GenIC Clearance for CDC/ATSDR Formative Research and Tool Development

Harmful Algal Blooms Shellfish Communication Evaluation

OMB Control No. 0920-1154

1/23/2025

Supporting Statement A

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LIST OF ATTACHMENTS

- 1. Eligibility Screener
- 2. Recruitment Materials
- 3. Eligible Participant Screener
- 4. Privacy Agreement
- 5. Respondent Consent Form
- 6. Standard Invitation for FGs
- 7. Participant Confirmation Email
- 8. Focus Group Moderator Guide
- 9. Messages/Materials to be Tested
- 10. Human Subjects Determination

A. JUSTIFICATION

- **Goals of the project:** The goal of this project is to conduct focus group discussions with U.S. adults (general population individuals who collect shellfish to eat for recreational, subsistence, or cultural reasons) to improve CDC's harmful algal bloom (HAB) and shellfish safety messaging and communications strategy. CDC is interested in collecting qualitative information to further explore and understand the context and rationale behind audience preferences, perceptions, and behaviors related to HABs, as well as testing specific CDC HAB-related messages and materials with audiences.
- **Intended use of the resulting data:** CDC will use the data to inform the agency's messaging strategy to better meet the needs of people who recreationally collect shellfish to eat. This includes using the data to update CDC's website content and improve the

agency's HAB communication resources available for people who collect shellfish to eat.

- Methods to be used to collect data: We will conduct virtual focus group discussions with U.S. adults (general population who collects shellfish to eat for recreational, subsistence, or cultural reasons). CDC's contractor, Banyan Communications, will conduct the focus groups.
- **The subpopulation to be studied:** U.S. adults who collect shellfish to eat for recreational, subsistence, or cultural reasons. This population includes adults who live near the East, West, Gulf, or Alaskan coasts.
- **How data will be analyzed:** The contractor will use rapid analysis to identify key themes and subthemes captured in the qualitative data collected during focus groups.

1 Circumstances Making the Collection of Information Necessary

CDC requests approval for a new Gen-IC under OMB Control No. 0920-1154.

CDC is charged with communicating information about harmful algal blooms (HABs) and health to the general public. This information is primarily disseminated through social media and through the <u>Harmful</u> <u>Algal Bloom (HAB)-Associated Illness website</u>. The website serves to educate the public on steps they can take to prevent HAB-associated illness and provides information on symptoms, causes, and reporting of HAB-associated illnesses.

Through recent quantitative HABs-focused surveys conducted by CDC's Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) (September 2021, September 2022, July 2023), nationally representative audience feedback provided useful information about preferred terminology, preferred illness prevention measures, information seeking and reporting, risk perception, and behaviors around visiting water bodies. DFWED also conducted focus groups with parents, dog owners, and individuals in the general public about HABs and HABs sickness (March 2024) to get feedback on current CDC messages and materials, identify knowledge gaps, understand water safety behavior, and understand communication preferences. While previous DFWED data collection helped gain insights from the general population and audience segments who frequently visit bodies of water, such as parents and dog owners, there is a need for additional qualitative information among different audience segments. This need is particularly important among populations that have a higher risk of exposure to HAB toxins. Individuals who collect shellfish to eat for recreational, subsistence, or cultural reasons is a key example of a population at a higher risk of HAB toxin exposure and sickness due to the potential consumption of contaminated shellfish. Because of this gap in the research, CDC is interested in collecting additional qualitative information to further explore and understand the context and rationale behind audience preferences, perceptions, and behaviors related to HABs, as well as testing specific CDC HAB-related messages and materials with people who collect shellfish to eat for recreational, subsistence, or cultural reasons (henceforth people who collect shellfish to eat).

Objectives of this evaluation are to:

- Obtain information about how current CDC messages and materials about HABs and HABs sickness resonate and lead to action among people who collect shellfish to eat.
- Understand information gaps about HABs and HABs sickness among people who collect shellfish to eat.
- Obtain insights about group norms and societal or cultural factors that may influence the attitudes, perceptions, and behaviors about HABs and HABs sickness among people who collect shellfish to eat.
- Obtain insights about the best way to disseminate information to people who collect shellfish to eat.

Data collection will be used to:

- Provide updates to CDC's website content and linked materials and inform the messaging strategy to better meet the needs of people who recreationally collect shellfish to eat.
- Enhance CDC's HAB communication resources available for people who collect shellfish to eat.

CDC's contractor, Banyan Communications, will implement qualitative focus groups. The focus group respondents for this project will be a maximum of 32 individuals recruited by Banyan Communications, through a professional recruitment partner. The project will work with volunteer respondents. Participants must meet a set of criteria to ensure all focus groups will include a maximally diverse group of participants considering age, educational level, socioeconomic status, sex, and ethnicity and include a mix of geographical areas. The focus groups will be conducted between adults (18+) and at least one project staff member. The goal is to obtain feedback to support HABs communication initiatives.

Data to be collected include the following: sociodemographics; knowledge, attitudes, beliefs, and perceptions related to HABs; and reactions and receptivity to HABs messages and content. Questions shall assess ways in which participants obtain and/or seek information related to HABs and HABs-associated illness prevention, how they interpret this information, message receptivity and whether/how the participants intend to change their behavior based on the message. Participants shall also elaborate on ways in which the presented messages, through text or presentation changes, could be improved so that they are more effective.

The data collection will use

- (1) a 5-minute Eligibility Screener before the virtual focus group (Attachment 1)
- (2) a 10-minute Eligible participant screener (Attachment 3)
- (3) a virtual 60-minute focus group (Attachment 8).

This information collection does not involve websites or website content directed at children less than 13 years of age.

2 Purpose and Use of the Information Collection

The purpose of this project is to conduct focus group discussions (FGDs) with U.S. adults who collect shellfish to eat for recreational, subsistence, or cultural reasons on the east, west, Gulf, and Alaskan coasts

(henceforth people who collect shellfish to eat) to improve current messages about HABs and preventing HABs sickness. Banyan Communications will conduct the focus groups.

Objectives of this project are to:

- Obtain information about how current CDC messages and materials resonate and lead to action among adults who collect shellfish to eat.
- Understand information gaps about HABs and HABs sickness among adults who collect shellfish to eat.
- Obtain insights about group norms and societal or cultural factors that may influence the attitudes, perceptions, and behaviors about HABs and HABs sickness among people who collect shellfish to eat.
- Obtain insights about the best way to disseminate information to people who collect shellfish to eat.

Data collection will be used to:

- Provide updates to CDC's website content and linked materials and inform the messaging strategy to better meet the needs of adults who collect shellfish to eat.
- Enhance CDC's HAB communication resources available for use by individuals who collect shellfish to eat.

3 Use of Improved Information Technology and Burden Reduction

We will record each focus group to use for preparing reports. Our data collection requires that we employ qualitative methods using one-time virtual focus group discussions. We will receive recorded verbal confirmation from participants to record the discussion. Questions (within the focus group discussions) will be kept to a minimum required for the intended use of the data.

4 Efforts to Identify Duplication and Use of Similar Information

There are no other federal generic collections that duplicate the project types included in this request. Health messages developed by CDC are unique in their mix of intended audience, health behavior, concept, and execution. Therefore, in most cases, there are no similar data available. We have reviewed existing published data and consulted with outside experts to identify information that could facilitate message development prior to conducting any data collection.

DFWED works consistently with other U.S. government agencies to ensure there isn't any redundancy.

5 Impact on Small Businesses or Other Small Entities

This project does not have an impact on small businesses or other small entities.

6 Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data over a 12-month period.

7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with regulation 5 CFR 1320.5.

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

For subcollection requests under an approved generic ICR, Federal Register notices are not required, and none were published.

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Thummalapally			
Bria Berry	Banyan Communications		

Exhibit A.8.1. Outside Consultation

To ensure there is no duplication or redundancy of effort across projects and programs, program staff will consult with a variety of sources on the availability of data, frequency of collection, clarity of instructions, and record keeping, disclosure, and reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

9 Explanation of Any Payment or Gift to Respondents

We will provide a token of appreciation of \$75 for each individual who participates in a focus group. Tokens of appreciation were determined based on previous projects and experience with conducting focus groups with individuals. The range of monetary reward is consistent with current rates for participation in formative projects. Tokens of appreciation will take the form of gift cards.

Reviewed literature revealed the payment of incentives can provide significant advantages to the government in terms of direct cost savings and improved data quality (see references). As participants often have competing demands for their time, a token of appreciation for participation in a study is warranted. The use of a token of appreciation treats participants justly and with respect by recognizing and acknowledging the effort participants expend to participate. Numerous empirical studies have also shown that a token of appreciation can significantly increase response rates in cross-sectional studies and reduce attrition in longitudinal studies (e.g., Abreu & Winters, 1999; Castiglioni et al., 2008). It also should be noted that message testing is a marketing technique, and it is standard practice among commercial market researchers to offer incentives as part of respondent recruitment.

A similar communication evaluation project that was conducted in the summer of 2023 proposed and was approved for \$75 per person for a 60-minute focus group discussion (OMB Co. Number: 0920-1154, Food Safety Communication Evaluation Assessing Food Safety Messages, Knowledge, and Attitudes). During this project, the team was successful and was able to recruit 115 individuals (the goal was to recruit 144). Another communication evaluation project about HABs was conducted in the spring of 2024 and was approved for \$75 per person for a 60-minute focus group discussion (OMB Co. Number: 0920-1154, Harmful Algal Blooms Communication Evaluation). For this project, the team successfully recruited 27 individuals (the goal was to recruit 32).

10 Assurance of Privacy Provided to Respondents

Contractors and anyone listening to the project will be required to sign a privacy agreement prior to the start of the project (**Attachment 4**). CDC's contractor, Banyan Communications, will retain notes, audio/video files, and any other project-related documents on secure servers or in locked file cabinets; only project staff members will be able to access the servers via password-protected computers. Focus group findings will be reported in summary form, and participants' names and identifying information will not be included in the findings. Identifiable information will be kept separate from focus group data, so that participants' responses cannot be linked with their names. All audio and video files will be destroyed three years after completion of the project. No identifiable information describing individual respondents will be included in the analyzed data and aggregate reports provided to CDC.

In review of this application, it has been determined that the Privacy Act is not applicable. Banyan Communications will identify, screen, and recruit potential participants through a recruitment firm, using a proprietary recruitment list/database. Banyan Communications will use additional recruitment methods, such as including social media notices and snowball sampling as needed.

Individuals will first be screened to assess if they are eligible to be a part of the focus groups (Attachment 1). Those who meet the screening criteria for the focus groups will then receive a second demographic screener to assess which focus groups they will be put into (Attachment 3). Finally, they will be invited to attend a virtual 60-minute focus group. Participants will be asked to give verbal consent on a recording prior to the start of the focus group and will also fill out a consent form (Attachment 5) before starting. They will receive a copy for their records.

The screeners will be stored in an encrypted online file hosted by Banyan Communications throughout the project's duration. Once the project ends, the screeners will be destroyed. Banyan Communications will retain notes, video files, and any other project-related documents on secure servers; only project staff members will have access to the servers via password-protected computers. Findings will be reported in summary form and participants' names and identifying information will not be included in the findings. Identifiable information is kept separate from focus group data so that participants' responses cannot be linked with their names. All video files will be destroyed at the completion of the project. "CDC will treat data/information in a secure manner and will not disclose, unless otherwise compelled by law."

During the focus group, the moderator will go over key parts of the informed consent during the introduction to the focus group. The moderator will inform participants that the focus group is voluntary, and that they may choose not to answer any question and end participation at any time. The moderator also will inform participants that Banyan Communications will report findings in summary form so that

participants cannot be identified and that their identifiable information will be kept secure and separate from the focus group notes and video recordings. The moderator will inform the participant that there is a notetaker listening and taking notes. The informed consent includes the phone numbers for both Banyan Communications, in case participants have questions about their rights as a participant, as well as the principal investigator, in case participants have questions about the project itself.

11 Justification for Sensitive Questions

This data collection was reviewed by NCEZID's Human Subjects Advisor, and it was not deemed as human subjects' research and given a non-research determination (Attachment 10).

There is a minimal risk that some questions may make respondents feel uncomfortable. There will be potentially sensitive information collected such as race and income. These questions are critical to the project to ensure a demographically diverse sample. Therefore, the team needs to gather data surrounding race, ethnicity, income, etc.

The respondent consent form includes a statement about this risk and informs participants that they may choose not to answer a particular question if they wish and/or end the session at any time without penalty.

12 Estimates of Annualized Burden Hours and Costs

We estimate the total annualized response burden at 80 hours (**Exhibit A.12.1**). For the focus group discussions, every individual will be pre-screened using a 5-minute Eligibility and Demographic Screener. This process will be used to recruit the final focus group participants, not to exceed 32 participants. Those who screen in and agree to participate in the project will participate in a 60-minute focus group; consent activities will be included in the 60 minutes. Timing is based on our previous experience conducting evaluations with this population using these methods to determine the overall burden per respondent.

Type of	Form Name	No. of	Responses	Average	Total
Respondent		Respondents	per	Burden per	Burden
			Respondent	Response	Hours
				(in hours)	
Individual	Eligibility Screener for	420	1	5/60	35
	Focus Group				
	Attachment 1				
	Eligible Participant	80	1	10/60	13
	Screener for Focus Group				
	Attachment 3				
	Focus Group Moderator	32	1	60/60	32
	Guide				
	Attachment 8				
	Total				80

Exhibit A.12.1. Estimated Annualized Burden Hours

The estimates of the annualized cost to respondents for the burden hours for the collection of information is derived from the 2024 mean hourly wage of \$35.46 across all occupations, per the U.S. Department of Labor (DOL) October 2024 (the most up-to-date non-provisional data) National Occupational Employment and Wage Estimates. The total annualized burden cost is estimated at \$2,836.80.

			Average Burden			
		No. of	per			
	No. of	Responses	Response	Total		Total
	Respondent	per	(in	Burden	Hourly	Respondent
Activity	S	Respondent	Hours)	Hours	Wage Rate	Costs
Eligibility	420	1	5/60	35	\$35.46	\$1,241.10
Screener						
Attachment 1						
Eligible	80	1	10/60	13	\$35.46	\$460.98
Participant						
Screener for						
Focus Group						
Attachment 3						
Focus Group	32	1	60/60	32	\$35.46	\$1,134.72
Discussion						
Attachment 8						
Total				80		\$2,836.80

Exhibit A.12.2	Estimated Annualized Bur	den Costs
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13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no costs to respondents other than their time for participation.

14 Annualized Cost to the Federal Government

The contractor's costs are based on estimates provided by the contractor, who will carry out the data collection activities. With the expected period of performance, the annual cost to the federal government is estimated to be \$78,533 (**Exhibit A.14.1**). This is the cost estimated by the contractor, Banyan Communications, and includes the estimated cost of coordination with CDC, data collection, analysis, and reporting.

Expense Type	Expense Explanation	Annual Costs (dollars)				
Direct cost to the federal g	overnment					
CDC oversight of	CDC Project Officer	\$23,703.00				
contractor and project						
	CDC Co-Principal Investigator	\$26,250.00				
Subtotal, Direct Costs to th	Subtotal, Direct Costs to the Government					
Contractor and Other Exp	Contractor and Other Expenses					
Recruitment, data	Labor hours and other direct costs	\$28,580.00				
collection, analysis and						
reporting (contractor)						
Subtotal, contracted services						
Total cost to the governm	Total cost to the government					

Exhibit A.14.1. Estimated Cost to the Government

15 Explanation for Program Changes or Adjustments

Burden Change will be reflected in the overall burden of GENERIC (0920-1154), as this is a genIC information collection.

16 Plans for Tabulation and Publication and Project Time Schedule

During qualitative data collection, the Banyan Communications notetaker will enter data from the focus group discussion into a summary notes template, which will be stored on a password-protected computer. Findings from these summary notes will be put into an analysis matrix, which will also be stored on a password-protected computer. Analysis of the focus group data will start immediately after completion of data collection and will be conducted under the supervision of a senior staff member with extensive experience in qualitative methods. Banyan Communications will conduct rapid analysis of the data to understand information gaps, societal/cultural factors, dissemination channels, and participants' reactions to the materials, in as rigorous and detailed manner as possible. Banyan Communications will summarize results in a final report. The final report will include key data from the online eligibility and demographic screener and report it in descriptive data tables with accompanying narrative in the summary and final reports. **Exhibit 16.1** lists the key events and reports.

Activity	Time Schedule
Begin recruitment	February 28, 2025
Conduct focus groups	Weeks of 3/17, 3/24, 3/31, 4/7 of 2025
Report due	August 30, 2025

Exhibit A.16.1. Project Time Schedule

17 Reason(s) Display of OMB Expiration Date Is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

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