

Patient-Centered Stomach Cancer Prevention in Chinese Americans

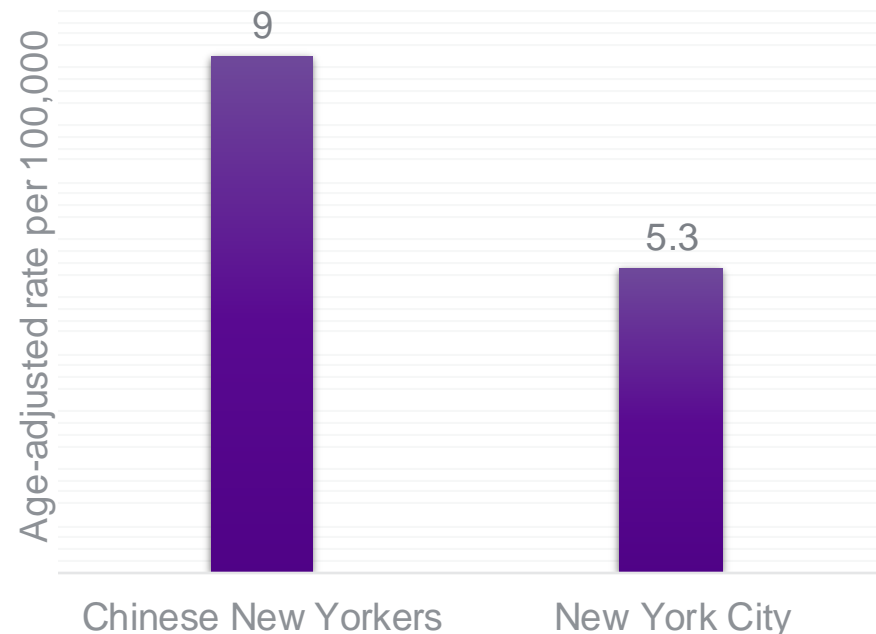
Main Study and Biosample Substudy

**Introduction and Refresher
10.22.21**

Helicobacter pylori (H. pylori)

- *H. pylori* infection is associated with increased risk of stomach cancer.¹
- Eradication through triple antibiotic therapy is the most effective prevention method for stomach cancer.²
- Treatment of H.pylori can potentially reduce burden of stomach cancers of up to 89%.³
- H. pylori infection within NYC & Chinese American populations is high.

Stomach cancer death rates in NYC, 2010-2014



Sources: NYC DOHMH Bureau of Vital Statistics, 2010-2014, American Community Survey Public Use Microdata Sample, 2010-2014, and NYC DOHMH population estimates

Barriers to *H. pylori* eradication

Adherence to American College of Gastroenterology (ACG) guidelines is not high

- 84% of physicians reported offering treatment to “every patient” with a positive *H. pylori* test; only 58% of physicians checked for eradication in patients who underwent treatment.¹

Medication adherence to *H. pylori* treatment is challenging

- Potential barriers to medication adherence to *H. pylori* treatment include: complexity of treatment (multiple drugs & dosing intervals) and uncomfortable side effects (e.g., diarrhea, abdominal pain, and nausea/vomiting).²
- Barriers are compounded in populations with limited English proficiency and low health literacy.

1. Murakami 2017

2. Scaccianoce 2006; Alahdab 2014

Stomach Cancer Prevention Project: Main Study (5 Year Study)

- Randomized control trial (RCT) to assess the efficacy, adoption and impact of an integrated intervention to improve adherence to recommended stomach cancer prevention guidelines for Chinese Americans in NYC
- **What will we do:**
 - Culturally and linguistically adapted community health worker (CHW)-led patient navigation program
 - Using electronic health records (EHR) tools to help facilitate *H. pylori* test-treat-and-retest strategies
- Funded by the National Institute of Minority Health and Health Disparities

Stomach Cancer Prevention Project: Main Study

EHR enhancements:

- Provider prompt to prescribe treatment
- Basic health education materials for the patient
- Medication order set for H.pylori

CHW led patient treatment and prevention programs

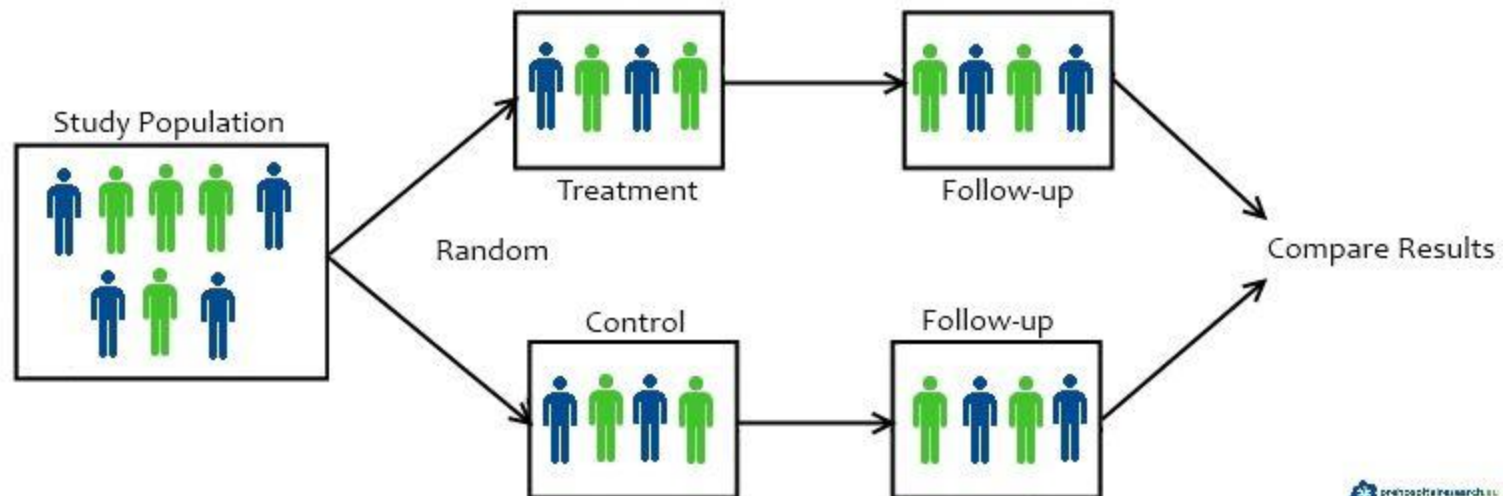
- 4 health education sessions on H. pylori and stomach cancer prevention strategies
 - Stomach cancer risk factors: H. pylori infection, diet, smoking, physical inactivity, drinking
- Reminders and follow-up calls

Main Study Objective

- Assess the **efficacy, adoption, and impact** of an intervention to prevent stomach cancer in at-risk Chinese New Yorkers

Main Study Design

- Randomized controlled trial



Participant Reimbursement: Main Study

Original method

- Grocery store gift cards (\$25 in value) mailed or given to participants after every survey
- 1st reimbursement: Completion of baseline survey
- 2nd reimbursement: Completion of 2-month survey
- 3rd reimbursement: Completion of 6-month survey

New method:

- ClinCards: reloadable
- Participants will have to keep the ClinCard mailed to them for the entirety of the study

Biosample Substudy 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.

Main Study Review

Eligibility criteria:

- Self-identifies as Chinese American
- Outpatient aged 21+
- Has a confirmed diagnosis of *H. pylori* infection

Recruitment will continue at the following sites:

- NYU Langone Hospital – Brooklyn; Bellevue Hospital; Gouverneur Hospital
- Seventh Avenue Family Health Center
- Private physicians: Dr Xiao's office and Dr Hu's office

Current Study Total (as of 9/29/22): 122 participants

Study Total Goal: 144 participants

Biosample Substudy Review

Eligibility Criteria

- Enrolled in Stomach Cancer Prevention Main Study

Study Design

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

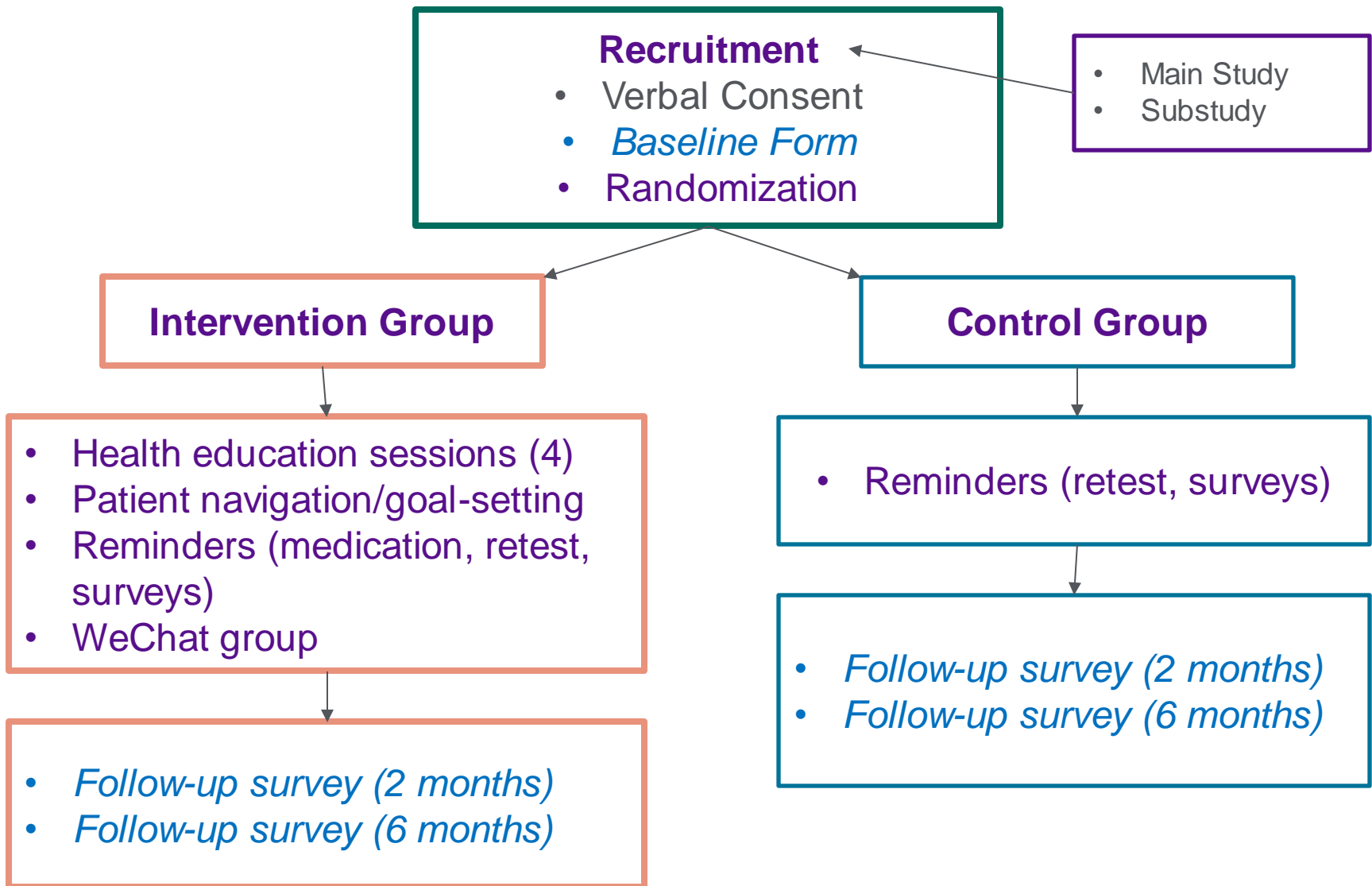
Participant Reimbursement

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

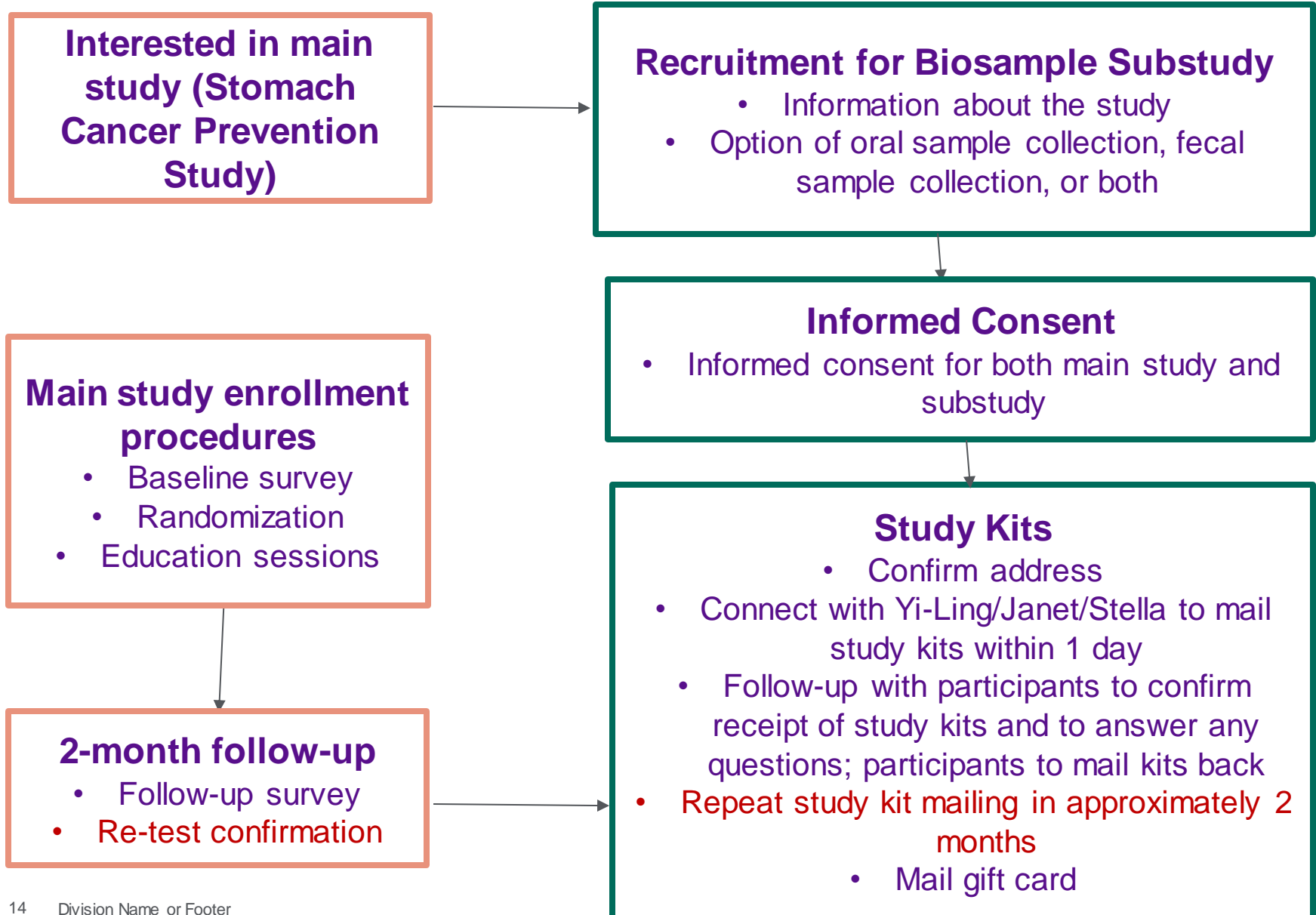
STUDY PROCEDURES

Phone Enrollment

Study Procedures Overview: Main Study



Study Procedures: Substudy



Referrals

NYU Epic referrals

- Providers will copy Yi-Ling, Stella and Janet on eligible H. pylori-positive patients, who will track follow-up appointments
- Study sites: 7th Avenue FHC; NYU Langone-Brooklyn; NYU Langone Ambulatory Care Bay Ridge

H+H Epic

- Yi-Ling, Stella, and Janet will confirm eligible patients with providers via H+H Epic or Providers will provide referral for eligible H. pylori positive patients
- Study sites: Gouverneur Hospital; Bellevue Hospital

Direct Referrals

- Providers and/or staff will refer eligible patients to study team
- Study sites: Dr Hu's office, Dr Xiao's office

TO HAVE READY FOR RECRUITMENT OVER PHONE

- RECRUITMENT MATERIALS

Located at: J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Study forms

1. Combined Telephone Script and Screening Form
 2. Combined Verbal Consent Script (*Folder: Screening and Consent Form*)
 3. Baseline survey (*Folder: Surveys*)
 4. Randomization envelope (Stella C. has envelopes as of 7/31/20)
 5. Document Encounter Log/Report (*J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\CHW Surveys & Encounter Reports*)
 6. Fully charged work phone (with WeChat)
- At end of enrollment/baseline completion:
 1. Inform participant about mailing gift card/health education materials
 2. Text Participant Key Information – Main study and/or Substudy (if participant confirmed it's OK) (*Folder: Screening and Consent Form*)

NOTE: If Randomization group is not known before this encounter ends, follow-up as soon as it is determined.

Screening

- Call participant to introduce yourself
- Refer to telephone screening script for study introduction and eligibility
J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Study forms\Screening and Consent Form
 - Use the COMBINED script (Stomach cancer + Substudy)
- Give information about the study and answer questions
 - Randomized study
 - Patient may be in control or intervention group: cannot choose which group he/she is in
- Let patient know that you might need approximately one and a half hour of his/her time

DISCUSSION:

**MAIN STUDY RECRUITMENT STRATEGIES AND
TALKING POINTS**

**SUBSTUDY RECRUITMENT STRATEGIES AND TALKING
POINTS**

Talking Points/Recommendations

- Doctor-recommended/Referred
- Working at 4 other NYU clinics
- Flexible – can work around your schedule
- Doctor has limited time; we can help you
- Their participation is very important to help the Chinese community understand H pylori and high risk for stomach cancer (very little data)
- If you're not doing it for yourself, do it for your family
- Stomach cancer is one of the most common cancers for Chinese people. In NYC, Chinese New Yorkers are more likely to get stomach cancer than other groups.
- H. pylori is most common bacterial infection in the world, but it can increase the chance of getting stomach cancer. Getting rid of H. pylori can help.
- You may be part of a health education program that may help you manage your H. pylori treatment and reduce the risk of stomach cancer. We want to find out how to improve ways that Chinese Americans can treat H. pylori and prevent stomach cancer.
- Participation is voluntary and will not affect your relationship with your doctor
- There are no costs to you for participating in this study.

Screening Form

- **REVIEW SCREENING FORM**

(J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Study forms\Screening and Consent Form\Screening Form)

- This is information that you already ask about such as Name, Phone, Address, Email, etc.
- Screening form to help check participant's eligibility
- Ask if any family members or people in their household are currently enrolled in this study. If yes, this is an exclusion criteria.
- Since these participants were already identified as eligible through EHR, it is unlikely that they will not meet the eligibility criteria on the *Screening Form*.
- Note if there are any reasons why a potential participant may not be able to participate outside of eligibility. Discuss with Yi-Ling/Janet/Stella or bring to Weekly Team Meeting.

ENROLLMENT

Verbal Informed Consent Form

- Patient should understand study purpose, procedures, risks/benefits, sharing health information.
- No data can be collected from the patient until he/she gives consent
- Document date that verbal consent was given on the Enrolled Participant Sheet (SHOW WHERE TO DOCUMENT ON SHEET)

REVIEW/READ THROUGH VERBAL CONSENT

KEY INFORMATION SHEET

REVIEW KEY INFORMATION SHEET

(CHW will text to participant, if they chose to after Verbal Consent)

PARTICIPANT CONTACT INFORMATION

- Record as many ways of contact as possible: address, various telephone numbers, email address
- Verify phone number
- Add to WeChat if participant is willing (as individual)
- Record preferred method of contact and best days/times to contact
- Ask participant to inform you if h/she changes contact information

CHW Contact Information

- Give them your work cell phone number. If no work cell phone yet, give work desk phone number (with forwarding to cell) OR team number.
- Do not give them your personal number.

ENROLLMENT/BASELINE SURVEY

If the participant does not have much time:

- Get participant contact information
- Arrange for another time (within 1-5 days of starting medication) when you can administer the baseline survey and possibly the first health education session in-person
- Do not assign Subject UID for now
- Assign Subject UID only if Consent and Baseline Survey is completed

BASELINE SURVEY

- All questions on the baseline survey should be collected:
 - **On the day of enrollment**
- Fill out the Subject UID on the top of every page
- Write legibly in black or blue ink
- Follow survey instructions (*ie. Read all options vs Do not read options*)
- Do not skip questions unless instructed to
- If patient does not want to answer questions, check or write in “**refused**” so we know that you did not miss the question
- If you make a mistake, cross out the wrong response, and write your initials and date next to it

SL 8/16/18 ☒ Less than \$25,000

RANDOMIZATION

Before opening a randomization envelope for the patient, check that:

- He/she has given verbal consent
- He/she is fully eligible for the study
- The baseline survey has been completed
- Check that the UID on the envelope corresponds to the UID assigned to the patient

As soon as the envelope is opened, the patient is considered enrolled in the study

- Check that the UID on the randomization card matches the UID on the envelope
- Record the patient's group in the baseline survey
- **DO NOT THROW RANDOMIZATION CARD AWAY:** We will staple to baseline form

RANDOMIZATION ENVELOPES



Blue card = Control Group



Yellow card = Intervention Group

POST RANDOMIZATION

Explain to the patient which group he/she has been assigned to:

CONTROL GROUP

- Will mail patient health education materials/gift card for baseline
- Encourage the patient to follow the doctor's orders for the medication, but do not provide additional information
- Remind patient to do a confirmatory test 6-8 weeks after completing the medication
- Schedule tentative follow-up interview date for 2 month survey

INTERVENTION GROUP

- Will mail patient health education materials/gift card for baseline
- Encourage patient to fulfill prescription; if necessary, accompany him/her to the pharmacist
- Together with the patient, discuss strategies to take the medicines on time. Set up schedule for reminder calls/texts.
- Discuss medication side effects
- Schedule follow-up appointment for Session 1 within the week.
- Tentatively schedule rest of the health education sessions.

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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NON-ENROLLMENT

- 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

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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 (including Address) into **Enrolled Participant Tracking Sheet**

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- Create new **Participant Folder** and new **CHW Encounter Log**
- Complete **CHW Encounter Report** to note enrollment encounter

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- Stella/Yi-Ling will mail via participant tracking sheet:
 - ClinCard and CinCard Letter
 - Patient Health Education Materials
 - Substudy biosample collection kit (if applicable)

Role Play Recruitment & Enrollment