

SUPPORTING STATEMENT

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title

Health Effects of Microbial Pathogens in Recreational Waters; National Epidemiological and Environmental Assessment of Recreational (NEEAR) Water Study (Renewal). EPA ICR Number 2081.04, OMB Control Number 2080-0068.

1(b) Abstract

This study will be conducted, and the information collected, by the Epidemiology and Biomarkers Branch, Human Studies Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency (EPA). Participation of adults and children in this collection of information is strictly voluntary.

This information is being collected as part of a research program consistent with the Section 3(a) (v) (1) of the Beaches Environmental Assessment and Coastal Health Act of 2000 and the strategic plan for EPA's Office of Research and Development (ORD) and EPA's "Action Plan for Beaches and Recreational Water." The Beaches Act and ORD's strategic plan have identified research on effects of microbial pathogens in recreational waters as a high-priority research area with particular emphasis on developing new water quality indicator guidelines for recreational waters. The EPA has broad legislative authority to establish water quality criteria and to conduct research to support these criteria. This data collection is for a series of epidemiological studies to evaluate beach goer exposure and effects of microbial pathogens in marine and fresh (Great Lakes) recreational waters as part of EPA's research program on exposure and health effects of microbial pathogens in recreational waters. The results of these studies will be used to document human health effects associated with recreational water use and correlate these health effects with ongoing EPA studies to identify new water quality indicators of human pathogens in recreational water with appropriate, effective, and expeditious testing methods for these indicators (addressed separately under Section 3(a) (v) (2 & 3) of the Beaches Environmental Assessment and Coastal Health Act of 2000). The epidemiological results will be used to develop mathematical relationships that will generate new national water quality guidelines and appropriate monitoring guidelines.

The beaches will be selected based on the potential number of beach goers, water quality parameters, and potential sources of microbial pathogens in the water. Studies will be conducted at sites impacted by domestic sewage, or non point sources such as runoff or animals. The sampling strategy is either a complete census (*de facto*) at the beach selection site or if beach population too large for a complete census, a representative sub-sample. Households (families/individuals) at selected beaches will be interviewed on the beach about a variety of exposures including those to recreational water (Appendix B). Ten to twelve (10-12) days later, families will be contacted by telephone and interviewed on the occurrence of selected symptomatology since swimming at the beach (Appendix C). In

addition, respondents may be asked to participate in a special study to identify specific microbial pathogens by contributing saliva and or a fingerstick blood sample. Concurrently, recreational waters will be monitored with a selection of water quality indicators developed under a separate EPA research effort. The epidemiologic information will be collected electronically and stored in a computerized database.

The questionnaire health data will be compared with routinely collected water quality measurements. The information collected by this study will be used to estimate the relationship between new water quality indicators and health effects. The analysis will focus on determining whether water quality parameters are associated with increased prevalence of swimming-related health effects.

Each data collection season the survey questionnaire was reviewed by the project team and modified in non-substantial ways to improve design and vocabulary usage. After the survey questionnaire was reviewed and modified by the project team, it was forwarded to the Office of Management and Budget to receive approval. Additionally, questions and modifications received prior approval through the study's designated institutional review board. The changes made to the interview tools are thematically the same as the original questionnaires submitted with the original Information Collection Request (ICR).

2. NEED FOR AND USE OF THE INFORMATION COLLECTION

2(a) Need / Authority for the Collection

The information is being collected as a part of a research program to identify and evaluate beach goer exposure and effects of microbial contaminants of recreational water as part of the U.S. Environmental Protection Agency's research program on exposure and health effects of microbial pathogens in recreational waters. The Beaches Act of 2000 specifically authorizes such studies (Appendix A).

These studies will provide information on the relationship between water quality indicators and health effects associated with recreational exposures. These studies will also provide information on the level of gastrointestinal disease and other related illnesses (skin, ear, eye, urinary tract, and respiratory infections) in adults and children that are associated with marine and fresh water (Great Lakes) recreational exposures.

2(b) Practical Utility/ Users of the Data

The EPA's Office of Research and Development, the Office of Water and the Centers for Disease Control and Prevention will use the information. EPA investigators will present the results of this program in a series of meetings for identified stakeholders, local and state public health officials, and EPA regional scientists. EPA investigators also will present the study results at scientific conferences and will prepare one or more scientific papers for peer-reviewed publications.

These peer-reviewed scientific publications may be used by EPA's Office of Water to develop water quality criteria or guidelines. Every attempt will be made to identify a wide range of marine and fresh (Great Lakes) water beaches so the sites will be as representative as is technically feasible. Information from the studies may be useful to local and state public health officials in the design and implementation of a beach monitoring and closure program.

3. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA.

3(a) Nonduplication

The studies proposed herein do not duplicate any existing information. While we have completed studies at freshwater sites impacted by sewage discharge, the proposed studies will be conducted at different types of beaches. Several other similar studies are being conducted in California but these will not replace the data proposed to be collected here.

3(b) Federal Register Notice

On May 14, 2008 (73 FR 27818) EPA sought comments on this ICR pursuant to 5 CFR 1320.8 (d). EPA received no comments during the comment period. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

3(c) Consultations

The following people have been consulted prior to implementation of study:

Michael Beach, Epidemiologist, CDC, National Center for Infectious Diseases

Abdel el-Shaawari, National Water Research Institute, Canada Center for Inland Waters, Burlington, Canada

David Parkhurst, Indiana University, School of Public and Environmental Affairs, Bloomington, IN

Richard O. Gilbert, Private Consultant, Rockville, MD

Paul Succop, University of Cincinnati, Cincinnati, OH

Public Meetings: The proposed studies have been publicly discussed at the following meetings:

East Coast Regional Beach Conference - October 18-19, 1999

West Coast Regional Beach Conference - August, 1999

Great Lakes Beach Conference - February 5, 2000

The response from these individuals and organizations has been favorable.

3(d) Effects of Less Frequent Data Collection

The questionnaire information may be collected from an individual household once every 28 days. The frequency of the study questionnaire attempts to reduce the amount of information collection without compromising data quality. It is estimated that an individual household will be eligible for the study a maximum of three times in a study season. Because some households visit the beach frequently, their exposure may have different symptomatic effects important to the study analysis. This interviewing strategy allows the data collection of households that visit the beach study site regularly without duplicating illness cycles.

In the pilot study conducted in the summer of 2002, there were a total of two telephone interviews. One interview at 4-7 days after the beach visit followed by another 10-14 days later. The pilot analysis indicated that data from the 10-12 day telephone interview range were most useful for the focus of this study. The first telephone interview was deleted in the survey process after the utility of the information was reviewed by panelists in the 2003 Study Peer Review. The remaining telephone interview time-frame was changed to 10-12 days.

3(e) General Guidelines

We have adhered to all of OMB's general guidelines.

3(f) Confidentiality

We will adhere to all standard steps to maintain confidentiality. These include the exclusion of personal identifiers from the database following completion of the phone interviews and storage of hard copies in locked files. There will be a limited number of paper copies since the interviews will directly entered using electronic interview devices described in Section 5(b) of this document. Contractor involvement will be monitored by requiring hard and/or electronic copies to be stored at EPA after the contractor has completed data processing. The contractor is required to observe the rules of confidentiality regarding the health information provided by individuals and their families. Also, Technical System Reviews are regularly scheduled by the EPA Quality Assurance Officer to ensure compliance by the contractor.

3(g) Sensitive Questions

No questions of a sensitive nature will be required.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents

This study will be conducted among households who are at the selected beaches around the U.S and U.S. territories. Based on previous studies, it is anticipated a maximum of 21,000 households will be enrolled from all sites in a single recreational season.

4(b) Information Requested

(i) Data Items:

Interviewers will ask a single adult member of the household to provide the information listed for all members of the household. The questionnaires can be found in Appendices B and C. The questions are presented in simple format for easy reading. The interviewers are given specific instructions on how to ask each question. The requested information includes questions specific to past illnesses, recreational experience, other risk information and general household characteristics.

(ii) Respondent Activities

The targeted population will be all eligible household groups within an identified beach area. A single respondent, that is an adult member of the household (e.g., mother), will be asked to participate in the study. The respondent member of the family will be given a brochure describing the study's risks and benefits and will be asked for verbal consent to enroll them in the study. The participants will be interviewed on the beach and interviewed via telephone ten to twelve (10-12) days later.

**5. THE INFORMATION COLLECTED -- AGENCY ACTIVITIES, COLLECTION
METHODOLOGY, AND INFORMATION MANAGEMENT**

5(a) Agency Activities

EPA's Epidemiology and Biomarkers Branch and an EPA contractor will be responsible for administering the questionnaire, answering respondent questions, reviewing respondent answers, developing and maintaining the database, analyzing the data and storing and reviewing the data.

5(b) Collection Methodology and Information Management

The initial interview questionnaire that contains household demographics and usual beach activities will be electronically collected using computer-assisted personal interviews (CAPI). The telephone interview that collects illness information about the household ten to twelve (10-12) days later will utilize electronic computer-assisted telephone interviews (CATI).

The water quality measurements will be collected under the same EPA research project in concurrence with the health data collection. The water quality parameters will include measurement of fecal indicators (e.g., enterococci, *E. coli*, chemical indicators) and/or measurement of fecal indicators and/or microbial pathogens with methods that give results in six hours or less. Beach monitoring sites will be selected to support a regulatory program and are located in areas representative of geographic differences and a range of exposures associated with point source fecal contamination of recreational waters. These sites are intended to support an epidemiological study and therefore have been designed to provide sufficient information on the gradient of exposures to fecal contamination found in recreational waters. No additional burden will be placed on the local water pollution agencies in the selected areas.

All data will be reviewed for unusual or unacceptable values. The CAPI/CATI questionnaire data will be verified through the daily data verification programs. Statistical data will be maintained in electronic format using the Statistical Analysis System (SAS). Two back-up data files will be stored separately from data that is used to create the analytical database. These back-up files will contain unedited raw data and will be write-protected. We will control access to the data in accordance with Federal privacy regulations and OMB Circular A-110.

5(c) Impact on Small Businesses or other Small Entities

This study does not have impact on small businesses.

5(d) Collection Schedule

The study has currently completed 5 years of data collection. Listed below are the study sites that have already been completed.

Pilot Study

- West Beach, Indiana Dunes National Lakeshore, Portage, Indiana – 2002

Full-Scale Study – Freshwater

- West Beach, Indiana Dunes National Lakeshore, Portage, Indiana – 2003
- Huntington Beach, Bay Village, Ohio – 2003
- Washington Park, Michigan City, Indiana – 2004
- Silver Beach, St. Joseph, Michigan – 2004

Full-Scale Study – Freshwater

- Edgewater Beach, Biloxi, Mississippi – 2005
- Fairhope Municipal Beach, Fairhope, Alabama – 2007
- Goddard Memorial State Park, West Warwick, Rhode Island – 2007

In future years of this study, we expect to do similar epidemiological studies at additional marine sites or fresh water sites. Water quality samples for measurement, will be collected at the same beaches concurrently with beach interviews. Preliminary data sets will be delivered to the EPA between January and March for each recreational season. These preliminary data sets will be extensively reviewed for quality assurance prior to any analysis.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a). Estimating Respondent Burden

Beach Interview & Telephone Follow-up: Based on consultation with the individuals listed in Section 3(c), and our experience with similar types of information collection, we estimate that each household will spend an average of 30 minutes completing both parts of the beach interview and will require no record keeping. This includes the time for reviewing the information pamphlet and answering the questions. We estimate that each family will spend an average of 15 minutes completing the home telephone interview. The telephone interviews will require no record keeping.

TABLE 1. ESTIMATED ANNUAL RESPONDENT BURDEN

Type of Respondent	Respondent Activities	Estimated Number of Respondents	Burden Hours	Frequency	Annual Reporting Burden	Annual Cost \$ 15.00
Head of household	Beach Interview Part A	21,000	0.25 hr.	1	5,250 hr	\$78,750 †
Head of household	Beach Interview Part B	21,000	0.25 hr.	1	5,250 hr	\$78,750 †
Head of household	Home Telephone Interview	21,000	0.25 hr.	1	5,250 hr	\$78,750 †
Totals					15,750 hr	\$236,250

† \$15.00/hour (median hourly wage for women)

ANNUAL REPORTING BURDEN: 15,750 hours

ANNUAL RESPONDENT COST: \$236,250

NO ANNUAL RECORD KEEPING BURDEN

6(b) Estimating Respondent Costs

Although volunteers were only allowed to participate if they were of legal age to participate in data collection activities (generally 18 years or older), the US Bureau of Labor only had tables for ages 16 years and older for the “Median Weekly Usual Earnings for Full-time and Salaried Workers by Detailed Occupation and Sex, 2006 Annual Wages” readily available for public use, hence, the detail for women 16 and over was used to calculate burden in the below statements.

Beach Interview Part A: Median Weekly earnings for women 16 and over =\$600; available at <http://www.bls.gov/cps/wlf-table18-2007.pdf> at \$15.00 per hour. Given the 0.25 hour burden, the respondent cost for each family is \$3.75.

Beach Interview Part B: Median Weekly earnings for women 16 and over =\$600; available at <http://www.bls.gov/cps/wlf-table18-2007.pdf> at \$15.00 per hour. Given the 0.25 hour burden, the respondent cost for each family is \$3.75.

Home Telephone Interview: Median Weekly earnings for women 16 and over =\$600; available at <http://www.bls.gov/cps/wlf-table18-2007.pdf> at \$15.00 per hour. Given the 0.25 hour burden, the respondent cost for each family is \$3.75.

NO CAPITAL COSTS ARE INVOLVED.

NO O&M COSTS ARE INVOLVED.

6(c) Estimating Agency Burden and Cost

TABLE 2. AGENCY COST ANNUAL BURDEN

AGENCY ACTIVITIES	Burden Hours			Cost (\$)	
	Contractor	EPA	Total Hours	Contractor \$103/hr	EPA \$45.00/hr*
Prepare and format questionnaires	600.00	80.00	680	\$61,800	\$3,600
Prepare computers	6,000.00	8.00	6,008	\$618,000	\$360
Plan logistics & coordination	5,000.00	120.00	5,120	\$515,000	\$5,400
Recruit and interview on beach	30,000.00	0.00	30,000	\$3,090,000	\$0
Telephone interview I	15,000.00	0.00	15,000	\$1,545,000	\$0
IRB package preparation & submission	40.00	50.00	90	\$4,120	\$2,250
Quality Assurance & Quality Control	3,200.00	80.00	3,280	\$329,600	\$3,600
Convert database	7,200.00	0.00	7,200	\$741,600	\$0
Collect/analyze water quality data	9,000.00	0.00	9,000	\$927,000	\$0
			76,378	\$7,832,120	\$15,210

- Average hourly pay for Human Studies Division Health Scientist
http://www.opm.gov/oca/08tables/html/ra_h.asp

AGENCY TOTAL ANNUAL BURDEN: 76,378 hours

AGENCY TOTAL ANNUAL COST: \$7,832,120 +\$15,210 =\$7,847,330

These agency burden estimates were based on our prior experience in developing and gathering information for research purposes. The agency costs have been based on a GS-13(6) for the investigators. The contractor costs are based on a composite cost given the people needed to conduct this study.

6(d) Estimating the Respondent Universe and Total Burden and Cost

Based on current studies conducted in the 2005-2008 and we estimated that the maximum respondent universe for each recreational water season is 21,000 households for the Beach Interview-Part A, 21,000 households for Beach Interview-Part B, and 21,000 for Telephone Follow-up. Thus the total estimated respondent burden for this study is 15,750 hours from 21,000 families and \$236,250.

6(e) Bottom Line Burden Hours and Costs / Burden Tables

The estimated respondent burden for this study is 15,750 hours and \$236,250. The estimated agency cost for conducting this study is 76,378 hours and \$7,847,330.

6(f) Reasons for Change in Burden

Because of increased pressure to expeditiously complete the study, the study team may complete more than two beaches per year, thus increasing the number of participants enrolled in the study annually. In the last renewal information collection request (ICR), the tables in Sections 6(a) and 6(c) reflect the estimated respondent burden and agency burden and cost for 2-3 beaches (1-2 beaches per year). This renewal burden estimate reflects 2-3 beaches per year for the next three years. This change substantially increased the number of respondents expected annually.

The increase in total respondents for the 3-year period is 42,000 (or approximately 14,000 annually.)

6(g) Burden Statement

Beach Interview-Parts A & B: Parental/guardian reporting burden for this collection of information is estimated to average 30 minutes for Parts A and B and will require no record keeping. This includes two 15 minute (.25 hours) responses. This includes the time for reviewing the informational brochure, obtaining verbal consent, and answering the questions.

Telephone Interview Follow-up: The respondent's reporting burden for this collection of information is estimated to average 15 minutes (.25 hours) per family. This includes time for reviewing information collected on the beach interview and answering questions regarding events since the family visited the beach.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average **0.25 hours** per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID No. EPA-HQ-ORD-2004-0023, which is available for public viewing at the Office of Research and Development (ORD) Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Office of Research and Development Docket is (202) 566-1752. An electronic version of the public docket is available through

<http://www.regulations.gov/>. Use <http://www.regulations.gov/> to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID No. (EPA-HQ-ORD-2004-0023) and OMB control number (2080-0068) in any correspondence.

APPENDIX A: Clean Water Act
Beaches Environmental Assessment and Coastal Health Act of 2000
(Public Law 106-284–October 10, 2000)

TITLE 42 - PUBLIC HEALTH

CHAPTER 85 - FEDERAL WATER POLLUTION CONTROL ACT

Section 303. Revisions to water quality criteria

(a) STUDIES CONCERNING PATHOGEN INDICATORS IN COASTAL RECREATION WATERS. - Section 104 of the Federal Water Pollution Control Act (33 U.S.C. 1254) is amended by adding at the end the following:

(v) STUDIES CONCERNING PATHOGEN INDICATORS IN COASTAL RECREATION WATERS. – Not later than 18 months after the date of the enactment of this subsection, after consultation and in cooperation with appropriate Federal, State, tribal, and local officials (including local health officials), the Administrator shall initiate, and, not later than 3 years after the date of the enactment of this subsection, shall complete, in cooperation with the heads of other Federal agencies, studies to provide additional information for use in developing:

- (1) an assessment of potential human health risks resulting from exposure to pathogens in coastal recreation waters, including nongastrointestinal effects;
- (2) appropriate and effective indicators for improving detection in a timely manner in coastal recreation waters of the presence of pathogens that are harmful to human health;
- (3) appropriate, accurate, expeditious, and cost-effective methods (including predictive models) for detecting in a timely manner in coastal recreation waters the presence of pathogens that are harmful to human health; and
- (4) guidance for State application of criteria for pathogens and pathogen indicators to be published under Section 304(a)(9) to account for the diversity of geographic and aquatic conditions.

APPENDIX B: Beach Interview
BEACH INTERVIEW

OMB Control No.: 2080-0068

Expiration Date: xx/xx/xxxx

Site ID _____

Friday _____ Saturday _____ Sunday _____ Monday _____

Date: __-__-__

Time: _____

18 Have you been interviewed by the National Beaches Survey in the last 28 days?

19 Would you be willing to participate in a study on illnesses associated with recreation at the beach?

Yes (give brochure with consent form, inform about 2 follow-up calls)

No (Terminate Interview).

2a. Our survey is primarily for households of one or more persons that live together at the same address; Do you all live at the same address?

20 How many members in your party are at the beach today including yourself?

21 What time did you and your household arrive at the beach today?

22 We are interested in asking about the health of your household during the few weeks following your beach visit. Could you please give me your telephone number so we can get in touch with you in 10-12 days from now?

5a. If "NO" Is it for one of the following reasons? Too busy, no longer interested, will not be available, specify, other reason?

5b. 10-12 days from now which phone number(s) should we call?

5c. Is this your home, vacation, or cell phone number?

5d. Additional phone numbers?

6. What are the best times to reach you during week days?

6a. Can I please have your mailing address so that we can send you your \$25 *Thank you* check? We will destroy your identifying information after we mail the check.

7. Please tell me the first name of the members of your household at the beach today, their birth dates, gender race ethnicity, and whether they are in diapers.
8. Will (you/all these people with you at the beach today) be living (with you) at the same address (es) during the next two weeks?
9. Have any of these household members at the beach today been ill in the past 3 days with:
 - Diarrhea or loose bowels
 - Urinary tract infection or burning sensation
 - Throwing-up or vomiting
 - Sore throat or cough
 - Earache, ear infection or runny ears
 - Eye infection
 - Rash or itchy skin
 - Sunburn
- 23 Are there any household members NOT present at the beach today?
- 10a. Have any household members NOT present at the beach today been ill in the past 3 days with:
 - Diarrhea or loose bowels
 - Urinary tract infection or burning sensation
 - Throwing-up or vomiting
 - Sore throat or cough
 - Earache, ear infection or runny ears
 - Eye infection
 - Rash or itchy skin
 - Sunburn
11. Do you or any household members at the beach today, not including anyone who stayed at home, suffer from any of the following chronic long-term conditions:
 - Gastrointestinal problems such as Crohn's disease or irritable bowel syndrome
 - Chronic respiratory diseases such as asthma or emphysema
 - Allergies, other than drug allergies
 - Skin problems such as psoriasis or eczema
12. How many times do you usually come to this beach each summer (Memorial Day to Labor Day)?
13. How many miles did you travel to the beach today?
14. During the past two weeks, did you (anyone in your household at the beach today) go bathing or swimming anywhere - at this or some other beach, pool or lake?
- 14a. Did you go bathing or swimming anywhere in the past one week (Monday through Friday) at this or some other beach, pool or lake?
- 14b. Did you actually get your head or face wet?

14c. During the past 2 weeks, did you get a sunburn that lasted more than 12 hours?

PART B– Exit Beach Interview

15. Were you the person that we interviewed on the beach or earlier today?

16a. Did you or anyone in your household wade, swim, or play in the water today?

16a1. Did you immerse your body, not necessarily your head, in the water today?

16a2. Did you put your face in the water or submerge your head in the water today?

16a3. Did you get water in the mouth today?

16a4. Did you swallow the water?

16b. Were you in the water at the following times today? {time charts given}

16b1. If “YES” what part of the beach did you swim in? {include all beach areas}

16b2. If “YES” what part of the beach did you swim in most of the time?

16c. What total time did you stay in the water? We are only interested in time actually in the water, not the total time at the beach?

16d. Did you engage in any of the following water-related activities while at the beach today?
{Dropdown list of water activities}

17. What would you estimate your total time in direct sunlight was? This does not include being indoors or under umbrellas, etc.?

18. Did you engage in any of the following activities while at the beach today?

a. Collecting sea shells, rocks, feathers, etc?

b. Digging in sand or building sand castles?

c. Had their body buried in the sand?

18c1. Did person get sand in their mouth

After digging in sand, or building sand castles...did person eat or drink anywhere (not necessarily at the beach)?

After digging in sand, or building sand castles...did person wash their hands before eating? Washing of hands may include the use of personal waterfree hand sanitizer?

18c1b. Was the sand the person dug in or played with dry or wet?

18d. Did you engage in any of the following activities while at the beach today?
Playing with algae or seaweed

- 18d1. Did you get any seaweed in their mouth?
- 18d1a. After playing with algae or seaweed...did you eat or drink anywhere (not necessarily at the beach)?
- 18d1b. After playing with algae or seaweed... did person wash their hands before eating? Washing of hands may include the use of personal water free hand sanitizer?
19. Did you cut yourself today or have an open cut when you came to beach today?
20. Did you wear sunscreen/sunblock today?
21. What was the SPF rating of the sunscreen/sunblock you used most often today?
- 21a. When you used sunscreen/sunblock today, how did you apply it? Only to certain areas of my body? All exposed skin?
- 24 Did you reapply at least once today?
23. Did you wear a hat today?
- 23a. Did the hat have a wide brim or another way to shade face, ears, and back of the neck from the sun?
- 23a1. Did you use protective equipment such as a canopy, umbrella or other type of sunshade today?
- 23b. Did you wear protective clothing, such as a long-sleeved shirt or cover-up?
- 25 During the summer, if you go out in the sun repeatedly without sunscreen or protective clothing, which one of these things most usually happens to your skin?
- A dark tan
 - Some tanning
 - No tan, maybe some freckles
 - Repeated sunburns
 - Other (specify)
 - Never go out in the sun
- 26 Did you wear insect repellent today?
- 27 Did your or any member of your household consume food while at the beach today?
- 26a. Was the food brought from home?
- 26b. Was the food purchased from vending machines or a vendor at the beach?
- 26c. Was the food purchased from a vendor outside the beach?

- 28 Did you or any member of your household consume drinks while at the beach today?
- 27a. Were the drinks brought from home?
- 27b. Were the drinks purchased from vending machines or a vendor at the beach?
- 27c. Were the drinks purchased from a vendor outside the beach?
- 28. In the past 48 hours has anyone who is at the beach today done the following...
- 29 Have you come in contact with any unknown animals?
- 30 Come in contact with someone who has complained of diarrhea, vomiting, or stomach illness?
- 31 Consumed raw shellfish?
- 32 Consumed rare/raw meat?
- 33 Consumed runny or raw eggs?

APPENDIX C: Telephone Interview

Telephone Interview - follow-up (10-12 days)

Is this person (primary respondent from beach interview)?

Yes (continue)

No (reschedule or continue)

Were you at the beach on (give date) with (primary respondent)?

Yes - Continue

I'm going to ask questions about any swimming you've done and illnesses you've experienced in the last week for the following people:

A1. May I have your first name please?

During your beach visit where you enrolled in this study on _____

A2. Did you wear ear plugs while in the water? Ask for all household members at the beach.

A3. Did you wear nose plugs while in the water? Ask for all household members at the beach.

A4. Did you wear eye goggles while in the water? Ask for all household members at the beach.

A5. During the beach interview, did you have contact with an animal? Ask for all household members at the beach.

A6. Between your beach visit on _____ date and today were you menstruating or pregnant? Ask for all household members at the beach.

We are now going to switch and ask you questions about activities that have occurred since the Beach Interview.

B1. Have you, or any of the people I just mentioned, gone bathing or swimming anywhere since we talked to you at the beach interview on _____? Please include any bathing or swimming such as at a beach, waterpark, public pool, private pool, or wading pool.

B2. Who was it that went bathing or swimming? Ask for all household members at the beach.

B3a. Did you go bathing or swimming at the beach (where the interview was taken) since the beach interview on this date {BEACH INTERVIEW DATE}.

B3b. Did you go bathing or swimming at any other beach since the beach interview on this date {BEACH INTERVIEW DATE}.

B3c. Was this beach at a:

Lake

River

Ocean

Other, specify

B3d. Did you go bathing or swimming at a waterpark?

B3e. Did you go bathing or swimming at a public pool?

B3f. Did you go bathing or swimming at a private pool?

B3g. Did you go bathing or swimming in a wading pool?

B3h. Did you go bathing or swimming any other place?

- B3i. Swim location of any other place?
- B4. Did you actually get your face wet while bathing or swimming? Ask for all household members at the beach.
- B5. On which days did you go bathing or swimming? Ask for all household members at the beach.
- B6. Have you or anyone else had a stomachache or abdominal cramping since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B6a. Who had a stomachache or abdominal cramping since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B7. Have you or anyone else had diarrhea or loose bowels since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B7a. Who had diarrhea or loose bowels since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B8. Have you or anyone else had nausea since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B8a. Who had nausea since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B9. Have you or anyone else had throwing-up or vomiting since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

- B9a. Who had throwing-up or vomiting since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B10. Have you or anyone else had urinary tract infection or burning sensation when urinating since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B10a. Who had urinary tract infection or burning sensation when urinating since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B11. Have you or anyone else had fever since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B11a. Who had fever since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B12. Have you or anyone else had headache lasting more than a few hours since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B12a. Who had headache lasting more than a few hours since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B13. Have you or anyone else had sore throat since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B13a. Who had sore throat since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

- B14. Have you or anyone else had a bad cough since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B14a. Who had a bad cough since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B15. Have you or anyone else had a cold since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B15a. Who had a cold since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B16. Have you or anyone else had a runny or stuffy nose since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B16a. Who had a runny or stuffy nose since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B17. Have you or anyone else had an earache, ear infection, or runny ears since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B17a. Who had an earache, ear infection, or runny ears since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B18. Have you or anyone else had watery eyes since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.
- B18a. Who had watery eyes since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B19. Have you or anyone else had an eye infection since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B19a. Who had an eye infection since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B20. Have you or anyone else had an infected cut since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B20a. Who had an infected cut since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B21. Have you or anyone else had a rash or itchy skin since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B21a. Who had a rash or itchy skin since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B22. Have you or anyone else had a sunburn since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B22a. Who had a sunburn since the interview at {STUDY BEACH} ON {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

We will now ask about some activities people may have done since the day of the beach interview on the {BEACH INTERVIEW DATE}

B23a. Since the day of the beach interview, have you or anyone else come in contact with any animals? Ask for all household members at the beach.

B23b. Who came into contact with animals since {BEACH INTERVIEW DATE}? Ask for all household members at the beach.

B23c. Was this animal or any of these animals unfamiliar to you?

B23d. What kind of animals were they?

B24a. Since the day of the beach interview has anyone come into contact with someone who has complained of diarrhea, vomiting, or stomach illness?

B24b. Who had contact with someone complaining of diarrhea, vomiting, or stomach illness since {BEACH INTERVIEW DATE}?

B25a. Since the day of the beach interview has anyone eaten raw shell fish, such as oysters, clams, mussels, crabs?

B25b. Who has eaten raw shell fish, such as oysters, clams, mussels, crabs since {BEACH INTERVIEW DATE}?

B26a. Since the day of the beach interview has anyone rare or raw meat?

B26b. Who has eaten rare or raw meat since {BEACH INTERVIEW DATE}?

B27a. Since the day of the beach interview has anyone eaten raw or runny eggs?

B27b. Who has eaten raw or runny eggs since {BEACH INTERVIEW DATE}?

SECTION C

This section is for all persons that experience symptoms.

C1. On what day did your stomachache or abdominal cramping start?

C1a. Do you still have a stomachache or abdominal cramping?

- C1b. (For persons that still have symptom) For how many days did you have a stomachache or abdominal cramping?
- C2. On what day did your diarrhea or loose bowels start?
- C2a. Do you still have a diarrhea or loose bowels cramping?
- C2b. For how many days did you have a diarrhea or loose bowels cramping?
- C2c. What was the maximum number of bouts or episodes of diarrhea experienced in a 24-hour period? Ask for each person with symptom.
- C3. On what day did your nausea start?
- C3a. Do you still have nausea?
- C3b. For how many days did you have nausea?
- C4. On what day did your throwing-up or vomiting start?
- C4a. Do you still have throwing-up or vomiting?
- C4b. For how many days did you have throwing-up or vomiting?
- C4c. What was the maximum number of bouts or episodes of throwing-up or vomiting experienced in a 24-hour period? Ask for each person with symptom.
- C5. On what day did your urinary tract infection or burning sensation start?
- C5a. Do you still have a urinary tract infection or burning sensation?

- C5b. For how many days did you have urinary tract infection or burning sensation?
- C6. On what day did your fever start?
- C6a. Do you still have a fever?
- C6b. For how many days did you have a fever?
- C6c. Was your temperature taken using a thermometer?
- C6d. What is the highest temperature that you had since your beach interview on {BEACH INTERVIEW DATE}?
- C7. On what day did your headache start?
- C7a. Do you still have a headache?
- C7b. For how many days did you have headache?
- C8. On what day did your sore throat start?
- C8a. Do you still have a sore throat?
- C8b. (For persons that still have symptom) For how many days did you have sore throat?
- C8c. (For persons that still have symptom) Was this sore throat related to allergies?
- C9. On what day did your bad cough start?
- C9a. Do you still have a bad cough?
- C9b. For how many days did you have a bad cough?

C9c. Was this bad cough related to allergies?

C10. On what day did your cold start?

C10a. Do you still have a cold?

C10b. For how many days did you have a cold?

C10c. Was this cold related to allergies?

C11. On what day did your runny or stuffy nose start?

C11a. Do you still have a runny or stuffy nose?

C11b. For how many days did you have a runny or stuffy nose?

C11c. Was this runny or stuffy nose related to allergies?

C12. On what day did your earache, ear infection or runny ears start?

C12a. Do you still have an earache, ear infection or runny ears?

C12b. For how many days did you have an earache, ear infection or runny ears?

C12c. Was this earache, ear infection or runny ears related to allergies?

C13. On what day did your watery eyes start?

C13a. Do you still have watery eyes?

C13b. For how many days did you have watery eyes?

C13c. Was this watery eyes related to allergies?

C14. On what day did your eye infection start?

C14a. Do you still have eye infection?

C14b. For how many days did you have eye infection?

C15. On what day did your cut first get infected?

C15a. Do you still have an infected cut?

C15b. For how many days did you have an infected cut?

C15c. Where were you cut? Mark all that apply

C16. On what day did your rash, itchy skin, or skin infection start?

C16a. Do you still have a rash, itchy skin, or skin infection?

C16b. For how many days did you have a rash, itchy skin, or skin infection?

C16c. Where did you have a rash, itchy skin, or skin infection? Mark all that apply

C17. On which parts of the body were you sunburned? Mark all that apply

Drop down list

SECTION D

Ask only once for each person reporting symptoms

- D1. When your condition began, were you working for pay either inside or outside the home?
Please include jobs for which you were self-employed.
- D2. During your illness, did you miss any time from work, for example because you called in sick or took time off to see a doctor?
- D3. How many days?
- D4. Did this illness prevent you from performing daily activities such as school, recreation, or vacation activities, or work around the home?
- D5. How many days?
- D6. Did this illness cause other household members to lose time at work?
- D7. How many days?
- D8a. Did you consult a healthcare provider over the phone about this illness/condition?
- D8b. Did you visit a healthcare provider?
- D8c. How many times?
- D8d. What illness did the healthcare provider say you had?
- D8e. Did you visit an emergency room?
- D8f. How many times?
- D8g. Were you admitted to a hospital?
- D8h. How many days were you hospitalized?

D8i. Were you given intravenous fluids?

D9a. Did you receive a prescription for an antibiotic or other drug for this illness/condition?

D9b. About how much of your own or your household's money was spent altogether for these prescription medicines? Amount to nearest dollar.

D10a. Did you use any over-the-counter medications, including things like special drinks, only because of this illness/condition?

D10b. About how much of your own or your household's money was spent altogether for these over-the-counter medications? Amount to nearest dollar.

SECTION E

E1. Before today, were you aware that people could become ill by swimming at the beach?

E2. After today, will you change the way you use the water at the beach?

SECTION Q

These are questions from beach interview to ensure data collection for important exposures. Ask for all households.

Q1. Did you or anyone in your household wade, swim, or play in the water on {BEACH INTERVIEW DATE}?

Q1a.1. Did you immerse your body, not necessarily your head in the water {BEACH INTERVIEW DATE}?

Q1a.2. Did you put your face in the water or submerge head in the water on {BEACH INTERVIEW DATE}?

Q1a.3. Did you get water in your mouth on {BEACH INTERVIEW DATE}?

Q1a.4. Did you gag or cough after getting water in your mouth on {BEACH INTERVIEW DATE}?

Q1a.5. Did you swallow the water on {BEACH INTERVIEW DATE}?

APPENDIX D

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