README

The README should a brief description of the study (including a general orientation to the study, its components, and its examination and follow-up timeline), a listing of all files being provided, a description of system requirements, a generation program code for installing a SAS file from the SAS export data file (if appropriate), and a frequency distribution for selected key variables.

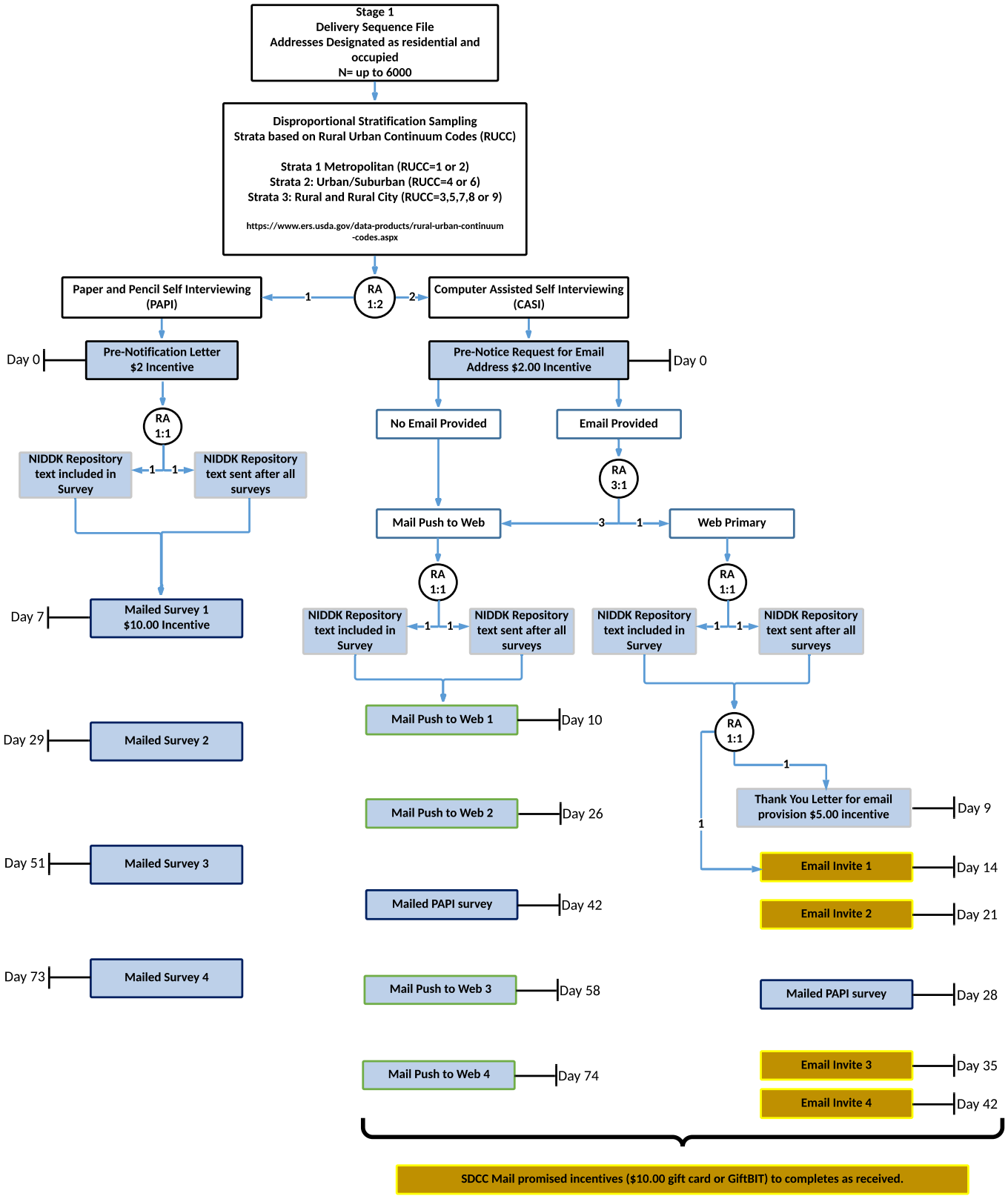
Description of the study – Excerpts from Protocol

The Prevention of Lower Urinary Symptoms (PLUS) Research Consortium is working to optimize prevention of lower urinary tract symptoms (LUTS) in women and adolescent females across their life spans. The ability to measure bladder health and key risk and protective factors is crucial to the PLUS mission. To describe and measure the spectrum of bladder health in diverse populations, researchers need a valid and reliable instrument. To date, the Consortium's work on design of a bladder health instrument has been a culmination of expert opinion, information from focus groups, and incorporation of previously validated items and language where appropriate, along with cognitive interviews of participants from the general public. The next step in the consortium's work is to prospectively collect data to test and validate bladder health instrument (BHI) items for inclusion in a final bladder health scale (BHS) that can assess the full range of bladder health of women.

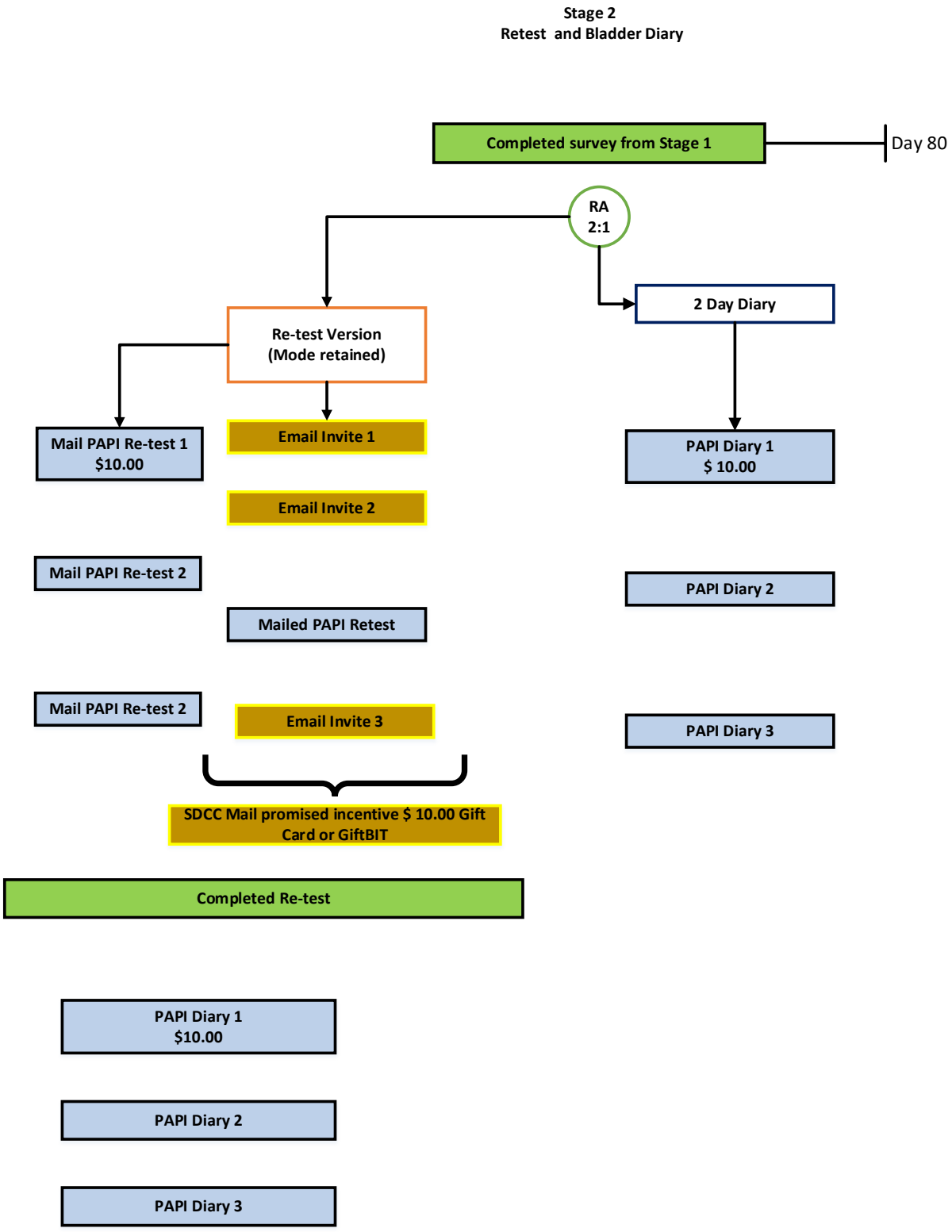
General Population Sample

To ensure the BHI is valid for use in both paper and pencil as well as electronic mode of administration, we plan to randomize participants to a paper and pencil instrument (PAPI) mailed version of the survey or a computer assisted survey instrument (CASI) web-based version of the survey. All sampled individuals will be asked for permission to be re-contacted after completion of the survey. Consenting respondents who have fully completed the initial validation survey will randomly assigned to either the retest and bladder diary sample or to a bladder diary only sample.

Stage 1 General Population Sample Plan



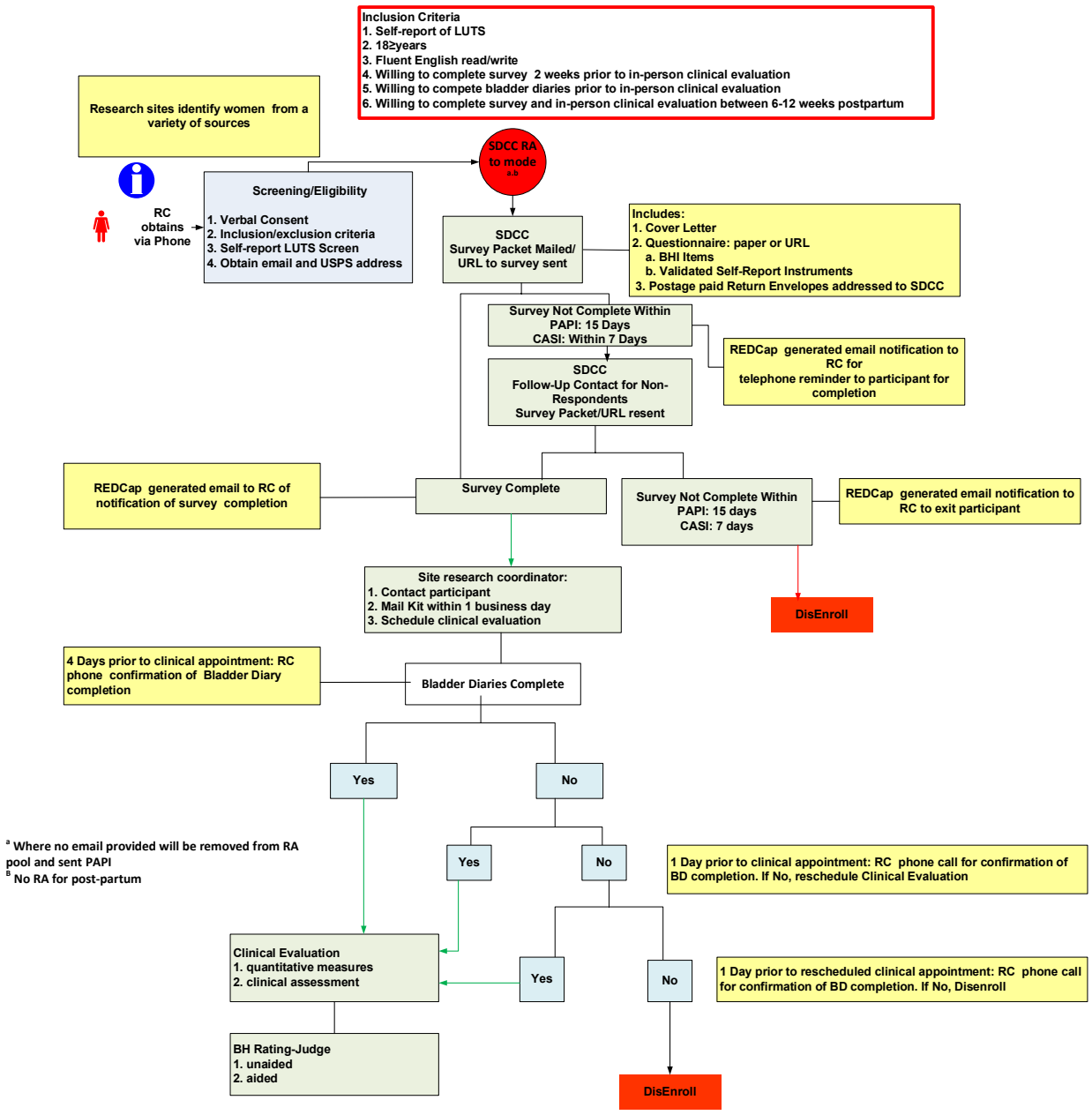
Stage 2 General Population Retest and Diary Sample Plan



Clinical Evaluation Sample

The other intended use of the BHS is to draw inferences related to bladder health for use in clinical research. Once participants are recruited and enrolled, only those who provide contact information for both home address *and* email will be eligible for randomization to PAPI vs. CASI survey administration. As participants are enrolled, they will be assigned (via block randomization by the SDCC) to either a PAPI or a CASI based mode of the BHI survey. Those who do not have email capability will be included in the PAPI arm.

Clinical Sample Recruitment and Enrollment



List of Provided Files

The data files have been split between the survey data (BHI and BHI Re-Test) and the clinic data. In the survey data file, there are a few key variables that identify groups:

- General Population vs Clinical Population
  - [gp_cp] indicates if the participant is a General Population (genpop) or Clinical Population (clinpop) participant.
- Clinical Post-Partum Population
  - [postp] indicates if the clinical participant is also a post-partum participant ([postp] = '1'
- Paper Survey Completers vs Electronic Survey Completers
  - [papi_comp] & [papi_rt_comp] indicate if the participant completed the survey on paper ([papi_comp] = '1' & [papi_rt_comp] = '1') or online ([papi_comp] = "" and [papi_rt_comp] = "").

1. **Study Data Collection Files**
   a. Annotated Forms
      i. Study Forms
         1. BHI
         2. BHI Retest
         3. Form 8 Participant Exit
         4. Form 9 Adverse Event
         5. Form 10 Protocol Deviation
         6. 2-Day Bladder Symptom Diary
      ii. Clinic Forms
         1. Form 1 Participant Screening
         2. Form 4 Clinical Tests
         3. Form 5 Judge Initial Rating
         4. Form 6 Judge Second Rating
         5. 1-Day Bladder Diary
   b. Formatted PDFs
      i. All formatted versions of the Study Forms and Clinic Forms
   c. List of Copyrighted Survey Sections
   d. Additional Form Instructions
      i. 1-Day Bladder Diary Instructions
      ii. 2-Day Bladder Diary Instructions
      iii. Judge Instruction Handout
2. **Study Data**
   a. Survey_Forms.sas
   b. Survey_Forms.csv
   c. Clinic_Forms.sas
   d. Clinic_Forms.csv
3. **Study Documentation**
   a. VIEW Protocol
   b. VIEW MOP

c. Survey_Forms_DataDictionary.csv
d. Survey_Forms_Codebook
e. Clinic_Forms_DataDictionary.csv
f. Clinic_Forms_Codebook
g. Bibliography of Publications
h. Contents File

Description of System Requirements

No specialized software required

Additional Data Information

Some clinpop participants (n=23) were removed from survey validation analysis because they received clinical study information in the mail before completion of their baseline survey. These participants are identified in the survey data by variable/value [cp_removal] = '1'.

Some clinpop participants (n=6) were also removed from analysis of clinic and diary data because their clinic visit was too far past their completion of the BHI. These participants are identified in the clinic data by variable/value [cp_removal_cvdiary] = '1'.