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TABLE OF CONTENTS

I. PURPOSE OF THE STUDY AND BACKGROUND

A. Purpose of the Study

The proposed study "Patient-Centered Stomach Cancer Prevention in Chinese Americans" aims to assess the efficacy, adoption, and impact of an integrated intervention to improve adherence to recommended stomach cancer prevention guidelines (*H. pylori* test-and-treat) for at-risk Chinese Americans in NYC. The integrated multifaceted theory-based intervention involves: 1) a health systems-level intervention using electronic health record (EHR)-based tools to facilitate *H. pylori* test-and-treat strategies; and 2) a community-engaged culturally and linguistically adapted community health worker (CHW)-led patient navigation program we are currently pilot testing for feasibility and acceptability. Using a 2-arm randomized controlled trial (RCT) design, we will enroll 144 Chinese American patients across NYC health care facilities (NYU Langone Health – which includes NYU Langone Brooklyn, NYU Langone Brooklyn Family Health Centers and affiliated provider practices, and NYU Ambulatory Care Centers – Bellevue Hospital Center and Gouverneur Hospital). The integrated intervention involves:

1. A collaboratively developed and refined EHR-based clinical decision support system and CHW-led culturally and linguistically adapted stomach cancer prevention program for the Chinese American community.
2. A *H. pylori* test-and-treat intervention using linked EHR tools with a CHW-led culturally and linguistically adapted program to improve *H. pylori* eradication and treatment among vulnerable Chinese American patients.

In addition, using a mixed-methods approach and the RE-AIM framework,[1] we aim to systematically assess the implementation process and delineate factors that influence feasibility, acceptability, adoption, sustainability and scalability of a combined EHR-CHW strategy within safety nethealth care systems. This will be achieved through the completion of:

1. Assessment of utilization patterns through extracted MCIT files.
2. Qualitative key informant interviews will be conducted by study coordinator with key providers (1-3 at each site), and administrator (1-2 at each site), and the CHWs (1 at each site). At baseline, the interviews will be incorporated into the workflow analysis to assess current satisfaction and EHR usage and health coaching. At follow-up, the interviews will assess barriers and facilitators to the implementation and adoption process of the integrated EHR-CHW intervention, intervention fidelity, and to solicit recommendations for the replicationand scalability of the intervention to other clinical sites.
3. Ethnographic data will be collected by CHWs in Year 1 and by the study coordinator in Year 5 and will be guided by the 5 key steps in a rapid assessment process.

Impact: The proposed study will inform efforts to prevent stomach cancer and reduce the burden of stomach cancer in Chinese American communities served in safety net health systems and establish a reproducible, sustainable patient-centered cancer prevention model integrated within health care systems serving vulnerable communities.

Substudy: The proposed substudy aims to evaluate the feasibility and response rate for the collection of biosamples among Chinese Americans with a clinically confirmed diagnosis of *H. pylori*. The biosamples will be used to assess differences in oral and gut microbiome profiles before and after *H. pylori* antibiotic therapy. This will be achieved through the optional collection of oral and/or fecal biosamples from participants in EHR-CHW Intervention component of the study 'Patient-Centered Stomach Cancer Prevention in Chinese Americans'. The proposed substudy will inform efforts to develop novel

biomarkers to improve stomach cancer prevention, risk assessment and early detection among Chinese Americans.

B. Background

B1. Stomach cancer rates in China and in NYC Chinese American communities. Stomach cancer is the third most common cause of cancer death worldwide (723,000 deaths annually).[2] Approximately 42% of new cases of stomach cancer worldwide occur in China.[3] In the US, the overall incidence of stomach cancer is lower than in other countries, about 8.7 per 100,000 people per year. There are clear disparities,however, in stomach cancer incidence in the US, particularly among Chinese American populations, who have incidence rates of approximately 11.1 per 100,000 persons per year.[4,5] While Chinese Americans generally have lower incidence and mortality rates for most cancers compared with non-Hispanic whites, they are at higher risk of stomach cancer in the US.[6] Similarly, cancer mortality studies indicate that Chinese Americans in NYC have lower all-cause mortality and total cancer mortality than whites, but they experience higher stomach cancer mortality.[7,8] In 2013, stomach cancer incidence among Asian Americans was almost twice that of whites in NYC (15.5 vs. 8.1 per 100,000).[9]

B2. Chinese Americans and *H. pylori,* the primary risk factor for stomach cancer. Globally, *H. pylori* is one of the most common bacterial infections with approximately 50% of the global population infected.[10,11] In 1994, the International Agency for Research on Cancer classified *H. pylori* as a Grade I carcinogen in humans.[12] Approximately 89% of non-cardia gastric adenocarcinomas can be attributed to *H. pylori* infection.[13,14] In East Asian populations, including Chinese, *H pylori* infection rates can be as high as 47-70%.[15-17] Our previous NIMHD-funded observational study of *H. pylori* seroprevalence in a NYC East Asian-born population that informs our proposal, found higher seroprevalence, 70.1% compared to other NYC groups (<20% seroprevalence), with higher rates reported for recent Chinese immigrants.[18]

B3. Chinese Americans, a vulnerable health disparity population. In NYC, the population of Chinese Americans is approximately 574,886: 72% are foreign-born, 34% lack a high school diploma, 61% have limited English proficiency (LEP), and 21% are living in poverty.[19,20]

B4. Chinese Americans, socio-cultural barriers and lifestyle-related stomach cancer risk factors. *Health care access.* For Chinese American communities, the risk of stomach cancer is compounded by difficulties in accessing healthcare services, and attendant linguistic, cultural, economic and social barriers, which contribute to delayed cancer screenings,[21-24] poor medication adherence, and poor disease self-management skills.[25-28] *Acculturation* (which includes indicators such as nativity, years in the US, English language proficiency) is a significant factor that influences health access and behaviors for Chinese American immigrant communities, including impacting screening and disease prevention.[25,26]

B5. Evidence-base for test-and-treat in high-risk Chinese populations.
The American College of Gastroenterology's 2017 clinical guidelines for treating *H. pylori* infection recommends clarithromycin triple therapy consisting of a proton pump inhibitor (PPI), clarithromycin, and amoxicillin or metronidazole for 14 days where *H. pylori* clarithromycin resistance is known to be <15%.[29] This is an oral regimen of 6-8 pills taken daily at different dosing intervals for 14 days. Test for treatment success of eradication therapy should occur at least 4 weeks after completion of antibiotics and with patients off PPI for 1-2 weeks, using urea breath test, fecal antigen test, endoscopic testing or other clinically approved *H. pylori* infection diagnostic test.

B6. Adherence to *H. pylori* treatment therapy. Adherence to medication, generally defined as ≥80% of medication uptake,[30] is a crucial part of successful treatment and indispensable for reaching clinical goals.[30,31] In the US, approximately 50%-60% of patients are non-adherent with their prescribed medicine, yet research into the causes of suboptimal adherence has been of variable quality and generally inconclusive.[30,32-35] Adherence to the treatment regimen is the single most important factor in *H.pylori* eradication and is of paramount importance in cancer prevention.[36,37] Suboptimal adherence may in fact contribute to antibiotic resistance and *H. pylori* reinfection, undermining the effectiveness of the therapy.[38,39] The benefit gained from *H. pylori* eradication such as reducing long-term risk of gastric cancer may not be obvious to the patient. Thus, patient education is critical for *H. pylori* therapy, especially given the multiple drugs and dosing intervals of the treatment regimen, along with the potential non-serious but uncomfortable side effects which can include diarrhea, abdominal pain, and nausea/vomiting.[40,41]

B7. Rationale for a culturally adapted multifaceted integrated approach. Two main factors that affect patients' compliance are the complexity of *H. pylori* treatment and the treatments' side effects.[37,42] One study in China identified the following specific factors for *H. pylori* medication nonadherence: lack of guidance on drug administration; lack of information about side effects; and preference for traditional Chinese medicine due to cultural beliefs that western therapies have more side effects.[43,44] Only a few *H. pylori* treatment adherence intervention studies have been conducted, most of which incorporated low-touch patient counseling and follow-up,[36,42,44-46] and outcomes have largely been inconclusive. Patients in an Irish hospital who were randomized to receive detailed counseling on treatment rationale, side effects, and compliance importance were significantly more likely to have *H. pylori* eradicated (94.7% compared with 73.7%; p-value=0.02).[45] *To date, no studies have targeted LEP or vulnerable populations for the prevention of stomach cancer.*

B7a. CHW approaches: a successful strategy for disease prevention in health disparity communities. The role of CHWs as important members of the healthcare workforce to improve health outcomes for vulnerable minority communities is recognized by the Institute of Medicine, Centers for Disease Control and Prevention, and the American Public Health Association.[47-49] (By serving as cultural and linguistic bridges between community resources and health systems, CHWs have the potential to address health disparities and disseminate efficacious interventions to vulnerable communities. Linking Chinese American patients with CHWs in clinical settings will help patients understand and navigate the complex *H. pylori* eradication treatment to reduce stomach cancer risk.

B7b. Electronic Health Record (EHR) interventions can improve cancer prevention and cancer outcomes. Physician recommendation and regular visits to the doctor significantly influence rates of screening within Asian American communities.[21,50] EHR provider prompts are effective tools in health care delivery[51,52] and have been shown to significantly improve cancer screening, including among Asian Americans.[53] Furthermore, EHRs can be used as a powerful tool to increase medication adherence[54] and improve disease management.[55,56] The use of clinical decision support systems or alerts using EHR can increase provider adherence to recommended screening guidelines and drive quality improvement for disease management and prevention.[56-59]

B7c. An integrated approach (EHR + CHW) is needed to improve education and adherence to stomach

cancer prevention for high-risk groups. Several systematic meta-analyses[35,60-63] have identified the lack of behavioral, theory-based, multifaceted interventions and have collectively called for future research to integrate multiple theories and models to inform adherence-enhancing interventions. Similarly, there is demonstrated adequate evidence of the effectiveness of CHWs[64-68] operating within structured health systems[69,70] and of the potential for innovations in health information technology to support medication adherence.[54] *Given the complexity of medical adherence, integrated strategies that include socio-behavioral science research and theories along with EHR-based decision support tools are needed to help identify and address these complex challenges. To our knowledge, no study has tested an intervention combining the complementary strategies of EHR enhancements and CHW-led coaching for stomach cancer prevention in a health disparity population*.

B8. Summary. This project builds upon an evidence base of CHW effectiveness in low-income, LEP communities, and CSAAH's experience in conducting CHW and EHR-based interventions for chronic disease prevention, past observational and current pilot intervention study on *H. pylori* and stomach cancer prevention, and comprehensive hepatitis B-related liver cancer control work. This study proposes a unique integration of a health systems-based EHR and CHW-led intervention to address stomach cancer disparities among Chinese American communities. *H. pylori* eradication has demonstrated effectiveness in reducing the stomach cancer disparity in at-risk populations; however, insufficient numbers are being treated effectively in US. Hence, there is a critical need for theory-informed intervention research in real world settings to facilitate *H. pylori* eradication and reduction of stomach cancer disparities in at-risk Chinese American immigrants.

B9. 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 [105-107]. 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. This substudy aims to evaluate the feasibility and response rate for the collection of biosamples among Chinese Americans with a clinically confirmed diagnosis of *H. pylori*. The biosamples will be used to assess differences in oral and gut microbiome profiles before and after *H. pylori* antibiotic therapy.

C. Study Design

C1. Overall Design

The purpose of this study is to implement and test the relative effectiveness of an integrated *H. pylori* test-and-treat EHR-CHW intervention among Chinese American patients compared with usual care of EHR-only intervention. The primary outcome of interest is *H. pylori eradication*. The secondary outcomes of interest are *medication adherence, self-efficacy, health literacy and other factors*. This stomach cancer prevention study will use a 2-arm RCT design to evaluate the efficacy, adoption, and impact of an integrated EHR-based decision-support intervention with CHW-led coaching for high-risk Chinese American patients to achieve optimal adherence to *H. pylori* eradication medication regimen. An advisory group will guide the development of a user-friendly EHR intervention and culturally adapted materials relevant for Chinese Americans. The interventions will be collaboratively developed and implemented in NYC safety net hospitals and clinic sites that serve large proportions of Chinese American patients.

In Year 1, we will engage in a collaborative effort to develop and refine an evidence-based clinical decision-support and physician feedback mechanism that can be integrated into existing EHR systems. In

Years 2 to 4, we will implement and evaluate the specific EHR intervention and integrated culturally adapted CHW-led patient navigation program. In Year 5, we will assess the implementation process and use findings to develop a set of best practices and toolkits for public health and healthcare agencies regarding integrated EHR-CHW strategies to improve *H. pylori* test-and-treat strategies for this stomach cancer disparity population. Guided by the RE-AIM framework, we will systematically assess program adoption and sustainability to enhance reproducibility of findings and transferability to other Chinese American and vulnerable health-disparity populations.

The intervention will be implemented at NYU Langone Health – which includes NYU Langone Brooklyn, NYU Langone Brooklyn Family Health Centers and affiliated provider practices, and NYU Ambulatory Care Centers – Bellevue Hospital Center and Gouverneur Hospital.

Timeline.

Table 4. Project Timeline	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Convene advisory group	X		X		X		X		X		X		X		X		X		X	X
Conduct formative data (workflow analysis)				X				X				X				X				X
Develop, adapt, integrate intervention, tools	X	X	X	X																
Train CHWs, providers and staffs on tools			X	X	X															
Recruit, randomize & implement intervention					X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Baseline and follow-up data collection						X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Ongoing supervision and fidelity checks					X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Data analysis and process evaluation										X	X	X	X	X	X	X	X	X	X	X
Dissemination implemented													X	X	X	X	X	X	X	X
Conduct Substudy															X	X	X	X	X	X

Q1: July-September; Q2: October – December; Q3: January-March; Q4: April-June

C2. EHR-CHW Intervention

Planning Process. Applying a community-engaged approach, we will convene a transdisciplinary advisory group and meet on a monthly basis during Year 1 to engage in a collaborative planning process. Stakeholders will include representatives from the NYU Medical Center Information Technology (MCIT), physician champions from the implementation clinics, project CHWs, representatives from Chinese-serving community organizations (e.g. the Chinese American Planning Council) and study investigators and staff. We will review existing quality improvement, Health Information Technology (HIT) initiatives, and other patient education resources that are currently integrated with the systems. We will host a series of MCIT supported WebEx online web conference learning exchanges within the first 4 months to share information about safety net hospital and clinic sites quality improvement initiatives addressing *H. pylori* eradication and stomach cancer prevention. Information from these learning exchanges will guide the advisory group's efforts in planning the integrated EHR-CHW initiative.

EHR Components. We will conduct a workflow analysis,[71] an analysis of the processes by which a clinic or hospital provides care to a patient, that will be guided by a transdisciplinary, community-engaged advisory group. Using a rapid assessment process[72-77] that is informed by the Agency for Healthcare Research and Quality (AHRQ) recommendations on workflow assessments,[71] a baseline analysis will be conducted at each site. The workflow analysis consists of an iterative process, including ethnographic observation and key informant interviews, to provide contextual data on organizational workflow, culture, and practice. Analysis results will inform the design of alert and registry functions and alignment with the workflow of each site.

CHW Components. We will refine the CHW protocol and curriculum. We will conduct a scan of CHW and/or care coordination efforts at the sites to determine possible leverage points for the placement of CHW initiatives or opportunities to support train-the-trainer models. The advisory group will also review any existing materials, adapt them culturally and linguistically for the target population, and integrate with the existing pilot CHW educational curriculum. The Ecological Validity Model[78] complemented by a social marketing approach[79] will be applied, to assess and adapt the materials. Small media materials will be produced by the advisory group using a participatory process, adapted from our previous studies,[80-82] and may include bilingual palm cards and pamphlets on *H. pylori* eradication therapy, side effects and stomach cancer prevention.

To enhance scientific rigor, measure selection was based on: 1) brevity; 2) presence of domains with face validity for Asian American or low-literacy communities; and 3) valid psychometric properties. The **primary outcome** measure is the most rigorous outcome measure related to *H. pylori* eradication: confirmation of *H. pylori* eradication by fecal antigen test or other clinically approved *H. pylori* infection diagnostic test conducted 4 weeks–3 months post-treatment (to be extracted from EHR). **Secondary outcomes** include: self-efficacy, health literacy, medication adherence and other factors. Medication adherence measured using simplified medication adherence questionnaire (SMAQ) and medication adherence report scale (MARS-5). Self-efficacy will be measured by the Ottawa Decision Self-Efficacy Scale. Health literacy will be assessed using the short form of the European Health Literacy Survey Questionnaire (HLS-EU-Q12). Health-related quality of life will be measured by the Patient-Reported Outcome Measurement Information System Global Health Scale (PROMIS).[86]

During the intervention period, patients that meet the eligibility criteria will be identified. The bilingual CHWs will complete a brief screening form with potential participants in person or via phone (See *Script for Telephone Screening and Screening form*). The screening form will assess demographic characteristics, participant eligibility, interest in our program, and reasons for refusal to participate. For in-person screenings, if the patient is eligible and interested in the study, the CHW will obtain verbal informed consent for study participation and describe the randomization process (See *Combined Verbal Informed Consent*). For individuals identified from the EHR registry list, CHWs will conduct phone screenings, and will complete the verbal consent process by phone with interested, eligible individuals. CHWs will compile and share contact information for consented study participants with the study coordinator on a weekly basis. All consented participants will be randomized in a 1:1 ratio using a computer-generated randomization[87]scheme to one of the study arms.

Consented participants randomized to the EHR-CHW intervention arm will receive a standardized protocol. The protocol, designed to be flexible, consists of 4 educational sessions to be delivered in a group, or per the participant's preference one-on-one or via telephone or other social networking platforms (eg. WeChat). The sessions employ adult learning techniques and group-based learning activities. All session materials will be culturally and linguistically adapted. The in-person sessions will be held at the clinics and community spaces identified by partner agencies. Data will be collected by study staff via surveys at baseline, 2, and 6 months. Scheduled office visits will be tracked via data pulls from the EHR system. If no visit is scheduled during the follow-up period, project CHWs will conduct follow-up calls to schedule participants for data collection events in the community, at the clinic, or in their home, with permission.

C 3. Assessment of Implementation, Adoption, Sustainability, and Scalability

To capture data on utilization patterns of the tailored EHR decision support, provider feedback tools and integrated EHR-CHW initiatives, Dr. Mann will work with MCIT to extract system files monthly that indicate date and time stamps and user logins for each time the tools were used and/or CHW embedded templates were accessed. Data will be extracted into a spreadsheet and analyzed by the study staff. Qualitative key informant interviews (See *Key Informant Interview Guide*) will be conducted by study coordinator with key providers (1-3 at each site), administrators (1-2 at each site), and the CHWs (1 at each site). At baseline, the interviews will be incorporated into the workflow analysis to assess current satisfaction and EHR usage and health coaching. At follow-up, the interviews will assess barriers and facilitators to the implementation and adoption process of the integrated EHR-CHW intervention, intervention fidelity, and to solicit recommendations for the replication and scalability of the intervention to other clinical sites. Questions will be adapted from existing validated measures on acceptability, feasibility, adoption, organizational culture, and scalability.[88-93]

Qualitative ethnographic data will be collected through observations at the clinic sites. Ethnographic data will be collected by CHWs in Year 1 and by the study coordinator in Year 5 and will be guided by the 5 key steps in a rapid assessment process. Observations will occur in clinic waiting and administrative areas. Fidelity checklists will be conducted during CHW educational sessions and follow-up.

C4. SUBSTUDY

Substudy Design. The substudy is an observational feasibility pilot study. We aim to enroll a minimum of 10 participants. Only participants already enrolled in the main study are eligible for the substudy (*see Section II*). After enrollment into the main study, trained study staff will introduce study subjects to the substudy and offer subjects the opportunity to participate in the substudy in several ways: 1) provision of oral wash sample only; 2) provision of stool sample only; and 3) provision of both oral wash and stool samples. Study staff will obtain verbal informed consent from interested individuals (See *Combined Verbal Informed Consent).* Study staff who have obtained the verbal consent will document the consent and the date of consent on the Enrolled Participants Log. The Enrolled Participants Log is the only record linking a participant's name, subject ID and substudy ID (if applicable). Substudy participants will have the option of mail or in-person pick-up for receiving study materials, which include the kits to collect oral wash and fecal samples, participant instructions (See *Substudy Instruction Booklet*), and return stamped envelope. Once the substudy materials are received, study staff will set up an appointment to call or meet with substudy subjects remotely via WebEx and answer any questions about sample collection and returning the samples of the participant's choice.

After the completion of their *H. pylori* antibiotic therapy (approximately two months after enrollment), subjects will be sent or given another biosample collection kit with instructions and a return stamped envelope for sample collection. For those who did not return study samples, study staff will give a reminder call by phone and/or text message (See *Script for Substudy Telephone Text Reminders*). Subjects who return incomplete or unusable study samples will be sent or given another biosample collection kit with instructions and return stamped envelope.

II. CHARACTERISTICS OF THE RESEARCH POPULATION

The overall number of subjects expected to participate in the EHR-CHW Intervention study is 144. Key

informant interviews will be conducted with approximately 10-12 individuals (project CHWs, providers, and administrators).

EHR-CHW Intervention
Inclusion Criteria: An individual is eligible for the intervention if s/he: a) self identifies as Chinese American; b) is an outpatient aged 21+; c) plans to continue to live in the region during the next 12 months; d) is willing to be randomized to either treatment or control groups; and e) has a confirmed diagnosis of *H. pylori* infection by at least one of the following methods: C-urea breath test, histology, rapid urease test or bacterial culture, fecal stool antigen test or other clinically approved *H. pylori* infection diagnostic test.[94]

Exclusion Criteria: The exclusion criteria include: a) advanced chronic disease that would not allow the patient to complete follow-up or attend visits; b) allergy to any of the treatment drugs; c) previous gastric surgery; d) pregnancy or currently breastfeeding; e) taking antibiotics or bismuth salts within 2 weeks before the study.

Rationale for proposed exclusion of gender and racial/ethnic group members: Individuals from other racial/ethnic groups are excluded from participation in the intervention as this study is focused on Chinese American adults. Men and women will both be invited to participate in this intervention. No children or vulnerable subjects will be enrolled in this study.

Substudy
Inclusion criteria: An individual is eligible for the substudy if s/he is: a) enrolled in the EHR-CHW Intervention main study; and b) is willing to provide either an oral sample, a fecal sample, or both. Individuals will be excluded from the substudy if they are unable to mail the samples back to the study team.

Key Informant Interviews
Inclusion Criteria: Interviewees must be an adult (18 years and over) and they must be a provider, an administrator, or a community health worker. Individuals will be excluded from the interview if the interview cannot be conducted in the English language.

III. METHODS & PROCEDURES

A. Methods & Procedures

A1. EHR-CHW Intervention Components

EHR Component
Epic, the EHR system, has been integrated at NYU Langone Health, and is being implemented at Bellevue and Gouverneur Hospitals. Dr. Mann will oversee MCIT in creating the proposed EHR enhancements.

The integrated EHR-CHW protocol will support team-based care by supporting feedback between clinic staff and CHWs, including: First, templates will be created that CHWs can complete and upload into the EHR. Healthcare providers will be able to access these templates using EHR and building upon existing workflow. Second, health coaching and referral materials, to be developed by the advisory committee, will be made available to providers through the EHR. Third, CHW communication with the healthcare

team will be facilitated by participation and report-backs from CHWs during regular team "huddles" or staff meetings; the frequency of participation will be site-specific and determined by findings from the workflow analysis.

Integrated EHR-CHW Protocol Intervention.
Orientation, Implementation and Training. CHWs have been trained through the NYU-CUNY Prevention Research Center Training Program in a set of core competencies, which was developed by CSAAH faculty Trinh-Shevrin and Islam.[95]
Enrollment & Randomization. *H. pylori* infected individuals will be identified and recruited into the study from NYC health care facilities (NYU Langone Health – which includes NYU Langone Brooklyn, NYU Langone Brooklyn Family Health Centers and affiliated provider practices, and NYU Ambulatory Care Centers – Bellevue Hospital Center and Gouverneur Hospital). Participants will be identified by 2 approaches: 1) using ICD codes for *H. pylori* and Chinese ethnicity identified through a race and language code available in EHR, with recently diagnosed *H. pylori* infection (within 7-days) will be identified; via a EHR registry list, and 2) patients will be recruited directly from the above mentioned clinics. All consented participants will be randomized in a 1:1 ratio using a computer-generated randomization scheme[87] to one of the study arms.

CHW Intervention Components. The intervention arm protocol consists of 4 educational sessions: session 1 will focus on medication adherence, treatment side effects, and the link between *H. pylori* and stomach cancer; and sessions 2 through 4 will focus on reinforcing session 1 themes, stomach cancer risk reduction, and links to community-based resources. The sessions employ adult learning techniques and group-based learning activities. All session materials are culturally and linguistically adapted. The in-person sessions will be held at the clinics, community spaces identified by partner agencies or by telephone. These sessions will be accompanied by phone call, text or voicemail medication and follow-up reminders in the preferred language (frequency depending on participant preference). The intervention materials will model scripts and messages informed by Social Cognitive Theory and will include reviewing and reinforcing individualized challenges, strategies and action plans for medication adherence and stomach cancer prevention.

A2. Data Collection
The recruitment and data collection protocol will be finalized with substantial feedback from the advisory group. All study staff involved in recruitment and data collection will receive a standardized training orientation on administering surveys and will be certified in human subjects research via the Collaborative Institutional Training Initiative (CITI Program).

EHR data will be used for recruitment and for the determination of primary outcomes. Dr. Mann will work with MCIT to identify potential participants from EPIC databases. During the recruitment period, registry lists will be generated weekly from EHR for physicians who have approved participation of their patients. Patients will be contacted either by phone (up to 3 calls) or in person by CHW. All preliminary EHR data will be deleted or shredded after one week of retrieval. EHR data to be shared with the study team include: demographics (gender, age, race/ethnicity (if available), language (if available), diagnosis of *H. pylori* through ICD codes, dates of clinic visits, name, and telephone number. Scheduled office visits will be tracked via quarterly EHR data pulls. EHR data will also be used to follow-up with the

outcome of treatment regimens and to determine *H.pylori* eradication via fecal stool antigen tests based on treatment follow-up procedures of physicians.

Contact information will be collected from participants, including cell phone and home phone numbers, home and work address, email address, and Facebook/social networking account information. We will also assess whether participants are willing to receive text reminders on their cell phone. Additionally, a reminder letter and a small gift (tote bag, etc) will be sent to every participant who is willing to receive mail 4 months after enrollment. These strategies have been shown to be effective in retaining participants in community-based research.

Data will be collected by study staff via surveys at baseline, 2, and 6 months. Scheduled office visits will be tracked via quarterly data pulls form the EHR system. If no visit is scheduled during the follow-up period, project CHWs will conduct follow-up calls to schedule participants for data collection events in the community, at the clinic, or at their home, with permission. Participants will be compensated $25 for each assessments and will receive reminder calls and/or texts 2 weeks prior to data collection events to ensure attendance.

***Substudy Biosample Collection*.** Substudy participants will have the option of mail or in-person pick-up for receiving study materials, which include the kits to collect oral wash and/or fecal samples and return stamped envelope. Once the substudy materials are received, study staff will set up an appointment to call or meet with substudy subjects remotely via WebEx and answer any questions about sample collection and return.

Substudy subjects will have the option to provide oral wash sample only, fecal sample only, or both. Study staff who have obtained the verbal consent will document the consent on the Enrolled Participants Log. The Enrolled Participants Log is the only record linking a participant's name, subject ID and substudy ID (if applicable).

Fecal biospample collection: Substudy participants will provide fecal samples (about 8 grams which is about 2 teaspoons) in a OMNIgeneGUT fecal sample tube (*DNAgenotek, Ontario, Canada*).
Directions for performing the test:

1) Remove the fecal sample tube with preservation liquid inside from packaging.
2) Flush the toilet, allow it to refill. The stool cannot touch the toilet bowl or water. Use one of the following collection options:
    a. Place saran wrap or provided stool collection paper over the toilet bowl to collect a sample of stool.
    b. Just before finishing a bowel movement, use a piece of toilet paper to collect a small sample of stool.
3) Use spoon attached to cap to collect 2 marble sized samples.
4) Carefully screw the cap closed with sample on spoon. Shake well.
5) Once the collection is complete, place the tube in the preaddressed package and seal carefully. Return to the study center by mail within one day of collection.

Oral wash biosample collection: Study participants will be asked to swish vigorously with one aliquot of 10 ml Scope Original mouthwash sample (*Proctor & Gamble, Cincinnati, OH*) for 30 seconds.

Participants will be directed to expectorate the mouthwash into a clean specimen tube, and return to the study center by mail within one day of collection.

B. Data Analysis and Data Monitoring

B1. EHR-CHW Intervention Analysis.

We will conduct analyses to determine the comparability of the participants in the 2-arms using standard techniques, including Student's t-tests for normally distributed variables (after necessary transformations) and chi-squared tests for dichotomous variables. If the randomized groups differ in baseline characteristics, we will adjust for those variables in subsequent analyses of program effects. Descriptive statistics will be calculated to characterize study participants and to evaluate the distribution of key clinical, sociodemographic, and outcome variables. Summary data on medical history, years in the US, access to and utilization of primary health care services, and social characteristics (e.g., marital status, employment) will be reported.

All analyses will be conducted using intention-to-treat methods to minimize the risk of attrition bias. The *primary analyses* of differences in *H. pylori* eradication between the intervention and usual care groups will first be tested using a chi-squared test of binomial proportions. We will assess level of participation for those randomized into the intervention arm, and explore whether level of participation is associated with greater changes in health outcomes. Logistic regression analysis will be used to analyze differences in outcome between those who receive the intervention and those who do not, controlling for potential confounding factors. All quantitative data will be entered and analyzed using standard statistical packages (e.g., SAS, R, Stata).The primary analysis will assume that any patient lost to follow-up failed to achieve *H. pylori* eradication. As a sensitivity analysis, we will apply multiple imputation to impute missing outcomes assuming a missing-at-random mechanism.

The analysis of *secondary outcomes* is guided in part by the Social Cognitive Theory. We hypothesize that the intervention group, when compared with usual care, will report: 1) increased medication adherence; 2) increased self-efficacy for adherence; 3) improved health literacy; 4) improved knowledge about stomach cancer prevention; and 5) higher levels of perceived health related quality of life. We will compare these intermediate outcomes between groups using t-test or its non-parametric equivalent, the Wilcoxon rank-sum test. Sex as a biological variable will be addressed by exploring gender as a potential moderator of intervention effects.

Power calculations. For the control group, we conservatively estimate that approximately 55% will achieve *H. pylori* eradication based on several studies of overall and, specifically, Chinese American populations.[36,45,46,100] We wish to detect an increase in this rate to approximately 80% in the intervention group; this difference is reasonable based on studies in Ireland and China that showed increases of approximately this magnitude in rates of knowledge and high adherence in similar populations.[36,44,45] Accrual of 144 participants, evenly randomized to intervention or usual care, provide greater than 80% power to detect this difference, using a 2-sided, 0.05-level test.

B1a. Substudy Data Analysis.

Oral and gut microbiome data will be derived from the 16S rRNA sequencing assay from the oral wash and fecal samples. Based on barcoded 16S rRNA gene sequence read, each sample will be described as

having "relative abundance of taxa (from bacterial phyla, genera, and species)". The pre-processed sequences will be further analyzed using QIIME pipeline for analysis of community sequence data. In short, the pipeline consists of the following baseline/upstream statistical analyses: (a) sequence sorting by barcode into individual samples; (b) pairwise alignment and clustering of sequences into operational taxonomic units (OTUs); (c) computation of absolute abundance matrix; (d) computation of alpha (species richness, Shannon index, Simpson index) and beta diversity (e.g. weighted and unweighted Unifrac) with rarefaction; and (e) principal component analysis (PCA) generation. All representative sequences from OTUs will be classified at taxonomic levels from phylum to genus using the high throughput Classifier at RDP II. Community structure will be described using membership and distribution of every member for a given sample. Because the number of reads generated from samples will vary, we will compare the relative distribution instead of the absolute frequency of organisms between samples. The relative abundance for a given taxon will be calculated as the number of reads from this taxon divided by the total number of reads from all taxa.

Anonymized demographic information will be extracted from the main study database and shared with authorized study staff on a weekly basis. Descriptive statistics will be calculated to characterize substudy participants and to evaluate the distribution of key clinical, sociodemographic, and outcome variables. Summary data on medical history, years in the US, access to and utilization of primary health care services, and social characteristics (e.g., marital status, employment) will be reported.

B2: Assessment of Implementation, Adoption, Sustainability, and Scalability Analysis.
B2a. Evaluation Framework. Guided by RE-AIM,[1,101] we will collect data on the delivery of the intervention and its potential for sustainability and scalability with the goal of facilitating its implementation into routine practice. The process evaluation will assess the feasibility, acceptability, and sustainability of the intervention.

B2b. Data Sources and Collection. We will use mixed methods to document challenges, barriers, and facilitators associated with implementing the multifaceted intervention; these will help to characterize feasibility and acceptability in clinic settings, to assess fidelity to the evidence-based strategy, and to determine model sustainability and scalability. Data sources will include: 1) quantitative data on utilization patterns captured from the EHR; 2) qualitative in-depth interview data (key informant interviews) from providers, clinic staff, and CHWs; and 3) ethnographic observational data of workflow at clinic sites, use of EHR tools, and organizational barriers and facilitators.

B2c. Analysis. Analysis to address this aim will be guided by the following questions:
1. Utilization Patterns: How frequently do providers utilize the integrated EHR-CHW system and does the utilization pattern change over time? Does the intervention increase the utilization and quality of measurement reports? The system utilization files from MCIT will be used to analyze utilization patterns of the enhanced decision-support or physician alert function, as well as the integrated EHR-CHW options. These data will yield descriptive trends for frequency of utilization across the clinic sites as well as an estimate of the percentage of adoption in terms of patient follow-up visits. The frequency of quality measurement reports will be described and compared 6 months pre- and post-intervention.
2. Providers and Clinic Staffs' Attitudes Regarding the Integrated Intervention: What are providers' attitudes regarding *H. pylori* eradication guidelines? How satisfied or dissatisfied are the providers and staff with the integrated EHR-CHW tools? What are the barriers and facilitators of point-of-care use of

the tools? How does the intervention affect providers and staffs' satisfaction with workflow for stomach cancer prevention and *H. pylori* eradication? This set of research questions and the following set will be primarily addressed with data from in-depth interviews. Qualitative analysis is described below.

3. Barriers and Facilitators to Implementation Adoption and Implications for Scalability: What organizational barriers and facilitators appear to influence implementation of the integrated EHR-CHW intervention and its component strategies and how? Did members of the clinics understand and respect the respective roles of providers, CHWs, and other members of the team? How were users involved in design and implementation? Interview data will be transcribed and observational data will be collected in the form of field notes.

Analysis of qualitative data from transcriptions and field notes will follow the "constant comparison" analytic approach.[102] The "constant comparison" approach is a method of explanation building in which the findings of an initial case are compared with a provisional category, property or proposition, revised as necessary and then other details or new cases are then compared against the revision and revised again as needed. This iterative process is continued until theoretical saturation is reached.[102] Central to this process is the "thematic" coding scheme. We will develop an initial set of codes, which will be reviewed by the advisory group to ensure that they are relevant and complete. For each core code, we will ultimately develop one or more "secondary codes" that represent either more specific or restricted aspects of the phenomenon, to contextualize it, or to suggest underlying meanings. The secondary codes will vary in specificity or subtlety depending on the judged substantive value of additional refinements. Transcripts will be coded by at least 4 coders. Coding discrepancies will be discussed and resolved, then the process will be repeated with a new set of transcripts until an acceptable level of inter-coder reliability has been achieved, estimated using an appropriate chance-corrected statistic (e.g., kappa for nominal data and T-index for ordinal data).[103] Coded transcripts will be analyzed with ATLAS.ti, a software package for qualitative data analysis.[104] Analysis will be conducted to inform best practices for dissemination and scalability.

C. Data Storage and Confidentiality

Confidentiality will be maintained for participants according to mandatory Institutional Review Board regulations, under the supervision of Dr. Simona Kwon.

EHR-CHW Intervention. Data safety procedures will be implemented for this study to minimize the likelihood that PHI will be improperly used or disclosed. All patient data will be de-identified by NYU staff prior to transfer to NYU databases via a secure sftp site. All electronic PHI associated with the study, including data received from EHR and information received from questionnaires will be stored on password-protected computers behind the NYULMC firewall. Data will ultimately be disseminated through oral presentations, reports and manuscripts and will only contain anonymized data (no PHI).

The following steps will be taken to keep subject's private information secured: any paper files will be stored in locked file cabinets; only NYULMC IT approved and encrypted storage devices will be used to transport/store patient data. Databases will be secured with password protection. The data will be stored indefinitely. Patients' personal information will be kept confidential to the extent permitted by law and will not be released without their written permission except as described in this paragraph. To safeguard confidentiality and anonymity, a unique code will be assigned to participants. Only the study staff will have access to the information that links participants with their unique code. Names of survey participants will not be reported in any publication. All computer systems are protected from possible

external access. Only necessary study personnel will have access to subjects' private information. Efforts will be made to minimize invasion of privacy by using the minimum PHI needed to conduct this research and by protecting the confidentiality of all private information through restricted access and protected storage of study data.

Patient Surveys
To safeguard confidentiality and anonymity, unique identifiers will be assigned to all participants for all portions of the study and all data collection instruments will identify participants only by these unique identifiers. On the baseline and follow-up surveys, the first page of the survey will ask participants for updated contact information so that study staff can maintain contact throughout the intervention period. After the data is collected, the first page of the survey will be removed from the remainder of the survey instrument (which will only contain unique identifiers). Data will be entered into REDCap, a survey database platform, by a study staff member. Only study staff will have password protected access to the data. Laura Wyatt, MPH will serve as the data manager for this study. The Data Manager will be responsible for the management of information obtained at the various clinic sites.
The database will be stored on REDCap's secure database system, which will be utilized for data management purposes. Survey pages containing participant names and contact information and logs linking subjects' identifying information to study numbers will be kept locked in a file cabinet in a secure location. Paper baseline and follow-up survey data will be kept separate from identifiable information and kept in locked file cabinets in a secure location. Contact information from consented participants will be kept on file for the duration of the trial and will be destroyed (both electronic and hard copy) upon the dissemination of trial results (approximately 5 years).

Substudy Biosample Handling and Security. The samples in containers will be received by mail via USPS at NYU Smilow Research Center and stored at -80 ˚C at a laboratory facility with space dedicated to our study samples. Within two weeks of receipt, DNA will be isolated from these specimens and used to conduct microbiome assays. Vials will only be labeled with unique study numbers and be clearly marked as substudy samples. No samples will be collected in a vial labeled with patient identifiers. If a sample does arrive with patient identifiers, those identifiers will be removed and discarded by study staff before storage and will be replaced with a unique study number. Samples will be stored for the duration of the study and destroyed upon the dissemination of trial results (approximately 5 years).

Substudy Data Handling and Security. All samples are traced with a computer database that records sample type, storage location, date of collection and storage, and study identification number. A separate Enrolled Participants' Log will be maintained which links the specimen to the patient through the study identification number. This log will also link the patient to the main study. This log will only be accessible to authorized study staff. Neither patient identifiers nor the key will be available to staff managing samples at the specimen bank. Data and specimens will be stored without linkage codes to ensure the permanent anonymity of the study subjects. Anonymized demographic information will be extracted from the main study database and shared with authorized substudy staff on a weekly basis. Main study and substudy data will be maintained on separate password-protected databases and server locations, and made accessible only to study staff.

Key Informant Interviews. Unique study IDs will be assigned to each key informant in REDCap, and these unique study IDs will track interview logistics (including interview date/time, location), interview audio file names, and interview transcripts. The REDCap data, audio-recordings and interview transcripts

will be saved on a password protected desktop and backed up on a password protected external hard drive, which will be locked in a file cabinet at the NYU Center for the Study of Asian American Health office. Once audio recordings are transcribed and entered onto a password protected database, the recordings will be deleted from the study files. Only study staff will have access to these audio-recordings and study data. To safeguard confidentiality and anonymity, audio-files are de-identified, and subject names will not be collected or included in interview transcripts.

D. Data Sharing Policy

The Principal Investigator, advisory committee and research team staff will be responsible for developing publication procedures and establishing authorship policies. This study will comply with the NIH Public Access Policy, the public will have access to the published results of this intervention. Manuscripts will be submitted to peer-reviewed journals and accepted manuscripts will be submitted to PubMed Central upon acceptance of publication. The study will be submitted to clinicaltrials.gov and updated as necessary in accordance with study development. The clinicaltrials.gov record id is NCT03340454.

IV. RISK/BENEFIT ASSESSMENT

Risks and protection against risks

The proposed study and substudy poses minimal risk to participants. Loss of confidentiality is the greatest potential risk to study subjects. There is very minimal risk in providing oral and/or fecal biosamples. Participants may feel uncomfortable collecting the samples. Participants can choose not to collect the sample(s) if they are uncomfortable. Locked file cabinets will be used to store materials with identifying information. All computer systems are protected from possible external access. All data and interviews will be stored on a password-protected computer at the NYUGSOM. Names will be replaced with identification numbers. All audio recorded key informant interviews will be stored on a password-protected secure computer at the NYUGSOM. Once audio recordings are transcribed and entered onto a password protected database, the recordings will be deleted from the study files. Key informant participants will have the right to refuse to participate without any compromise of their employment status, reputation or professional relationships. Records of participations will not be linked to employment records. Also, if a participant is uncomfortable during an interview situation, they may stop the interview at any time without penalty. The data collected for this study will be used strictly for the purposes stated in this application and will only be available to NYU research staff.

Potential Benefits to the Subjects

CHW Intervention: By participating in the proposed research, participants may gain the benefit of augmented services related to their *H. pylori* treatment and stomach cancer-related risk factors. Some patients may individually experience no benefit. This study will yield knowledge regarding methods for increasing adherence to evidence-based guidelines for treating *H. pylori* among providers and health staff serving Chinese American populations. Overall, the benefits of understanding effective methods for helping patients reduce their risk of stomach cancer through incomplete treatment of *H. pylori* far outweigh the remote possibility of a breach of confidentiality.

Substudy: While participants may individually experience no benefit, the substudy will yield further knowledge of the oral and gut health of Chinese Americans with H. pylori and the impact of antibiotic therapy on their microbiome.

Key Informant Interviews: Participating providers and clinic staff may benefit from the interventions which are meant to assist them with improving the quality of care they provide for Chinese American patients at-risk of stomach cancer. The study may also have relevance to the US health care system by testing a practice facilitation model to enhance implementation of team-based care integrated with EHR systems for preventing stomach cancer.

Unanticipated adverse events

An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.
Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in nature, severity, or frequency (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
- Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)

Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

Unanticipated adverse events reporting

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. The investigator is responsible to report unanticipated problems to their IRB and to the study sponsor. The unanticipated problem report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an unanticipated problem;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, Unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the IRB and to the study sponsor within 10 business days of the investigator becoming aware of the event.
- All unanticipated problems will be reported to the IRB and to the study sponsor within 10 business days of the investigator becoming aware of the problem.

V. INVESTIGATOR'S QUALIFICATIONS & EXPERIENCE

NYU Personnel

Simona Kwon, DrPH, MPH is an Associate Professor of Population Health within the NYU School of Medicine and will serve as the PI of this study; she has substantial experience in adapting and implementing evidence-based research interventions in Asian American communities. Dr. Kwon is the director of the CSAAH (NIMHD U54MD000538) and has established research partnerships with 20 Asian American-serving community organizations with a track record of recruiting thousands of study participants in various CSAAH research trials. Dr. Kwon's research includes the following: director of the 5-year B Free CEED:

National Center of Excellence in the Elimination of Hepatitis B Disparities, a multi-level hepatitis B and liver cancer prevention center (CDC U58DP001022) where she played a critical role in the design and dissemination of evidence-based strategies to reduce hepatitis B and liver cancer disparities among Asian American communities; and co-investigator on several CHW-led interventions, including Project DREAM examining the effectiveness of CHWs in diabetes management in Bangladeshi Americans in community settings (NIMHD P60MD000538). This proposal builds on a completed Perlmutter Cancer Center pilot grant (PI: Kwon) to test the feasibility and acceptability of a CHW intervention for stomach cancer prevention to enhance adherence to *H. pylori* eradication treatment in LEP, Chinese American patients.

Devin Mann, MD, MS, is an Associate Professor of Medicine at the NYU School of Medicine and the Senior Director of Informatics Innovation and will serve as co-investigator on this study. Dr. Mann has extensive expertise in health systems and EHR-based interventions which will be critical for ensuring pragmatic workflow integration and clinical adoption for the proposed integration of the Community Health Worker workflows into the electronic health record.

Thaddeus Tarpey, PhD will serve as the biostatistician for the study. He is the current Director of the PhD Graduate Program in Biostatistics. Dr. Tarpey will provide epidemiological and biostatistical support.

Chau Trinh-Shevrin, DrPH, is an Associate Professor of Population Health and Medicine, the Vice Chair for Research within the Department of Population Health and the Chief for the Section for Health Equity within the New York School of Medicine. Dr. Trinh-Shevrin and will serve as a scientific advisor to this study. Dr. Trinh-Shevrin ‘s research for the last 20 years has been centered on the rigorous development and evaluation of multi-level strategies to reduce health disparities and advance health equity.

Renee Williams, MD is an Assistant Professor of Medicine within the Division of Gastroenterology at the NYU Langone Medical Center and will serve as co-investigator from NYC Health+Hospital/Bellevue. Dr. Williams will provide clinical and site workflow experience and access to the patient communities.

Yu Chen, PhD, MPH is a Professor of Population Health and Environmental Medicine within the NYU School of Medicine and will serve as a co-investigator of the substudy. She has extensive experience as a chronic disease epidemiologist. Her research has focused on the role of the gastric and oral microbiome in gastric premalignant and malignant lesions.

Yi-Ling Tan, MPH is the Program Manager for the NYU Center for the Study of Asian American Health. She has managed various multi-site clinical trials and community-based research studies in numerous settings. Ms. Tan received her MPH in Forced Migration and Health from Columbia University, Mailman School of Public Health.

Angel Mui, MEd, is the Project Coordinator for the NYU Center for the Study of Asian American Health. She provides patient and community outreach and engagement and assist with project and research coordination activities including data collection, data analysis, and participant recruitment and retention. She has experience in supporting a number of public health projects in the fields of community health research for Chinese-American communities. She received her BA in Psychology and Asian Studies from Cornell University and earned her MEd in Mental Health Counseling at Teachers College, Columbia University.

Laura Wyatt, **MPH** is the Research Data Manager for the NYU Center for the Study of Asian American Health. She manages and oversees the data sources across CSAAH, which includes the NYU-CUNY PRC, and performs analyses and assists with the dissemination of study findings. In addition, she provides epidemiological and biostatistical support for grant development activities within the center. Ms. Wyatt received her MPH in Epidemiology from Columbia University, Mailman School of Public Health and also studied public health at the University of North Carolina at Chapel Hill.

VI. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

A. Method of Subject Identification and Recruitment

EHR-CHW Intervention: H. pylori infected individuals will be identified and recruited into the study from the following NYC health care facilities: NYU Langone Health – which includes NYU Langone Brooklyn, NYU Langone Brooklyn Family Health Centers and affiliated provider practices, and NYU Ambulatory Care Centers – Bellevue Hospital Center and Gouverneur Hospital. Participants will be identified by 2 approaches: 1) using ICD codes for *H. pylori* and Chinese ethnicity identified through a race and language code available in EHR, patients with recently diagnosed *H. pylori* infection (within 7-days) will be identified; via a EHR registry list, and 2) patients will be recruited directly at the above mentioned sites, all of which serve a substantial Chinese American population. In endoscopy clinics, patients are routinely evaluated for *H. pylori* infection.

CHWs will complete a brief screening form with potential participants in person or via phone, depending on the preference of the potential participant and the safety of the study staff and potential participants. The form will assess demographic characteristics, participant eligibility, COVID-19 symptoms, interest in our program, and reasons for refusal to participate. For in-person screenings, if the patient is eligible and interested in the study, the CHW will obtain verbal informed consent for study participation and describe the randomization process (See *Combined Verbal Informed Consent*). All study staff will follow COVID-19 workplace safety, personal protective equipment and social distancing policies at each recruiting clinic site and as required by NYUGSOM.

Individuals identified from the registry list will receive phone calls by CHWs (See *Combined Script for Telephone Screening*), during which CHWs will explain the study and elements of informed consent, and will complete the process for verbal informed consent over the phone with interested, eligible individuals. Participant names and phone numbers will be needed in order for the CHWs to contact participants regarding participation in the intervention (Please see *Application for Waiver of Authorization and Documentation of Consent*). In addition, a screening form (See *Telephone Screening Form for CHW Intervention*) will be completed to verify eligibility. CHWs will call patients a maximum of 3 times over a one-week period at varying times of the day to invite them to enroll in the study. CHWs will compile and share contact information for consented study participants with the study coordinator on a weekly basis.

Substudy. The substudy is only open to participants who are enrolled in the EHR-CHW intervention. Once participants have consented to being in the EHR-CHW intervention, CHWs will explain the substudy and elements of informed consent, and will complete the process for verbal informed consent over the phone with interested individuals. Study staff who have obtained the verbal consent will

document the consent and the date of consent on the Enrolled Participants Log. The Enrolled Participants Log is the only record linking a participant's name, subject ID and substudy ID (if applicable). No undue pressure will be given to subjects to participate in both studies as participation is entirely voluntary (See Combined Verbal Informed Consent).

Key Informant Interviews. Participating providers, administrative staff and community health workers of clinic sites will receive an invitation to participate in the interview (See *Invitation and Elements of Informed Consent for Key Informant Interview*). No undue pressure will be given to subjects for participation as the participation is entirely voluntary (See *Verbal Consent Script for Key Informant Interview*).

B. Process of Consent

All study personnel will have completed the NYU IRB Mandatory Tutorial and IRB Health Insurance Portability and Accountability Act (HIPAA) Training before commencing any data collection activities. The informed consent form for this study have been created by the NYU School of Medicine Office of Science and Research in accordance with Federal guidelines, including HIPAA.

EHR-CHW Intervention. To maintain consistency in consent procedures and to reduce selection bias, verbal informed consent obtained for both in-person and telephone enrollment (see *Application for Waiver of Authorization and Documentation of Consent*).

If screening is conducted in person, consent processes will take place at clinic sites in a manner that maximizes confidentiality and privacy and allows questions to be asked. All study staff will follow COVID-19 workplace safety and personal protective equipment policies at each recruiting clinic site and as required by NYUGSOM. Participants will be screened in advance for symptoms and asked in advance to wear a mask/face covering. All study staff and participants will follow efforts for social distancing whenever possible. Eligible participants demonstrating interest in participating in the project will meet with a study team member who will explain the intervention and answer any questions. Verbal consent (*see Combined Verbal Informed Consent)* will be obtained in a location allowing privacy and appropriate social distancing, on a one-on-one basis.

Participants are free to withdraw from participating in the study at any time without repercussions. Participants will be advised during the consent process that they have the right to withdraw entirely and that their refusal will not jeopardize their relationships with their CHW or primary care physician.

*Substudy***.** Only participants already enrolled in the main study are eligible for the substudy. Study staff will obtain verbal consent from interested participants (*see Combined Verbal Informed Consent*) and offer subjects the opportunity to participate in the substudy in several ways: 1) provision of oral wash sample only; 2) provision of stool sample only; and 3) provision of both oral wash and stool samples. Participants will be advised participation in the substudy is optional and that their refusal to participate in the substudy will not jeopardize their participation in the EHR-CHW Intervention. Participants are free to withdraw from the substudy at any time without repercussions.

Key Informant Interviews. A Waiver of Documentation of Consent is being requested for participants of Key Informant Interviews for this study (See *Application for Waiver of Documentation of Consent for*

Key Informant Interview). This request is being made because the consent form, if collected would require names to be collected and in doing so would be the only record linking the subject's name to the research. Verbal consent will be obtained to audio-record prior to the start of the interview, but we will not collect any personal information or identifiers. Individual names will not be recorded or appear in interview notes. Participants will be free to withdraw from the interview at any time without repercussions. Participants will be provided with an invitation including the elements of the written consent as well as contact information for the study PI. Verbal consent will be obtained from the key informants prior to beginning the interview in-person or over the phone as preferred by participant (See *Verbal Consent Script for Key Informant Interview*).

C. Capacity

We anticipate that all subjects will have the capacity to give informed consent. Language barriers will be minimized by having data collectors who speak Chinese and translated consent scripts for the CHW intervention (to be translated upon approval of the English version).

D. Subject/Representative Comprehension

To determine that the subject or his/her authorized representative understood the information presented, they will be given the opportunity to ask questions before giving consent to participate. They can also choose at that time not to be in the study. The individuals authorized to obtain consent will do so by going over the Verbal Informed Consent script with the potential subject. The individuals will explain the purpose of the study, the procedures, possible risks and anticipated benefits, that it is voluntary, and how to withdraw if they choose to at a later time. Chinese speaking personnel will obtain consent from limited English-speaking individuals using a translated Verbal Informed Consent script. Subjects will also be asked if they are willing to receive key information about the study by text message. If they are, the Key Information Sheet will be texted to them using an NYU-issued, password-protected telephone.

E. Debriefing Procedures

Information will not be withheld from the subjects related to their participation in the study.

F. Consent Scripts

Please refer to the consent scripts: *Combined Verbal Informed Consent Script* and the *Key Information Sheets for CHW Intervention* and *the substudy;* and *Invitation and Elements of Consent* and *Verbal Consent Script* documents for the Key Informant Interview.

G. Documentation of Consent

EHR-CHW Intervention and Substudy. Study staff will obtain consent by reading the verbal informed consent script to the subject or the subject's legally authorized representative, and the subject or representative will be given adequate opportunity to ask questions before verbally consenting. The subject will receive a copy of the key information sheet by text message if they choose so. A translated verbal informed consent and key information sheet will be used for non-English speaking subjects, depending on their preferred language.

Study staff who have obtained the verbal consent will document the consent and the date of consent on the Enrolled Participants Log. The Enrolled Participants Log is the only record linking a participant's name, subject ID and substudy ID (if applicable).

Signed informed consent forms from participants consented in earlier versions of the protocol will be stored in a separate folder in a locked cabinet accessible only to study staff.

Key Informant Interviews. A Waiver of Documentation of Consent is being requested for participants of the Key Informant Interview for this study (see *Application for Waiver of Documentation of Consent for Key Informant Interview*). This request is being made because the consent form, if collected, would require names to be collected and in doing so would be the only record linking the subjects name to the research. Verbal consent will be obtained prior to the start of the interview, but we will not collect any personal information or identifiers. Names of individuals will not be recorded nor appear in interview notes. Participants will be free to withdraw from the interview at any time without repercussions. Participants will be provided with an invitation including the elements of written consent as well as contact information for the study PI. Verbal consent will be obtained from the key informants prior to beginning the interview (See *Verbal Consent Script for Key Informant Interview*).

H. Costs to the Subject

There are no costs to participate in this study. Any doctor visits and laboratory tests, including the fecal antigen test or other clinically approved *H. pylori* infection diagnostic test, are part of standard care.

I. Payment for Participation

Participants will receive a payment of $25 each time they complete a questionnaire (baseline, 2 months and 6 months). Participants may receive metro cards for travel associated with the project.

Substudy. Subjects will be given a $20 gift card if they provide one type of sample only (either oral wash or stool), and a $35 gift card if they provide both oral wash and stool samples. Gift cards will be mailed or given to subjects upon successful return of biosamples collected post-*H. pylori* medication completion.

J. Subject Withdrawal

Any of the participants may withdraw from the study at any time. This will not affect their services and care at the clinic site. If a participant is uncomfortable during an interview or survey administration, the participant may stop at any time without penalty. If a participant withdraws consent, no further data from that participant will be collected.

Early Termination. The study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the investigator and/or the NIH NIMHD, as applicable. If the study is prematurely terminated or suspended, the PI will promptly inform the Institutional Review Boards (IRBs) and provide the reason(s) for the termination or suspension. Circumstances that may warrant termination include, but are not limited to:

- Determination of an unexpected, significant, or unacceptable risk to subjects.
- Insufficient adherence to protocol requirements.
- Data that are not sufficiently complete and/or evaluable.

VII. FUNDING SOURCE

The main study is supported by NIH-NIMHD U54 MD000538. The substudy is supported by NIH-1P20CA252728-01

VIII. APPENDIX

A. Combined Script for Telephone Screening
B. Screening Form for CHW Intervention
C. Combined Verbal Informed Consent
D. Key Information Sheet for CHW Intervention
E. Key Information Sheet for Substudy
F. Baseline Survey for CHW Intervention
G. Follow-up Survey for CHW Intervention
H. Script for Substudy Telephone Text Reminders
I. Substudy Instruction Booklet
J. Key Informant Interview Guide
K. Invitation and Elements of Informed Consent Written Text for Key Informant Interview
L. Verbal Consent Script for Key Informant Interview
M. Application for Waiver of Authorization for Telephone Screening Form
N. Application for Waiver of Documentation of Consent for Key Informant Interview
O. Application for Waiver of Authorization and Documentation of Consent

IX. REFERENCES

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