

December 18, 2020

## **Change Request for OMB Control No. 0923-0062**

### Justification/Brief Explanation for the Change Request

*The Request:* This is a non-material/non-substantive change request for “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 October 31, 2021). This change request reflects modifications to the currently approved information collection request (ICR) and reflects the need to practice social distancing to the extent possible. Where necessary, ATSDR has modified its scripts and forms to let the public know of the COVID-19 precautions that the agency is implementing. We are requesting OMB approval by February 1, 2021. We will then contact and select facilities, and plan to be in the field for recruitment and sample collection, in early March, 2021.

*Background:* ATSDR is planning to start Synthetic Turf recruitment and sampling activities in the Spring of 2021. Precautions will be put in place to ensure that staff, contractors, and members of the public are protected from COVID-19. This plan is based on interim CDC guidance for non-COVID-19 public health activities that require face-to-face interaction during the COVID-19 pandemic and will be used to outline practices for conducting Synthetic Turf activities <https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-covid-19-client-interaction.html>.

Since that time, the agency has developed its plan in collaboration with, and reviewed and approved by, the CDC Office of Safety, Security, and Asset Management (OSSAM), CDC Leadership, the CDC Emergency Operation Center (EOC) Joint Information Center (JIC), and CDC EOC COVID-19 Task Forces including Environmental Health, Epidemiology and Surveillance, State Tribal Local and Territorial, and Health Systems and Worker Safety.

ATSDR plans for resumption of field work activities will be determined on a site by site basis. Work at the sites will be staggered. Decisions about when to start activities will be made in consultation with regional ATSDR staff as well as state and local public health officials.

*Summary of the Field Work Plan:* Appropriate safety precautions, including the use of all appropriate personal protective equipment (PPE), will be implemented to keep the Synthetic Turf team and participants safe during the study. Appendix N8, the Synthetic Turf COVID-19 Precaution Plan, has been included that outlines the additional procedures that will be implemented during recruitment, field work and community meetings to ensure that recruitment and sampling activities are completed in compliance with state, local and CDC requirements.

The activities that will be modified include:

- Ensuring that social distancing and the use of PPE are employed to comply with local, state and CDC COVID-19 guidelines during field recruitment.
- Asking participants about their and their family's health/COVID-19-status prior to beginning the testing process.
- Monitoring the temperature of field team members (CDC/ATSDR) twice daily and taking participant's temperatures prior to entering the sampling area.
- Administering the questionnaire and collection of urine samples with appropriate social distancing precautions in place.

Below is the change request cross-walk table. Attached please find the revised protocol and modified forms and appendices. The overall number of respondents and requested burden hours remain the same. Once these changes are approved by OMB, ATSDR will submit the protocol to the CDC IRB for Amendment #6.

ICR Files	Requested Change	Justification
<i>Supporting Statement A</i>	<ol style="list-style-type: none"> <li>1. Additional information has been added to the goals of the research study section.</li> <li>2. Changed attachment numbers in the table of contents and in the text.</li> <li>3. Additional information on changes have been added to section A.15.</li> </ol>	<ol style="list-style-type: none"> <li>1. Information on the COVID-19 prevention and protection measures should be included as this is the reason for the change request.</li> <li>2. To facilitate IRB review and minimize further confusion to ICR preparers, the List of Attachments and Protocol Appendices have been modified in SS-A and SS-B to reflect the format that is IRB-approved. This will make IRB amendments easier to submit.</li> <li>3. All changes should be included in section A15 including information on COVID-19 prevention and protection measures and any changes to the protocol appendices.</li> </ol>
<i>Supporting Statement B</i>	<ol style="list-style-type: none"> <li>4. Additional information has been added to section B.1.</li> <li>5. Changed attachment numbers in the table of contents and in the text.</li> </ol>	<ol style="list-style-type: none"> <li>4. information on the change request and addition of COVID-19 prevention and protection measures should be included as it impacts recruitment and sampling methods.</li> <li>5. To facilitate IRB review and minimize further confusion to ICR preparers, the List of Attachments and Protocol Appendices have been modified in SS-A and SS-B to reflect the format that is IRB-approved. This will make IRB amendments easier to submit.</li> </ol>
<i>List of Attachments and Protocol Appendices in SS-A and SS-B</i>	<ol style="list-style-type: none"> <li>6. The research protocol has been pulled out of the list of ICR attachments, and protocol appendices have been renumbered to reflect the way they are currently IRB-approved. The remaining attachment numbers have been adjusted accordingly. See below.</li> </ol>	<ol style="list-style-type: none"> <li>6. To facilitate IRB review and minimize further confusion to ICR preparers, the List of Attachments and Protocol Appendices have been modified in SS-A and SS-B to reflect the format that is IRB-approved. This will make IRB amendments easier to submit.</li> </ol>
<i>Privacy Impact Assessment</i>	<ol style="list-style-type: none"> <li>7. Change attachment number from 4 to 3.</li> </ol>	<ol style="list-style-type: none"> <li>7. See List of Attachments and Appendices justification above.</li> </ol>

<i>CDC IRB Amendment Approval Memo</i>	8. Change attachment number from 6 to 4.	8. See List of Attachments and Appendices justification above.
<i>Supplemental Exposure Measurement Study Materials</i>	9. All Attachment 3 subfiles have been renumbered as they are IRB-approved in the protocol. See below for the specific changes.	9. See List of Attachments and Appendices justification above.
<i>Protocol</i>	10. Remove Attachment 4 label and present the protocol as a standalone document. 11. Appendix N7(Site Health and Safety Plan) and Appendix N8(Synthetic Turf COVID-19 Precaution Plan) have been added and indexed in the protocol table of contents.	10. See List of Attachments and Appendices justification above. 11. Appendix N7 documents general site health and safety measures for field work. Appendix N8 documents the precautions that ATSDR is undertaking to protect the public and its workers from COVID-19.
<i>Fact Sheets</i>	12. Change from Attachment 3a and 3b to Appendix N1a and N1b. 13. Recruitment materials will include information on procedures that CDC/ATSDR will be taking to address concerns associated with COVID-19.	12. See List of Attachments and Appendices justification above. 13. The recruitment materials will provide information to potential participants on the procedures that CDC/ATSDR will take to comply with local, state and CDC guidelines at the time of Synthetic Turf field activities.
<i>Eligibility Screening</i>	14. Change from Attachment 3c to Appendix N2. 15. Eligibility screening will include information on procedures that CDC/ATSDR will be taking to address concerns associated with COVID-19.  16. Change mode of data collection from EpiInfo to Survey123.	14. See List of Attachments and Appendices justification above. 15. The eligibility screening materials will provide information to potential participants on the procedures that CDC/ATSDR will take to comply with local, state and CDC guidelines at the time of Synthetic Turf field activities. 16. Survey123 is easier to use in the field on tablets than EpiInfo for the eligibility screening. This technology will also allow for fewer data entry errors with built in checks before submission.
<i>Consent Forms</i>	17. Change from Attachment 3d to Appendix N3.	17. See List of Attachments and Appendices justification above.
<i>Questionnaires</i>	18. Change from Attachment 3e and 3f to Appendix N4a and N4b. 19. Change mode of data collection from EpiInfo to Survey 123.	18. See List of Attachments and Appendices justification above. 19. Survey123 is easier to use in the field on tablets than EpiInfo for the questionnaires. This technology will also allow for fewer data entry errors with built in checks before submission.
<i>Exposure Measurements Forms</i>	20. Change from Attachment 3h1, 3h2, and 3g to Appendix N5a, N5b, and N6. 21. The exposure measurement forms were modified to include information on procedures that CDC/ATSDR will be taking	20. See List of Attachments and Appendices justification above. 21. A screening for self-reported COVID-19 symptoms and a temperature check will be conducted prior to participants

	to address concerns associated with COVID-19 and include a screening and temperature check for COVID-19.	entering the sampling area.
<i>Site Health and Safety Plan</i>	22. Appendix N7 has been added to provide information on PPE requirements and safety procedures.	22. The Site Health and Safety Plan is needed for safety measures for federal employees, and the general public.
<i>Synthetic Turf COVID-19 Precaution Plan</i>	23. Appendix N8 has been added to provide methodology for safely completing field activities in compliance with state, local and CDC COVID-19 guidelines in place at the time the field activities are conducted.	23. Policies and procedures must be followed to modify activities to address concerns associated with COVID-19. Procedures will comply with the guidance in place at the time an activity is conducted.