

Request for Approval under the “Generic Clearance for Citizen Science and Crowdsourcing Projects” (OMB Control Number: 2080-0083)

TITLE OF INFORMATION COLLECTION: Using Citizen Science to Improve Drinking Water Epidemiology Studies

PURPOSE: This project showcases the simplicity of an innovative saliva test and improves the way epidemiology studies are designed using citizen science. Families with school age children will report incidences of gastrointestinal disease to school nurses and/or science teachers to facilitate follow-up stool and saliva tests in impacted school districts. The project will allow citizens to investigate the incidence and type of gastrointestinal illness in rural communities in Puerto Rico without municipal (PRASA) drinking water treatment plants. This will better characterize and inform public health concerns related to drinking water treatment processes.

NEED AND AUTHORITY FOR COLLECTION: InterAmerican University received an Institutional Review Board (IRB) for Protection of Human Subjects in Research on January 26, 2018. On April 5, 2018 this project received approval from EPA’s Human Subjects Research Review Office for use of Human Subjects Research according to the requirements of EPA Order 1000.17 Change A1 (Policy and Procedures on Protection of Human Research Subjects) and can confirm that this study complies with EPA Regulation 40 CFR 26 (Protection of Human Subjects).

USES OF RESULTING DATA: The resulting data may provide a direct link between community health and drinking water treatment using citizen science in underserved communities in rural Puerto Rico.

DATA COLLECTION METHODS: School nurses, science teachers, and/or volunteers from InterAmerican University will recruit and enroll local families with at least one child in the 4th to 6th grade. An adult family member or guardian will complete one baseline survey to gather limited demographic data and information about risks related to waterborne illness (*i.e.* water usage and sanitation). At approximately one-month intervals, for a total of 3 months, an adult family member or guardian will complete a health survey on symptoms experienced by the child participant. Completed surveys will be returned to school nurses and science teachers by the child participant or family member. Study staff from InterAmerican University will collect surveys from schools.

PARTICIPANT UNIVERSE:

| Category of Respondent | No. of Respondents | Number of responses per respondent | Participation Time per response | Burden Hours |
|------------------------|--------------------|------------------------------------|---------------------------------|------------------|
| Family members | 500 | 4 (1 baseline + 3 health surveys) | 15 minutes | 500 hours |
| Totals | 500 | 4 | 15 minutes | 500 hours |

AGENCY COST: The estimated annual cost to the Federal government is \$70,000 for project design and implementation and \$30,000 in sampling supplies over 2 years.

STATISTICAL ANALYSIS:

The objective of statistical analysis is to assess and compare associations between water quality and infections with specific potentially waterborne pathogens. Anticipated survey results will satisfy the survey objectives.

Two approaches to statistical analysis of assay data will be used. For acute infections which have a relatively short incubation period and produce short-term immunity, such as noroviruses, *Campylobacter*

spp. and *Cryptosporidium spp.*, immunoconversion will be used as an indicator of incident infection as described previously (Griffin et al., 2015). Immunoconversion will be defined as at least four-fold increase in salivary antibody response between consecutive samples. Additional criteria may be used to improve the specificity of the immunoconversion tests, such as age-specific cut-off values derived from regressing antibody data on age using penalized splines as described previously (Egorov et al., 2010), and at least three-fold increase in third sample (S3, collected 2 months after baseline) compared to baseline (S1) sample (Wade et al., manuscript in review). For chronic infections, *H. pylori* and *T. gondii*, analysis will focus on identifying chronically infected individuals.

Analysis of associations between water quality and acute infections will be conducted using logistic regression models. Analysis will be repeated for asymptomatic infections (immunoconversion, no symptoms) and symptomatic infections (immunoconversion with symptoms). For chronic infections, demographic, socioeconomic and behavioral risk factors for infections will be explored. In addition, potential impacts of chronic infections on antibody responses to incident acute infections will be explored.

DATA QUALITY ASSESSMENT PROCEDURES:

All samples from the same individual will be assayed at the same time to minimize assay variability. Samples from at least 20% of study participants will be assayed in duplicate. Controls (human samples positive to pathogens included in this study) as well as negative controls (blanks) will be assayed on each 96 well microplate. All analytical errors, such as insufficient number of Luminex beads (less than 50 beads of each type) acquired by the Luminex device, will be documented. All samples associated with errors as well as all other samples from the same individuals will be re-analyzed on a new plate. Plates with unusually high antibody responses to controls (GST or total IgG) will be identified using analysis of distributions of plate-specific responses at the end of the study. Plates with antibody responses to internal control antigens above the mean plus two standard deviations (outliers) will be re-analyzed.

ADMINISTRATION OF THE INSTRUMENT: (Check all that apply)

Web-based or Social Media Mail
 Telephone Other, Explain
 In-person

INSTRUMENT: Append a copy of the questionnaire or a screen shot of the website or app that includes the information collection.

CONTACT NAME: Craig Patterson **EMAIL:** patterson.craig@epa.gov

REFERENCES:

Egorov, A.I., T.L.M. Montouri, L. Ascolillo, H.D. Ward, D.A. Levy, R.D. Morris, E.N. Naumova, J.K. Griffiths. 2010. Recent diarrhea is associated with elevated salivary IgG responses to *Cryptosporidium* in residents of an eastern Massachusetts community. *Infect.*, 38(2): 117-23.
Griffin, S.M., R.R. Converse, J.S. Leon, T.J. Wade, X. Jiang, C.L. Moe, A.I. Egorov. 2015. Application of salivary antibody immunoassays for the detection of incident infections with Norwalk virus in a group of volunteers. *J. Immunol. Methods*, 424: 53-63.
Wade, T.J., S.A.J. Augustine, S.M. Griffin, E.A. Sams, K.H. Oshima, A.I. Egorov, A.P. Dufour. 2017. Asymptomatic norovirus infection associated with swimming at a tropical beach. *PLOS ONE*, submitted.

ID# _____
(home / survey number)

Self-Report Health Questionnaire & Risk Factor Survey

Complete one per student

Name of Interviewer: _____

Date of Interview: _____

Place of Interview: _____

Name of Interviewee: _____

Home Address: _____

Interviewee's information

1. Age: _____
2. Sex: 1- Male 2- Female



Household information

3. How many people live in the house? _____

Please complete the following table for each person that lives at this address:

| Name | Relation to the Head of the Household | Age | Sex | Occupation/Student |
|------|---------------------------------------|-----|-----|--------------------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

ID# _____
(home / survey number)

1. What is the occupation of the head of the household?
2. What is the highest educational degree achieved?

No School Elementary or Less Middle School
 High School University Post Graduate

3. How long has your family lived at this location?

- a. If less than 10 years, where did you move from? (address)

4. How many bedrooms are there in the house?

5. Do you own the house?

Yes No, the home is rented
 Living with friends Living with family
 Other (explain) _____

Water usage

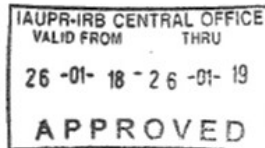
6. How often do you drink from the tap without boiling the water?

Always Most of the time
 Sometimes Never

7. Do you treat the water before drinking it? Yes No

- a. If yes, please explain how.

with filter by boiling
 with chlorine other method



ID# _____
(home / survey number)

8. Do you have any problems with your drinking water? Yes No

If yes, which of the following happened?

- bad odor bad taste
 cloudy color
 other (explain) _____

9. Do you drink water at school? Yes No

If yes, which?

- drinking fountain bottled water
 tap water other

10. Do you drink water from other sources? Yes No

If yes, which?

- bottled water river water
 rain water other

Sanitation

11. Does your home have access to any of the following?

- toilet discharging into a sewage system toilet discharging into a septic tank
 latrine toilet discharging into a river or land
 other (explain) _____

12. If you have septic tank, how often is emptied?

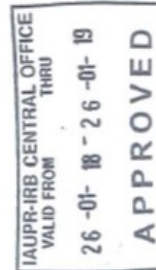
- never once a year or less
 more than once a year

13. Are there problems with your septic tank? Yes No

- leaks bad odor
 other (explain) _____

14. Do you own any of these pets or farm animals?

- dogs cats pigs
 chickens ducks cows



ID# _____ (home / survey number)

Daily Report Card Study ID Number _____

Participant: _____

First Name _____

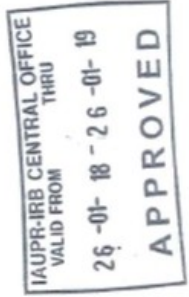
Last Name _____

Date: / /

Please note any symptoms experienced during trips you made for each day of the week.

| Day | Had any symptoms? | | | | | | | | | | Were you traveling? | | | | |
|-----------|-------------------|---|----|-------------------|---|-------------------------|-------------------------------|---|-----------------------|----------|---------------------|--|-------------|-------------------------|----------------|
| | Diarrhea | | | Diarrhea w/ blood | | Vomiting (feeling sick) | Stomach ache/pain or cramping | | Nausea (feeling sick) | Headache | Fever or chills | Cough, nasal congestion, sore throat, or infection | No symptoms | Abroad (outside the US) | Did not travel |
| Monday | 1 | 2 | 3+ | 1 | 2 | 3+ | 1 | 2 | 3+ | | | | | | |
| Tuesday | | | | | | | | | | | | | | | |
| Wednesday | | | | | | | | | | | | | | | |
| Thursday | | | | | | | | | | | | | | | |
| Friday | | | | | | | | | | | | | | | |
| Saturday | | | | | | | | | | | | | | | |
| Sunday | | | | | | | | | | | | | | | |

If you experience diarrhea or vomiting this week, please complete questions 1 through 12 of the Extended Daily Record



ID# _____
(home / survey number)

| Comprehensive report card | | Study ID number | |
|--|--|---|--|
| Participant: First Name _____ Last Name _____ | | Date | Month Year |
| Please note if you experienced vomiting or diarrhea during the week, before completing this questionnaire. | | | |
| As a result of the symptoms listed on the daily report card | | No | Yes |
| 1. Did you visit the doctor? | | | |
| 2. Have you contacted a doctor in another manner? | | | |
| 3. Did you consult with a nurse or a doctor? | | | |
| 4. Did you call a 24-hour medical care facility (Urgent Care)? | | | |
| 5. Did you go to the Health Services Center? | | | |
| 6. Did you go to an Emergency Room? | | | |
| 7. Were you hospitalized for this condition? | | | |
| a. How many days did you spend? | | | |
| 8. Were you hospitalized during the night? | | | |
| 9. Was a stool sample taken? | | | |
| a. What were the results of the analysis? | | | |
| 10. Did you take any medication for the symptoms? | | | |
| a. <input type="checkbox"/> over the counter <input type="checkbox"/> with prescription | | | |
| b. What was the name of the medicine? | | | |
| 11. Are you taking any antibiotic medications? | | | |
| 12. Are you taking probiotic supplements or eating probiotic foods prepared by bacterial fermentation like yogurt? | | | |
| 13. Do you suffer from chronic disease (lasting > 6 months)? | | | |
| 14. Do these symptoms require that a family member miss work or attend school? | | | |
| a. Total days of work missed due to symptoms | | | |
| b. Total days of school missed due to symptoms | | | |
| | | What do you think caused the disease? Please mark one box below | |
| | | <input type="checkbox"/> | Medicine (i.e. antibiotic, steroids) |
| | | <input type="checkbox"/> | Person to person contact (transmission) |
| | | <input type="checkbox"/> | Alcohol |
| | | <input type="checkbox"/> | Food Poisoning |
| | | <input type="checkbox"/> | Drinking water at the house |
| | | <input type="checkbox"/> | Contact with water or consumed from another location |
| | | <input type="checkbox"/> | Pregnancy or Menstruation |
| | | <input type="checkbox"/> | Contact with Animals |
| | | <input type="checkbox"/> | Chemotherapy or Radiation |
| | | <input type="checkbox"/> | Recent stomach or intestinal surgery |
| | | <input type="checkbox"/> | Intestinal Disorder |
| | | <input type="checkbox"/> | Unknown Infection |
| | | <input type="checkbox"/> | Other (Explain) |
| | | <input type="checkbox"/> | Unknown |

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APPROVED

ID# _____
(home / survey number)

Consent Form

If you want to be part of the health study, please print your name and **school name** and then sign and date in the boxes shown below. Parents or guardians must sign on behalf of children under the age of twelve (12). If you are under 21 years of age, please sign the document and have your parent or guardian sign the document as a witness to your signature. If you (or a family member or friend) would like more information about this study, please do not hesitate to contact Graciela Ramirez Toro at 787-264-1912 ext. 7630, 7631.

I confirm that I read the information sheet on this study and I have the opportunity to ask questions. I agree to take part in the health study.

| Name of Student Participant | Signature | Date | School Name |
|--|-----------|------|-------------|
| | X _____ | | |
| Name of Student Participant's Parent (If student is less than 21 years old) | Signature | Date | |
| | X _____ | | |

