

Patient-Centered Stomach Cancer Prevention in Chinese Americans: Biosample Substudy

July 2021

Study Background

- Gastric cancer is usually incurable when diagnosed at an advanced stage. About four out of five stomach cancers in the United States are diagnosed after the cancer has spread to other areas of the body, with the five-year survival rate at 4 percent.
- Since there is no standard or routine screening test for gastric cancer in the US, it is therefore critical to develop novel biomarkers to improve prevention, risk assessment and early detection among Chinese Americans.
- Biomarkers are characteristics of the body you can accurately measure – eg. blood pressure, heart rate.
 - Can take place at the cellular or molecular level

Substudy Objective

- Assess the feasibility and response rate for the collection of biosamples among Chinese Americans with a clinically confirmed diagnosis of *H. pylori*.
- Biosamples (fecal and/or oral) will be used to assess differences in oral and gut microbiome environments before and after *H. pylori* medication, and help to develop biomarkers.
- Achieved through the **optional** collection of oral and/or fecal biosamples from participants in the Stomach Cancer Prevention study.

Study Information

Eligibility Criteria

- Enrolled in Stomach Cancer Prevention Study

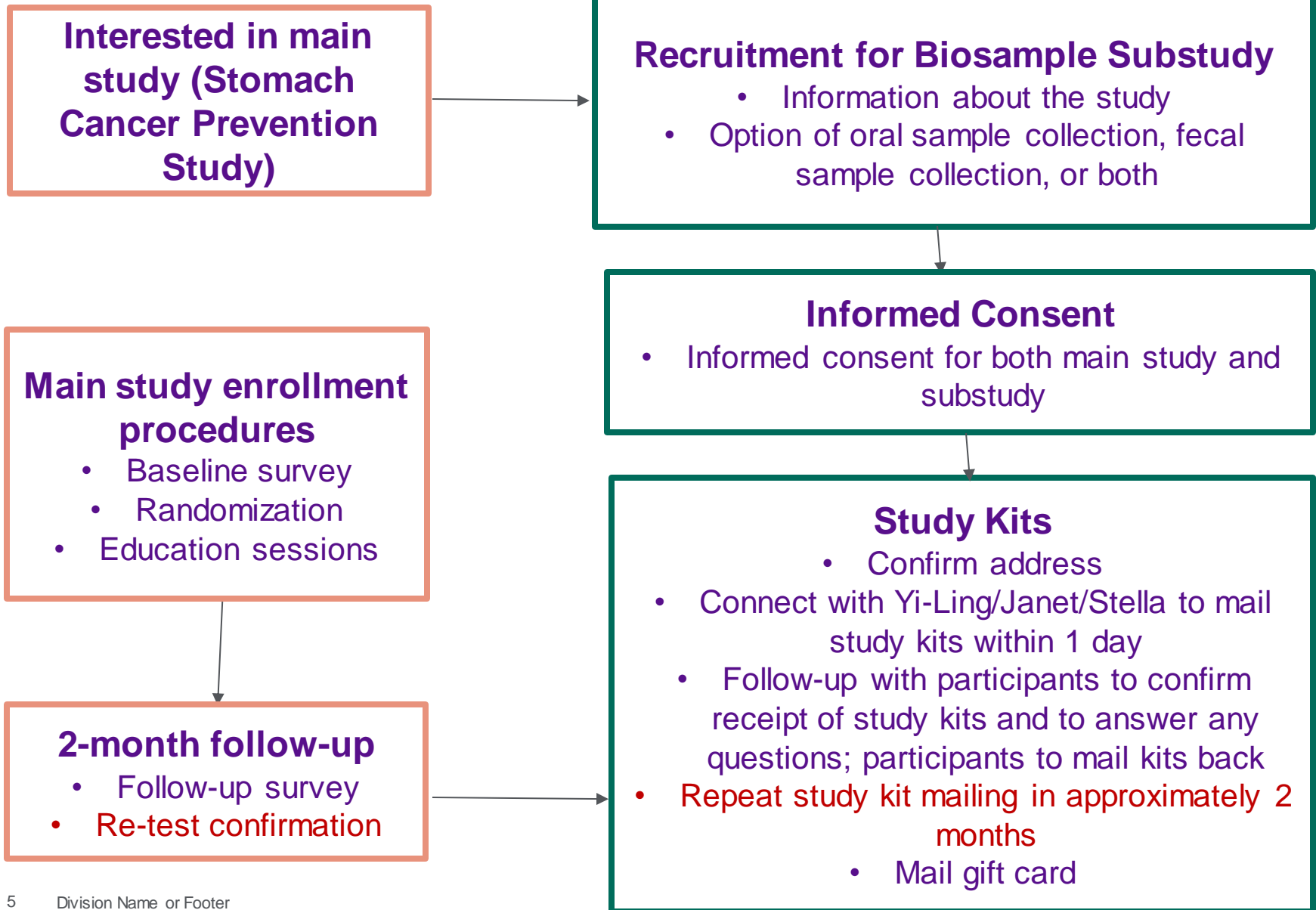
Study Design

- Observational pilot study
- Goal is at least 10 participants.

Participant Reimbursement

- \$20 for one type of sample (oral or fecal)
- \$35 for both samples
- Gift cards will be mailed after receipt of the second sample kit (2 months after enrollment)

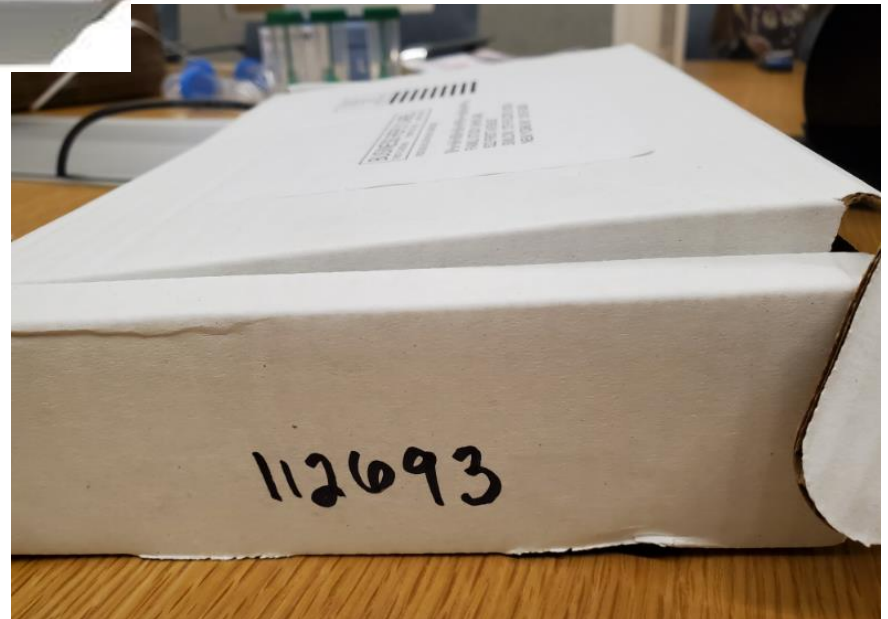
Study Procedures



Study Mailing Kit



Prepaid address label



Study Kit: Oral Sample Collection



Mouthwash



Blue-cap tube



Specimen bag

Study Kit: Fecal Sample Collection



Stool collection paper

Gloves

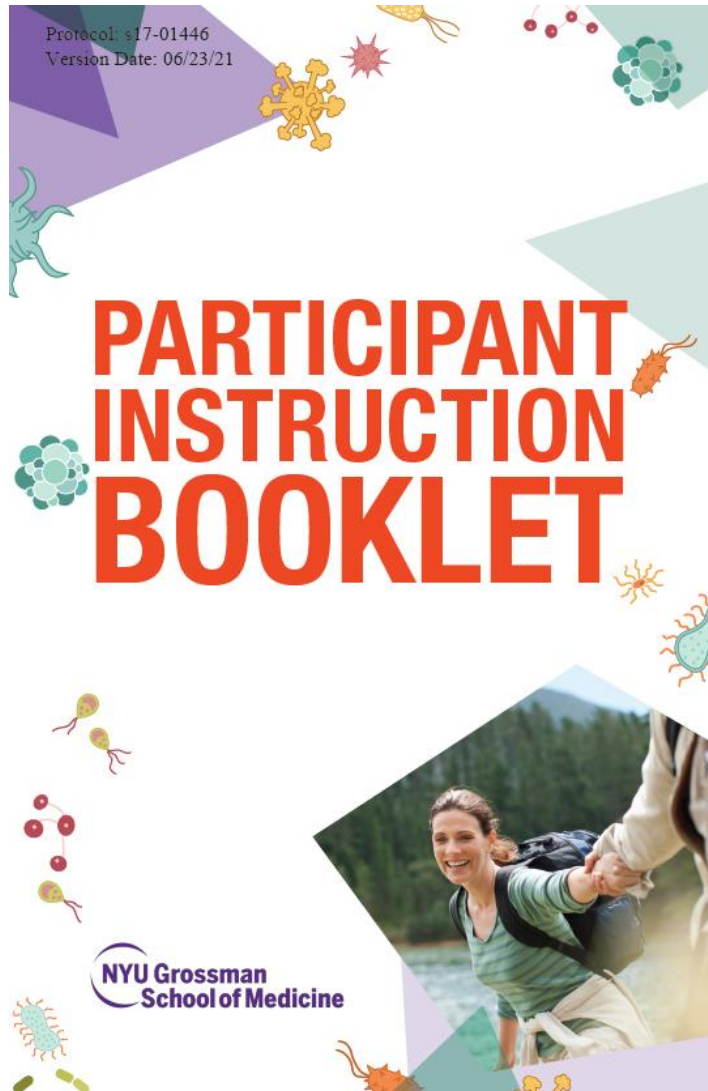


Green-cap tube
with preservation
liquid inside



Specimen bag

Study Kit: Participant Instruction Booklet



Please be sure to read all of the instructions in the booklet. The study results will only be accurate if you follow these instructions closely. Call us at 718-722-1370 if you have any questions.

STEP 1 Review the contents of the kit

STEP 2 Collect your mouth wash sample

STEP 3 Collect your stool sample

STEP 4 Mail back study materials

- Steps 2 and 3 can be completed in any order.
- You may also choose to send only your mouth wash sample OR only your stool sample.
- After your first sample collection is received, we will send a second sample collection in approximately two months.
- For your second sample collection, please send us the same sample type that you chose for your first sample collection.
- For example:

1 st Batch Enrollment	2 nd Batch Follow-Up (2 months later)
Oral	Oral
Stool	Stool
Oral and Stool	Oral and Stool

Screening and Informed Consent Procedure

- Review new COMBINED script and verbal informed consent.

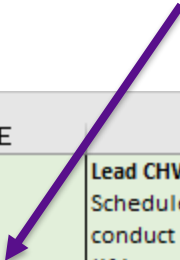
FAQs

- **Will I receive the results of my samples?** *We often get asked if individual participants will receive their microbiome data, or if we will let them know if we find anything suspicious.*
- We do not provide individual data or results.
- All samples go into the freezer and we wait until the end of the study to run all the samples together. Samples are combined and we cannot get individual results.
- We do not run diagnostic tests. We analyze the samples to see if there are common differences between the samples with *H. pylori* and samples without *H. pylori*. The differences may be at the cellular or molecular level.
- The results of the study will be published and available to all a few months after the end of the study.

FAQs

- **DNA information and privacy?** *If concerns about DNA and privacy come up, we try to explain that we will be **sequencing the DNA of the bacteria** that lives in the body, **but we are not sequencing their human DNA**. We are not using the samples to extract human genetic information.*
- *We also try to assure the person that all of their information is kept confidential, and that we comply with HIPAA to protect their privacy. Sometimes people worry about us sharing their genetic information with insurance companies or government agencies, so we try to assure them that this does not take place.*

New Procedures for Documenting Substudy Participants: Enrolled Participant Tracking Sheet



A	B	C	D	E	F	G	H
Next Step	Status				Lead CHW Schedule and conduct Sessions (if intervention grp) and Interv Surveys)		
		Group	Participant	Enrolled in Substudy		Addtl CHW	Consent Form
Participant responded on: 12/7/18, not interested; Categorize as Lost to Follow-Up at 2-mos	Lost to Follow-Up	Intervention	001		Stephanie	Funing	9/4/2018
6-mos follow-up in March; No response from Pt; continue to try to reach in case return from China** Unable to contact/ Categorize as Lost to Follow-Up at 2-mos	Lost to Follow-Up	Intervention	002		Funing	Stephanie	9/7/2018
COMPLETED	Completed	Control	003		Funing	Stephanie	9/11/18

NON-ENROLLMENT

- If you meet with the participant and he/she decides not to enroll or is ineligible, document this in **the Participant ID tab** of the Enrollment Participant Tracking Sheet.

3					
9					
	Enrolled Patients	Participant ID	Substudy ID&Tracking	Retest Tracking (EPIC_REDCap)	

A	B	C	D	E	F	G
	First name	Last name	Site Enrolled	Enrolled in Substudy	Reason for non-enrollment	Contact 1
85						
86						
87						
88						
89						
90						
91						
92						
93						
94						
95						

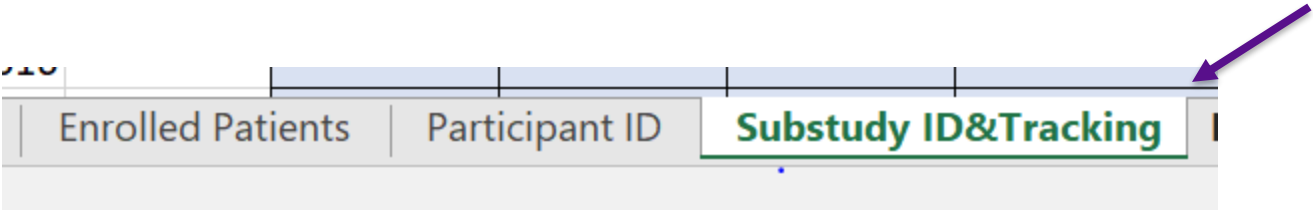
Non-Enrollment

Reasons for Non-Enrollment

Be as specific as possible!

- Not interested in study
- Not interested if unable to get individual results
- Does not want to give samples/discomfort with collecting samples
- No time to mail samples back

Substudy Participant UID and Enrollment Tracking



Enrolled Patients	Participant ID	Substudy ID&Tracking
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		Enrollment				
Substudy ID	Main Study ID	Informed Consent	Study Kit Mailed	Follow-up reminder	Oral Sample Date Received (NYU)	Fecal Sample Date Received (NYU)
1000						
1001						
1002						
1003						
1004						
1005						
1006						

Substudy Enrollment Procedures

- Once enrolled in substudy, confirm in group WeChat
- Yi-Ling/Janet/Stella will coordinate to mail out a kit (same/next day)
- USPS return label will be fixed to the kit
- CHWs to check with participant when they have received the kit; and whether they have any questions about sample collection
- CHWs to remind participant to return the kit as soon as possible
- CHWs to ask participant to text/confirm that they have sent the kit back

Substudy Follow-Up Tracking

- During the 2-month follow-up with participant (for main study), confirm that we will mail another study kit to the same address.
- Remind participant to send back the same type of sample(s) they collected the first time.
- Once the second study kit is received at NYU, we will mail the gift card.

H	I	J	K	L	M	N	O
			Follow-Up (2-MONTHS)				
Main Study: 2-month follow-up survey date	Medication Completion (yes/no/partial)	Retest Status (negative, positive, not yet retested)	Study Kit Mailed	Follow-up reminder	Oral Sample Date Received (NYU)	Fecal Sample Date Received (NYU)	Gift Card Mailed
			