

# Study Procedures: Main Study

## **\*\*All Gift Cards:**

Notify Yi-Ling and Stella when address is confirmed in Enrolled Tracking Sheet - Participant ID Sheet

## **Recruitment**

- Verbal Consent
- *Baseline Form*
- Randomization

## **Weekly Calls:**

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

## **Daily Check:**

Yi-Ling, Stella, Janet (EPIC)

## **Referrals: CHWs**

- Screening
- Consent
- Key Information Sheet

## **Randomization: Stella**

## **Enrolled Pt: CHWs**

- Enrolled Tracking Sht
- Participant Folder
- CHW Encounter Log
- CHW Encounter Report

## **Intervention Group**

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

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

## **Control Group**

- Reminders (retest, surveys)

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

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

Anna, Alice, Stephanie, Angel, George, Stacy

## **Data Entry (email when ready):**

Stella enter into REDCap)

# 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

# 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 desk phone number and the iPhone number
- Do not give them your personal number

# ENROLLMENT

If the participant does not have much time:

- Administer verbal consent
- Get participant contact information
- Arrange for another time (within 1-5 days) when you can administer the baseline survey and possibly the first health education session in-person
- Do not assign Subject UID for now

# BASELINE SURVEY

- All questions on the baseline survey should be collected:
  - **On the day of enrollment** (*as much as possible*)
- 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

GJ 8/16/21    ☒ Less than \$25,000

—

# RANDOMIZATION

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

- He/she has verbally consented
- 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:** 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

- Give patient health education materials
- 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

- Give patient health education materials
- 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

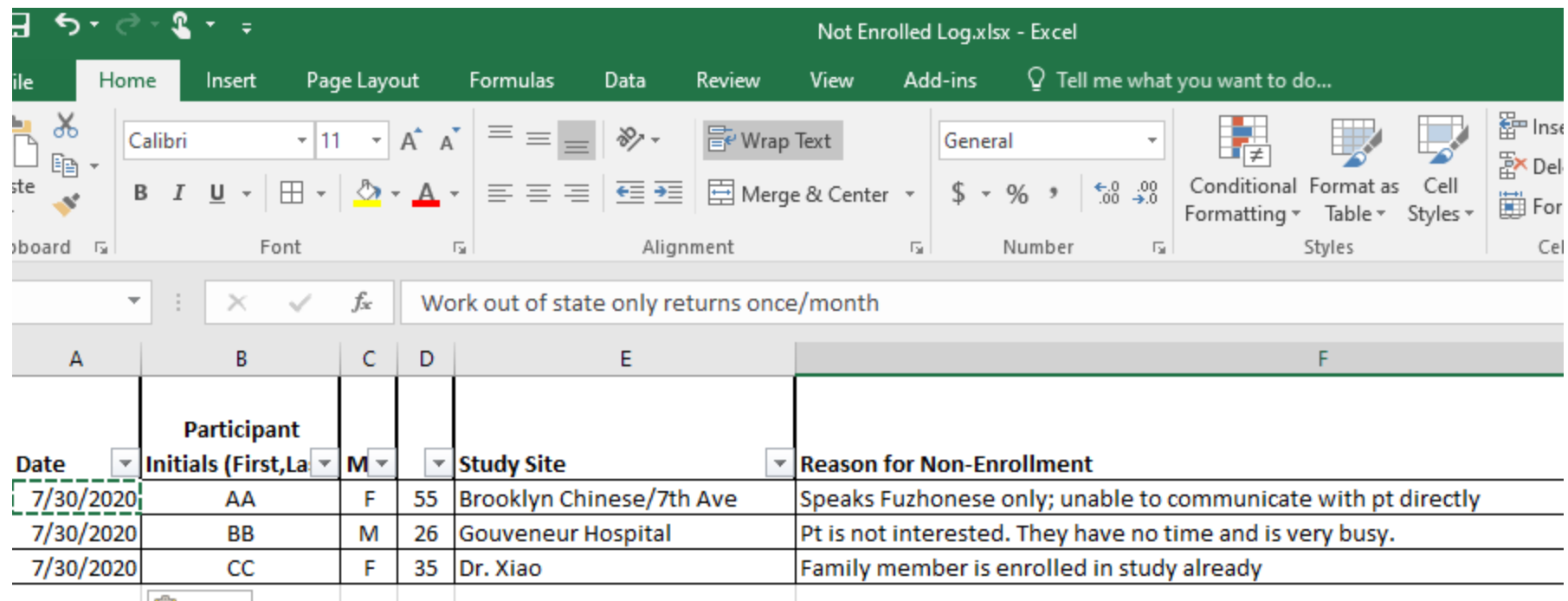
J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Study forms\Gift Cards

# 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



The screenshot shows an Excel spreadsheet titled "Not Enrolled Log.xlsx". The ribbon includes tabs for File, Home, Insert, Page Layout, Formulas, Data, Review, View, Add-ins, and a search bar. The Home tab is active, showing options for Font (Calibri, size 11), Alignment (Wrap Text, Merge & Center), Number (General), and Styles (Conditional Formatting, Format as Table, Cell Styles). The formula bar shows "Work out of state only returns once/month". The table below has columns A through F. Column A is Date, B is Participant Initials (First, Last), C is Middle Initial, D is Age, E is Study Site, and F is Reason for Non-Enrollment.

A	B	C	D	E	F
Date	Participant Initials (First, Last)	Middle Initial	Age	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 enrolled (Verbal Consent/Baseline):
  - Inform Team
  - Add Participant Information into Enrollment/Participant Tracking Sheet
  - J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants*
  - Create Participant ID folder and CHW Encounter Log
  - Complete CHW Encounter Report
  - J:\CSAAH\Gastric Cancer\U54 MAIN STUDY\Participants\CHW Encounter Reports*
- If address given, provide to Stella/Yi-Ling via participant tracking sheet. They will mail:
  - ClinCard and ClinCard Letter
  - Patient health education materials
  - Substudy biosample collection kit (if applicable)