

GTEN AMR Study

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Following are the key steps and procedures involved in participating in the GTEN AMR study:

1. **IRB:** Each participating site needs to obtain institutional IRB approval.
 - a) We will send a packet of IRB documents to you, which you may use as a template for preparing your IRB submission. This packet includes:
 - Detailed protocol
 - Protocol summary
 - Consent form
 - Assent form
 - Questionnaires
 - Enrollment
 - Traveler
 - Symptom
 - Household contact day 90
 - Household contact days 180 and 360
 - Fact sheet
 - Medical alert card
 - Recruitment documents
 - Sample collection instructions
 - MGH IRB approval letter
 - b) Once your IRB has approved the study, please send your documents and approval letter to Elizabeth.
2. **Reporting protocols:** Each site is responsible for reporting AMR organisms to the necessary agencies, including:
 - a) Department of Public Health (level of agency determined by site)
 - b) Hospital/institutional Infection control
 - c) Primary care physician (if desired by site)
 - We will assist you with communicating with your local Department of Public Health. The line of communication should ideally be established prior to enrolling subjects (i.e. agencies should be aware of plan). We will notify you by secure email when subjects from your site have positive results, so you can inform the appropriate agencies.
3. **Supplies:**
 - a) You will receive 10 stool collection enrollment kits from Elizabeth at MGH. The kits will be mostly assembled when you receive them. There will be instructions on how to complete assembly. Notify Elizabeth when you start to run low, so additional kits can be assembled and mailed.
 - b) You will receive a DYMO label printer and labels for printing subject vial labels. Notify Elizabeth when you have one roll of labels remaining, so she can send you more.

4. Enrollment:

a) *Guidelines for enrollment:* these are guidelines, not hard-set rules. Use your discretion.

- Subject should be traveling no longer than 6 months.
- Subject should visit no more than 8 countries.
- Subject should be departing within 6 months.

b) *Identifier:*

The 6-digit GTEN confirmation number will be the subject identifier for the study. The subject should bring that number with them to the visit and can provide it to you. This is the number you will use to create the record in the database.

c) *Vial labels:*

- Labels should include the following information: GTEN#_D#_site ID (example: 123456_D0_BL).

D# = day number

D0 = day 0 or before travel

D14 = day 14 or after travel

UT = Utah

BL = Bronx-Lebanon

You will be provided with a site ID to use.

You will create and apply the labels to the vials at the time of enrollment. You will be provided with a label printer and labels.



The image shows a screenshot of a vial label form. It is a rectangular box with rounded corners and a light gray border. Inside the box, there are three lines of text, each followed by a colon and a blank space for input. The first line is "ID#:123456_D0_BL", the second is "Date:", and the third is "Time:". The text is in a black, sans-serif font.

5. Documentation:

- 1) We use REDCap to document all study data. REDCap is a secure web application for managing online surveys and databases. You will be granted access to REDCap once you receive IRB approval and are ready to start enrolling. You will receive an email to get started with the program. Within REDCap you will have access to four instruments, the Subject Intake form, the Enrollment Questionnaire, the D0 USPS tracking form and the D14 USPS tracking form.
 - *Subject Intake Form:* Captures subject identifying information including name, DOB, MRN, gender, phone number, mailing address, email address, departure and return dates. Only enter the email address if the subject prefers to be contacted by email. **If it is entered, they will automatically receive emails.** There is also a checkbox to document that the subject has been provided with a copy of the signed consent. The dates at the bottom of the form will automatically populate once you save the form.
 - *Enrollment Questionnaire:* Captures age, gender and a brief travel/medical history. Age and gender will auto-populate from the information entered in the Subject Intake Form.
 - *USPS Tracking Forms:* You will find the tracking number on the bottom of the postage on the shipper box. It is a 22-digit number and you will need to enter it into the two USPS tracking forms.
- 2) Once all data has been entered, mark it complete and save.
- 3) See screenshots below:

Subject Intake

Assign record to a Data Access Group? -- sel

Save & Exit Form
Save & Stay
-- Cancel --

Adding new GTEN ID [REDACTED]

Event Name: **Intake**

GTEN ID [REDACTED]

Enrollment Date M-D-Y H:M

GTEN Site
 MGH
 Bronx
 Utah

First Name

Last Name

Date of Birth M-D-Y

MRN

Gender
 Male
 Female

Phone Number

Address

City

State

Zip Code

County

E-mail address

Enrollment Questionnaire

Data Access Group: [No

Save & Stay
-- Cancel --

Editing existing GTEN ID [REDACTED]

Event Name: **Intake**

GTEN ID [REDACTED]

Participant Information

Participant Gender

Participant Age

Travel and Brief Medical History

Have you traveled outside of the U.S. in the last year?
 Yes
 No

Do you live with someone that has traveled outside the U.S. in the last year?
 Yes
 No

Have you taken any antibiotics in the last year?
 Yes
 No

Have you been hospitalized in the past year?
 Yes
 No

Have you had contact with farm or riding animals in the last year?
 Yes
 No

Do you have pet animal(s)?
 Yes
 No

Which of the following types of animal products do you normally
 Dairy (cheese, milk, yogurt, etc.)
 Poultry (chicken, turkey, quail, duck, etc.)
 Beef (steak, meatballs, beef hamburgers, veal, etc.)
 Pork (ham, pork chops, pork ribs, etc.)

USPS Tracking Info

Assign record to a Data Access Group? -- select a group --

Adding new GTEN ID 123456

Event Name: **Before Trip (D0)**

GTEN ID 123456

Patient ID 123456

First Tracking Number

Form Status

Complete? Incomplete

Save & Exit Form Save & Stay

-- Cancel --

Form Status

Complete? Complete

Save & Exit Form Save & Stay

-- Cancel --



d) Enrollment “script”:

You do not need to follow this verbatim. It is just an example and includes the most important details that subjects should be aware of before deciding to enroll.

We are evaluating the risk of acquiring antibiotic resistant bacteria in the intestine after international travel. People that are otherwise healthy do not get actively sick from these organisms. They become what we call asymptotically colonized. This means the bacteria is present in the gut but doesn’t make you sick. We are looking to find out who picks these organisms up, where, how long they stay in the gut, whether they spread to household contacts after return and whether colonized people get sick. If you would like to enroll, I will send you home today with a kit containing all the supplies you need to collect and mail us a stool sample before you leave, as a baseline. We will ask that you send another sample shortly after you return. We will also call or email you at that time to conduct a brief questionnaire about any potential exposures you may have had and your health during your trip. If both of your samples are negative, then your enrollment is complete at that point. If either of your samples are positive, we will follow you for one year after your return date. During that year, we will ask you to complete a brief monthly questionnaire by phone or email and to submit three additional stool samples at 3, 6 and 12 months from your return date. We will mail you the supplies you will need to do that. This is a surveillance only study. There are no interventions and no study visits. Does this sound like something you might be interested in doing?

If yes:

We are funded by the CDC and are working with the Broad (pronounced “brode”) Institute of Harvard and MIT associated with MGH. They will perform a genetic analysis of the bacteria in the stool. Because these organisms are relatively rare in the U.S. and of public health concern, we are also required to follow routine reporting protocols. If we identify one of the organisms we are looking for in your stool, we report it to your local department of public health. We are also required to notify infection control at the hospital. They will make a notation in your medical record that

indicates you are colonized. That way, if you are ever admitted to the hospital or come in for a procedure your care team will be alerted and can take the necessary precautions to prevent spreading the bacteria to others. If you are sick from the bacteria (though this is unlikely), they will be better able to make antibiotic choices for you. We are also compensating with a \$15.00 Amazon gift card for each sample you send to us. The minimum you will receive is two and the maximum is five.

e) Study schedule:

- Subject can mail the pre-travel sample any time before departure.
- Subject will receive a reminder call or email (based on preference) two weeks before departure date if sample has not yet been received.
- Subject will receive call or email (based on preference) two days after returning. They will complete the traveler questionnaire at that time and receive a reminder to mail their D14 sample.
- Finalized results can take anywhere from 4 days to 3 months (at maximum). Subject will be notified of negative results by letter and positive results by phone.
- If AMR organism is identified, subject will be asked to complete a symptom questionnaire (by phone or email) every month and to submit three additional stool samples (kits will be mailed to them). Samples to be shipped 90, 180 and 360 days after return date. Subject will receive reminder to mail sample when due.

6. Follow up:

- a) MGH staff will perform all follow up with subjects after enrollment. No follow up will be required by external sites except:
 - Reporting (DPH, Infection Control, PCP)
 - Occasionally, an unexpected organism will be identified. Subject will need to be contacted by site and referred to care if needed.
- b) MGH staff will:
 - send compensation after sample is received by MGH lab.
 - notify subjects of sample results.
 - ask if household contacts are interested in enrolling and send kits for future samples.
 - send a medical alert card to the subject so they can provide information about their colonization status to their healthcare providers.
 - conduct questionnaires and remind subjects to mail samples when they are due.

7. Household contacts:

If a subject is found to be colonized, we will ask if they have household contacts interested in submitting samples on the same schedule as the subject. We will provide interested subjects with a letter describing the study that they can share with their household contacts. Household contacts will complete an anonymous questionnaire and submit it with each sample. We will not collect any identifying information from them. Mailing their samples implies consent. They will receive compensation when samples are received by MGH lab.