

Patient-Centered Stomach Cancer Prevention in Chinese Americans

Tracking Materials & Forms –
Remote Encounters
(Nov 2021)

Study Procedures: Main Study

****All Gift Cards:**

Notify Yi-Ling and Janet when address is confirmed in Participant ID

Recruitment

- Verbal Consent
- *Baseline Form*
- Randomization

Weekly Calls:

Alice (Dr. Hu)
Anna (Dr. Xiao)

Daily Check:

Yi-Ling, Stella, Janet (EPIC)

Randomization: Stella

Intervention Group

- Health education sessions (4)
- Patient navigation/goal-setting
- Reminders (medication, retest, surveys)
- Sharing resources

- *Follow-up survey (2 months)*
- *Follow-up survey (6 months)*
- *CHW Evaluation*

Control Group

- Reminders (retest, surveys)

- *Follow-up survey (2 months)*
- *Follow-up survey (6 months)*

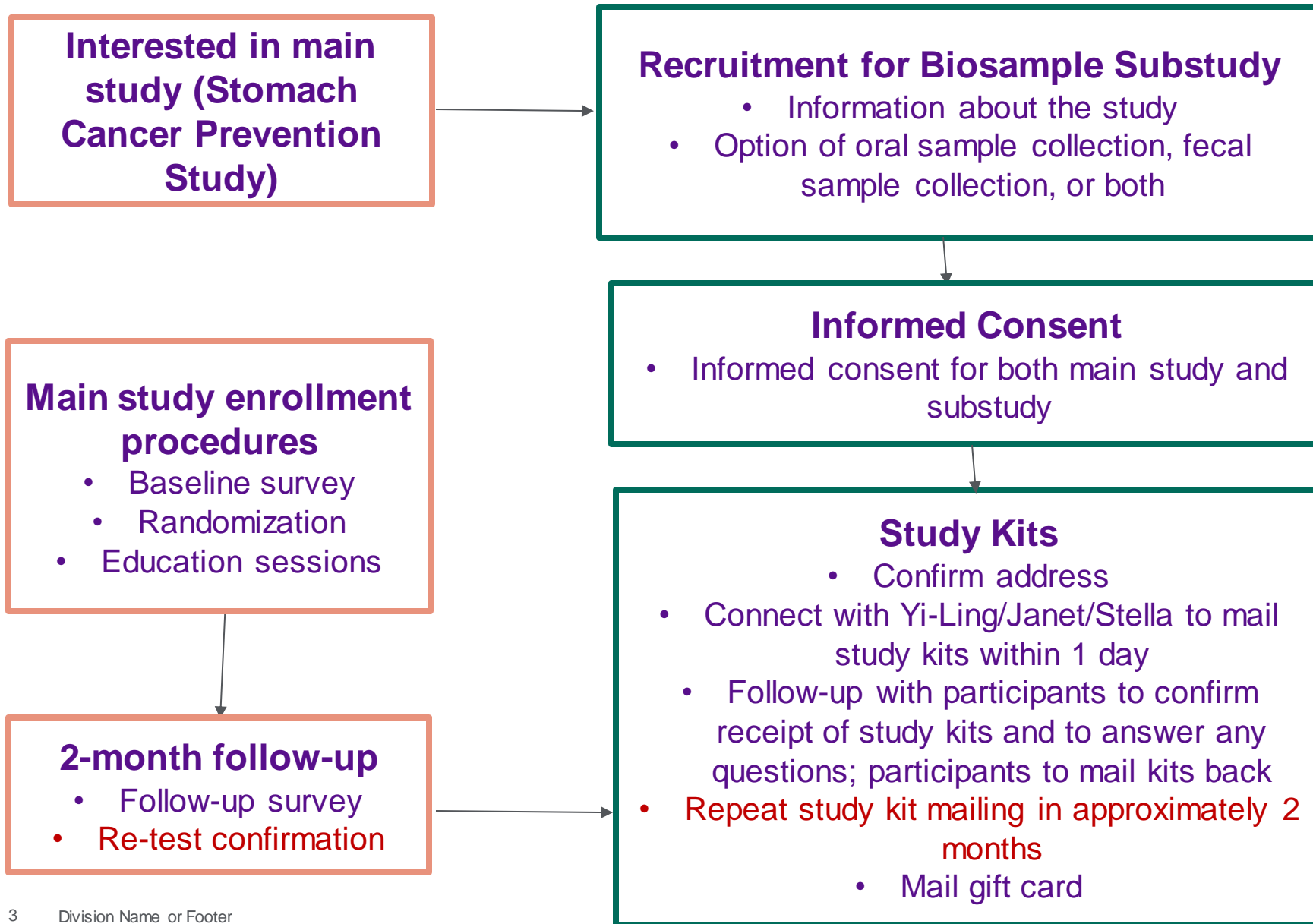
Data Collection (e-PDF Save to Pt Folder):

Anna, Alice, Stephanie, Angel, George, Stacy

Data Entry (email when ready):

Stella enter into REDCap)

Study Procedures: Substudy



ELIGIBLE PARTICIPANT (RECRUITMENT)

- Tracking Eligible Participants referred from Doctors
- Add any participants referred from Doctors; notify Janet, Stella and Yi-Ling
- Located on Drive:
J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\Eligible Participant Tracking Notes.xlsx

	Updated as of: 5/26/2020	CHW Update (Was the patient enrolled? Or not enrolled and reason?)						
Date Eligible Pt Was Entered	NEXT STEP - CHW: Please provide update notes on status. If Enrolled/Not Enrolled, please indicate the date	Write Result: Enrolled OR Not Enrolled OR Not Contacted	Patient Name - Enter Initials after Enroll/Not Enroll (First, Last)	MRN	Clinic	Age	Gender	Phone
8/18/2020	Referred by Dr. G. Pt started medication on 8/20/20. CC contacted pt on 8/21/20. Enrolled 8/21/20	Enrolled	Tong, Yun		Seventh Avenue/BC		M	(###) ###-####
8/21/2020	Referred bt Dr. R. Pt appt on 8/21/20 at 11am. CC will contact pt after appt on 8/21/20		Chan, Peter		Gouvernuer Hospital		F	(###) ###-####

NON-ENROLLMENT (RECRUITMENT)

- If you speak with the participant and he/she decides not to enroll or is ineligible, document this in the Not Enrolled Log
- Located on Drive:
J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\Not Enrolled Log.xlsx

Not Enrolled Log.xlsx - Excel

File Home Insert Page Layout Formulas Data Review View Add-ins Tell me what you want to do...

Calibri 11 A A Wrap Text General

B I U Font Alignment Number Styles

Work out of state only returns once/month

A	B	C	D	E	F
Date	Participant Initials (First,La	M		Study Site	Reason for Non-Enrollment
7/30/2020	AA	F	55	Brooklyn Chinese/7th Ave	Speaks Fuzhonese only; unable to communicate with pt directly
7/30/2020	BB	M	26	Gouverneur Hospital	Pt is not interested. They have no time and is very busy.
7/30/2020	CC	F	35	Dr. Xiao	Family member is enrolled in study already

WHAT TO DO AFTER RECRUITMENT/ENROLLMENT

- If participant is interested and enrolled (Verbal Consent/Baseline):

- Inform Team
- Add Participant Information into **Enrolled Participant Tracking Sheet**

J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants

- In “CHW Surveys & Encounter Reports”:
 - Create new **Participant Folder** and new **CHW Encounter Log**
- Complete **CHW Encounter Report** to note enrollment encounter

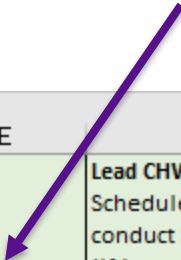
J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\CHW Encounter Reports

- When address is confirmed, add to Participant ID sheet in **Enrolled Participant Tracking Sheet**.
- Stella/Yi-Ling will mail via participant tracking sheet:
 - ClinCard and CinCard Letter
 - Patient Health Education Materials
 - Substudy biosample collection kit (if applicable)

ENROLLED PARTICIPANT TRACKING SHEET (ENOLLMENT)

- Tracking Participants that are enrolled into the study
 - Enrollment Date
 - Intervention or Control Group Assignment
 - (If intervention case) Session Dates
 - Upcoming And Completion dates for Baseline, 2-mos & 6-mos Follow-up Survey and (if intervention) CHW Survey
 - Lead CHW
 - Next Steps/Status Updates/Reminders
 - Address in “Participant ID” Sheet
- Substudy: Note if Participant agreed to Substudy or Declined & Reason (*Next 2 slides*)
- Located on Drive:
J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\Enrolled Participant Tracking Sheet.xlsx

Documenting Substudy Participants: Enrolled Participant Tracking Sheet



A	B	C	D	E	F	G	H
Next Step	Status	Group	Participant	Enrolled in Substudy	Lead CHW Schedule and conduct Sessions (if intervention grp) and Interv Surveys)	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

Located on Drive:

J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\Enrolled Participant Tracking Sheet.xlsx

Substudy 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						

Located on Drive:

J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\Enrolled Participant Tracking Sheet.xlsx

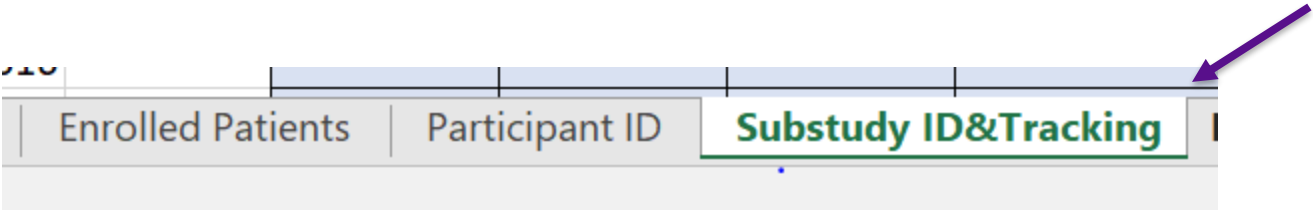
Substudy NON-ENROLLMENT

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 Follow-Up Tracking

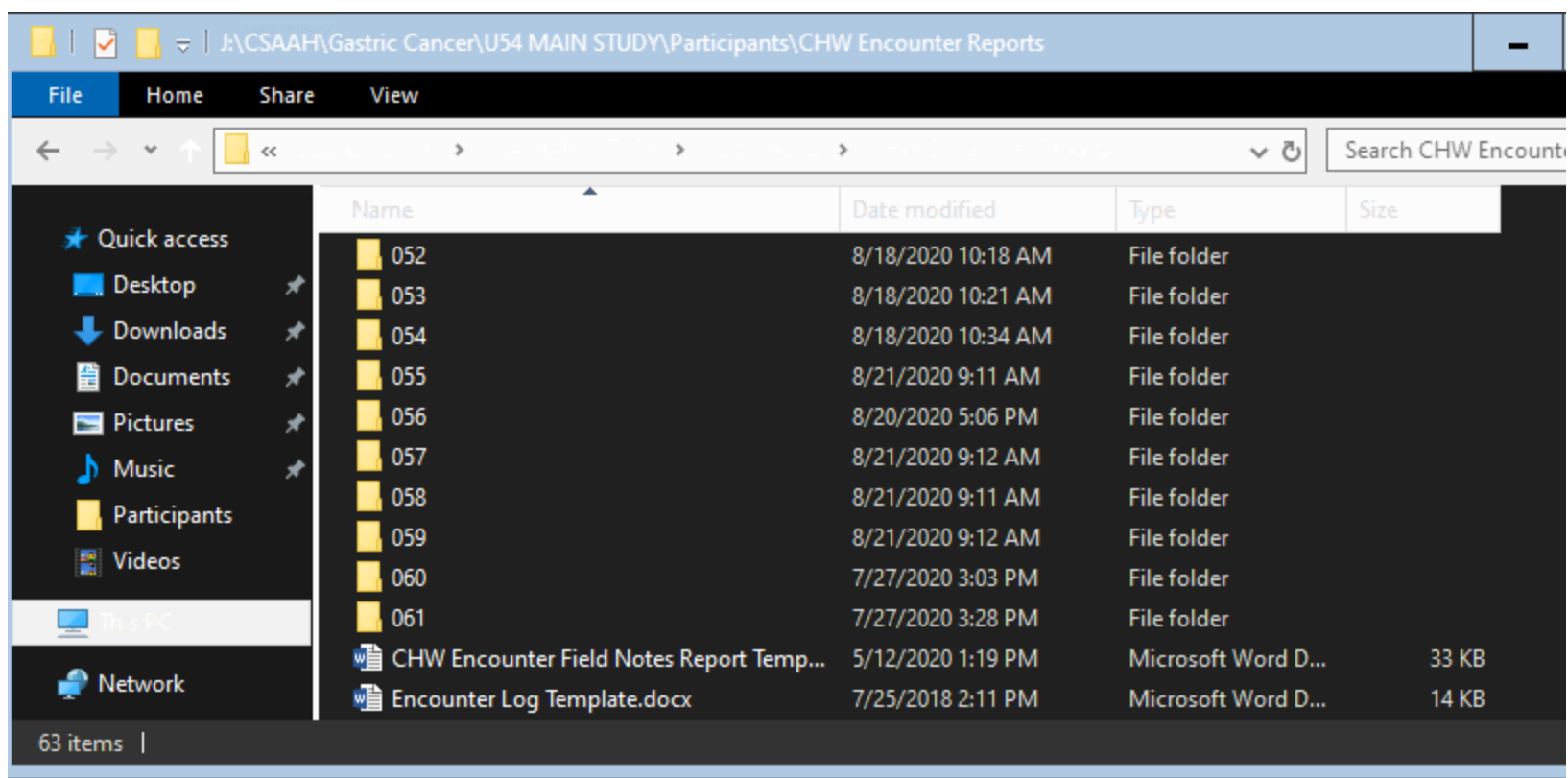
- During the 2-month follow-up with participant (for main study), confirm that we will mail another study kit to the same address.
- Remind participant to send back the same type of sample(s) they collected the first time.
- Once the second study kit is received at NYU, we will mail the gift card.

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
							

PARTICIPANT FOLDER (Surveys-ePDF, Encounter Reports/Logs)

- Located on Drive:

J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\CHW Surveys & Encounter Reports



ENCOUNTER LOGS & CHW ENCOUNTER LOGS (During ENROLLMENT & FOLLOW-UP)

New Participant: Create an Encounter Log & Participant Folder

- Encounter Logs:
 - This is to log any phone calls, voicemails, text messages, etc.

J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants

Ongoing Participant:

- Add to Encounter Logs
- Complete CHW Encounter Reports:
 - Complete a report for each meeting with participant

J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\CHW
Encounter Reports

ENCOUNTER LOGS

Filename: Encounter Log Template.docx

J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\CHW
Encounter Reports

STOMACH CANCER PREVENTION STUDY	Enrollment date	
ENCOUNTER LOG	<i>H. Pylori Session</i>	
	<i>Healthy Eating Session</i>	
Participant UID:	<i>Alcohol Reduction Session</i>	
Randomized Group: Control / Intervention	<i>Physical Activity Session</i>	
	<i>Smoking Cessation Session</i>	
	Re-test	
	2-month Follow-Up Survey	
	6-month Follow-Up Survey	



Date / Time	CHW Initials	Encounter Type	Outcome Code	Comments/ Explanation

ENCOUNTER TYPE:

PHONE CALL (PC)
ONE-ON-ONE (OO)
OTHER (Explain)

OUTCOME CODES:

SP= Spoke with participant (explain)
AM= Left message on answering machine or voicemail
CC= Phone call from client (explain)

LM= Left message with person who answered the phone
NA= No Answer
OT= Other (explain)

CHW ENCOUNTER REPORT

Filename: Encounter Log Template.docx

J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\CHW
Encounter Reports

Version 05.01.19

STOMACH CANCER PREVENTION STUDY ENCOUNTER REPORT

Participant UID: Click or tap here to enter text.

Arm: Choose an item.

CHW Name: Choose an item.

Date of Report: Click or tap to enter a date.

Encounter Date: Click or tap to enter a date.

Encounter Type: ☐ Initial Enrollment (Baseline Survey) ☐ Check-in ☐ H. pylori Session ☐ Healthy Eating Session
☐ Alcohol Reduction Session ☐ Smoking Cessation Session ☐ Physical Activity Session
☐ 2-month Follow-up Survey ☐ 6-month Follow-up Survey

Contact Method: ☐ In-person ☐ Phone Call

Time: Click or tap here to enter text.

Location: Click or tap here to enter text.

Instructions:

Please check off completed tasks if applicable.

- ☐ Sign consent form
- ☐ Complete Survey
- ☐ Give Pt \$25 gift card
- ☐ Conduct education session
- ☐ Set short-term action plan with participant
- ☐ Review short-term action plan/goals from last encounter with participant

EXAMPLE FROM CHW PARTICIPANT FOLDERS

GOAL SETTING – REFER TO CHW TRAINING SLIDES

Compensation

- Mail the participant a Clincard (Stella/Yi-Ling)
- CHW inform participant when it is mailed and inform team when it is received by participant and review Clincard with participant
- Stella/Yi-Ling will load GC onto Clincard for survey completion
- Complete Gift Card Receipt (indicate “Mailed/Loaded [DATE]” on receipt, if gift card mailed)
 - ✓ Document date and amount
 - ✓ Participant signature (If In-Person)
 - ✓ Study staff name (If Loaded/Mailed)
- Update Gift Card Log

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