does not have specific criteria for choosing the grass fields other than general proximity because ATSDR will not be comparing participants from a specific turf field with those from a specific grass field. The purpose of the collection is not to characterize grass users or make direct comparisons between turf and grass field users in general or at a given site. The goal is simply to provide insight into the measurements obtained and thus develop hypotheses that would be used to identify the types of additional research that would be fruitful.

ATSDR plans to screen 220 participants in order to meet the recruitment goal of 150 synthetic turf field users and 50 natural grass users. The sample sizes are based upon findings for 2-NAP in the original pilot study. Sample size estimates for hypothesis testing of mean paired differences, pre-activity and post-activity (our primary focus), are usually based on effect size, defined as the mean of paired differences of analyte levels, divided by the standard deviation of

the paired differences. The pilot study showed a mean paired difference (pre-test-post-test) for 2-NAP of 2.45 ($\mu\text{g/L}$) in urine with a standard deviation of 4.32. This corresponds to an effect size of 0.56. Thus, we chose it as a baseline effect size. Effect sizes for other analytes in the pilot study ranged from 0.5 to 1.0, generally larger. However, for synthetic turf, in order to detect smaller effect sizes and to make subgroup comparisons (see Table B2.1), we chose a smaller effect size of 0.25 for these calculations. Pilot-study results indicated that mean paired differences (pre-activity and post-activity) can be both positive and negative. Therefore, sample size calculations were based on 2-sided tests for paired mean differences of 2-NAP with 80% power and an alpha level of 0.05. PASS 11.0 software was used for all calculations.

An effect size of 0.55 (corresponding to the observed result for 2-NAP in the pilot study) corresponds to a sample size of 28 for grass. An effect size of 0.25 corresponds to a sample size of 128 for synthetic turf. Assuming a non-response rate of approximately 15%, and then rounding up to a multiple of 50, we arrive at sample sizes of 150 for synthetic turf and 50 for grass.

The respondents are a convenience sample of adults/adolescents and youth/children that routinely use natural grass or synthetic turf fields with crumb rubber infill for athletics, recreation, and/or physical education or physical training purposes. For natural grass fields users, we have an eligibility criterion to account for recent synthetic turf field use; the eligibility criterion for natural grass field users states that a participant is not eligible if they have played on a synthetic turf field within 24 hours. The estimated half-lives of the urinary PAH metabolites measured in the laboratory analysis ranges from 2.5 hours to 6.1 hours. Additionally, we have a question in the questionnaire as to whether or not they have played on synthetic turf fields within the last 48 hours. For other sources of PAHs, specific foods, e.g. smoked and grilled foods, are sources of PAHs. We are requesting that participants refrain from eating these foods for 24 hours prior to sample collection. Additionally, we have included an exposure section in the questionnaire.

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. ATSDR will initially focus on recruitment of children aged 7 and older (**Table B.2.1**). ATSDR will recruit field users from facilities that previously participated in the tire crumb rubber characterization study who provided agreement to allow for recruitment of field users for the Exposure characterization study.

B.2. Procedures for the Collection of Information

ATSDR proposes to collect only questionnaire data and urine samples for the exposure characterization and measurements study.

B.2.1. Exposure Characterization and Measurements Study Aims

There are two primary aims of the facility user exposure characterization and measurement study. The first aim is to collect human activity data for synthetic turf field users that will supplement default exposure factor assumptions in exposure and risk assessment. This information collection will use modified versions of previously OMB-approved questionnaires. Specifically, we have added new information to the questionnaires including a dietary subsection to account for known exposures to PAHs; specifically Section C in the questionnaires, Exposure-related Questions. Users will be adults and youth who use natural grass or synthetic turf fields with crumb rubber infill for several types of active uses including athletics and possibly physical education or physical training (**Appendix N4a, N4b**). Information will be collected to provide data about relevant parameters in addition to the original questionnaires for characterizing and modeling exposures associated with the use of synthetic turf fields for the cohort being studied. Additionally, the questionnaire will capture information regarding chemical-specific potential exposures in order to allow for more thorough interpretation of analytical results.

The second aim is to conduct this study for people using synthetic turf fields with tire crumb rubber infill, in what are likely to be among field users with higher exposure scenarios. Natural grass field users will be included to provide insight into the measurements obtained and thus develop hypotheses that would be used to identify the types of additional research would be fruitful.

B.2.1.1 Facility User Information Collection

Up to 150 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 (**Tables A.12.3 & 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 also aim to recruit up to 50 people who engage in physical activities on natural grass fields.

Participants will be recruited from users of non-military facilities already recruited for participation in the tire crumb rubber characterization activity. 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. Researchers will contact these field owners/managers and provide them with a fact sheet for the supplemental exposure characterization and measurements study (**Appendix N1b**). Researchers will contact sports league coaches prior to participant recruitment to determine scheduled activities and primary points of contact for initial engagement with potential participants. Participants will be recruited from a maximum of nine synthetic turf fields. Additionally, target activity groups are Groups C, D, and E. To achieve sample size goals, participants may be recruited from activity groups A and B.

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

Example Activity Types ^a	Total Number Of Users Recruited	Total Number Of Users Participating ^b	Synthetic Turf Field Users	Natural Grass Field Users	Maximum Number Of Synthetic Turf Fields
Professional athletics/Adults (Group A)	0	0	0	0	9
College athletics (Group B)	55	50	30	10	9
High school P.E. or athletics (Group C)	55	50	40	10	9
Youth ages 10 – 12 athletics (Group D)	55	50	40	15	9
Children ages 7 – 9 athletics (Group E)	55	50	40	15	9
Total Number of Users	220	200	150	50	9

^a These are examples of user groups 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.

^b It is anticipated that up to 200 of the 220 people recruited will participate.

We anticipate recruiting respondents from up to nine fields that participated in the tire crumb rubber characterization study to minimize the time and cost. Facility users will be contacted to determine eligibility using a screening form and be provided fact sheet (**Appendix N1a, N2**) and request consent to participate (**Appendix N3**). After facility users have consented to participate, they will be provided an instruction notice based on the timing of questionnaire

administration, pre- or post-activity (**Appendix N5a, N5b**). 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. Adult and adolescent facility users who agree to participate will be administered a questionnaire (**Appendix N4a**) by trained research staff in person or over the phone using a Computer Assisted Interview. For children 7-9 (Group E) and youth 10-12 (Group D), we will administer the questionnaire to the parent/guardian (**Appendix N4b**). 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 and information about potential external exposures to the chemicals of interest. Information categories include:

- 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,
- g) hygiene practices, and,
- h) dietary questions.

Questionnaire data 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.

These same 200 people who engage in physical activities at facilities with natural grass or synthetic turf fields with tire crumb rubber infill will also be asked to provide urine specimens pre- and post-activity (**Table B.2.1**). Pre- and post-activity urine collections will be recorded in the modified exposure measurement form (**Appendix N6**). ATSDR will not collect personal air samples, dermal wipe samples, or blood samples. The biological specimens will be analyzed for PAHs and will also be archived for potential analysis of other chemicals associated with tire crumb rubber at a future date. Although a statistical design is not being implemented, sample size calculations indicate the potential for determining differences for urinary PAH metabolite

levels pre- and post-activity and for determining differences in field users compared to the US reference values (NHANES, 2013-2014).

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. The pilot study indicated that the participation rate for field users was very high as only one individual was determined to be ineligible (96% participation rate). However, the pilot study did indicate that initial contact with potential participants and/or their guardians was difficult. For the new data collection, immediately upon request approvals, ATSDR will contact the participating facilities to provide a fact sheet and information about the purpose and value of the research and to request participation (**Appendix N1b**). We will employ a number of strategies in an attempt to maximize response rates. These include having trained study representatives: (1) reach out to the league/team managers to inform them of the study and request for distribution of the fact sheet to league participants and/or their guardians; (2) make multiple visits during practices to discuss the study with potential participants and/or guardians at different times of day and on different days of the week.

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

The procedures and methods to be used in this exposure characterization and measurements study have been previously tested and evaluated during the 2017-2018 collection. Based on the preliminary results from the pilot exposure measurements sub-study, ATSDR has reduced the scope of the data collection and will only collect questionnaire information and urine specimens from participants. For the new data collection, ATSDR will also include grass field users as a comparison group.

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
Michael Lewin	Statistician	CDC/ATSDR	(770) 488-3812	MLewin@cdc.gov

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

Name	Title	Affiliation	Phone	Email
Kelsey Benson	Epidemiologist, Environmental Epidemiology Branch	CDC/ATSDR	770-488-0684	yrn0@cdc.gov

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 and Protocol Appendices

Attachment 1. Authorizing Legislation

Attachment 2. 60-day Federal Register Notice

Attachment 2a. Public Comments and Agency Responses

Attachment 3. Privacy Impact Assessment

Attachment 4. CDC IRB Amendment Approval

Research Protocol

Appendix N1a. Field User Fact Sheet

Appendix N1b. Field Owner/Manager Fact Sheet

Appendix N2. Field User Eligibility Screening Form

Appendix N3. Exposure Characterization and Measurement Study Consent, Assent, Permission Forms

Appendix N4a. Field User Adult and Adolescent Questionnaire

Appendix N4b. Field User Youth and Child Questionnaire

Appendix N5a. Exposure Measurement Form - Pre-activity Questionnaire Administration Notice

Appendix N5b. Exposure Measurement Form - Post-activity Questionnaire Administration Notice

Appendix N6. Exposure Measurement Form

Appendix N7. Site Health and Safety Plan

Appendix N8. Synthetic Turf COVID-19 Precaution Plan