

Greater Plains Collaborative (GPC)



Greater Plains Breast Cancer Group University of Iowa Coordinating Center

Standard Operating Procedures Survey and Consent Processing and Data Entry

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Version 1.1



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1. MAIL RETRIEVAL

- a. Nick will check mail each day (unless on vacation); if Nick is unable to check, then the next staff member who is able to will.
- b. Place study envelopes on top of “To Be Processed” cabinet with date received on post-it note

2. RECEIVING

- a. Open envelope
- b. If envelope contains a booklet, write date and initials and an 'R' on page 1 of the survey (to the right of study ID)
- c. Affix a post-it with initials, study ID (if known), and date to any other study materials. Some examples include:
 1. Extra consent document
 2. Correspondence from the recipient
 3. Cover letter sent to the patient
- d. If the process needs to be paused at this stage, booklets and other materials should be placed together in the "To Be Processed" cabinet on the "Received" pile waiting to be logged

3. LOGGING (Receiving complete)

- a. Log survey, medical record consent, future studies and cash/gift card (if applicable) into REDCap
 - i. Enter 'Received' date for the following: 'Survey Status Date', 'Medical Record Consent Status Date', and 'Future Consent Status Date'
 1. If either consent requires follow-up, enter 'Received' date for now. Once the completed consent is received, update REDCap with the new 'Received' date for both/either 'Medical Record Consent Status Date' and/or 'Future Consent Status Date'
 - ii. Visually scan booklet for completeness and comments that may impact whether and how the booklet contents are logged
 1. Future Studies: If one/both yes/no question(s) is/are left blank, do not enter a response for that question. Leave it blank and fill out the rest of the form.
 2. If participant has completed the Medical Record OR Future Studies consent in the booklet, but completed the other consent in their extra copy, select 'Returned-Information Provided'. Leave all other responses blank except for the 'Consent Status Date' (enter the date that the consent is logged). In the comments section, explain what has happened along with the responses that the participant gave. Once logged, place booklet in "Needs Contact" folder with post-it explaining what is missing.
 - iii. If participant didn't have breast cancer, log this under 'Survey Status' and file whole booklet into respective folder. No other logging needs to occur for these types of cases.
 - iv. If any of the three elements (printed name/signature/date) for consent are missing, file whole booklet into "Needs contact" folder
 - v. If medical record consent is fully blank but participant completed the future studies section log the future studies section in REDCap as 'N/A – MR consent declined/blank'
- b. Check for 'Study Contact' entry (discussion of consent)
 - i. If participant contacted Nick or Betsy:
 1. File whole booklet in folder for "To Nick" or "To Betsy", respectively, with a post-it initialed/dated & write "Contacted by ___" on it
 2. Email them to let them know, and ask them to complete and place in the 'From' folder for their name
 - ii. If participant spoke with staff at another site:
 1. Find staff email and fax information
 2. Send email to let staff know that you will be sending a form for signature and dating
 3. Fax a cover sheet and Page 28 to the staff and ask them to complete and fax back to you

- iii. If there is nothing in Redcap to indicate that the participant spoke with research team staff, and the subject printed, dated and signed the medical record consent, put an 'x' in the first box on Page 28 of the booklet in black ink.
- c. If money/gift card was returned:
 - i. Give to Nick immediately with the affixed post-it note described in 2 above.
 - ii. If Nick is not in the office or unavailable
 - 1. Send an email to let him know those are waiting for him with the \$ amount he should be expecting
 - 2. Place in Questions/Misc. cabinet in the "To Nick" folder
- d. File other materials aside from the survey or medical record consent accordingly. Some examples include:
 - i. Extra consent document
 - 1. If patient completed the medical record consent in the booklet, then file the extra copy in the misc folder to be sent back to the patient
 - 2. If the medical record consent in the booklet was blank (patient declined), then file in the site drawer, in the extra consents folder
 - 3. If the medical record consent in the booklet was only partially completed or follow up with the patient is needed to check on the patients' intent, then retain the extra consent with the booklet version of the informed consent document and place in the appropriate folder in the misc. drawer
 - ii. Correspondence from the recipient
 - 1. If actionable, file and contact the appropriate person to resolve.
 - 2. If not actionable, file.
 - iii. Cover letter sent to the patient
 - 1. If there are no comments on the letter that need attention, shred.
 - 2. If there are comments on the letter that need attention, file and contact the appropriate person to resolve.
 - iv. Blank study booklets
 - 1. Once logged, file booklets that were returned with completely blank covers and guts in the appropriate site folder.
- e. Write date and initials and 'L' on page 1 of survey (to the right of first date/initials)
- f. If the process needs to be paused at this stage, booklets should be placed in the "To Be Processed" cabinet on the "Logged" pile waiting to be edited

4. EDITING (Receiving and Logging complete)

- a. For items that have light marks, darken the mark with a BLACK pen
- b. For items that are only slightly marked in the intended box, darken the mark with a BLACK pen
- c. If more than one response is completed for a given question, but one is correct:
 - i. In RED pen, draw two horizontal lines through all response categories
 - ii. Put a dark "X" in the correct response box and circle it
 - iii. Write date and your initials near that edit
- d. If a subject uses white out to cover over a response treat that whited out response as an additional response (see procedure directly above)
- e. If the year born, phone and/or email address is not clearly written, strike out the entry field with double horizontal lines, write in the correct value above or below the entry field and circle it, and write in date and your initials adjacent to the circled value
- f. If response is not meant to be checked, write 'Not checked' above or below the entry field and circle it, and write in date and your initials adjacent to the circled value
- g. If email does not contain a "@", cross it out and write "NULL" above it. Date/Initial.
- h. Any surveys with field editing questions that need discussing go in "Field Questions" folder for Natalie to address (email or meetings), resolve and log
- i. Surveys that contain likely full page omissions (e.g., all but two adjacent pages were completed, signaling that the pages may have been stuck together) an attempt at patient contact should be made. File in the 'Needs Contact' folder.
- j. Write date and initials and an 'E' on page 1 of the survey (to the right of the two prior dates/initials)
- k. If the process needs to be paused at this stage, surveys should be placed in the "To Be Processed" cabinet on the "Edited" pile waiting to be scanned

5. SCANNING (Receiving, Logging, and Editing complete)

- a. Reserve the TeleForm Scan Station software at
<https://sharepoint.uiowa.edu/sites/cph/teleform/layouts/15/start.aspx#/SitePages/Home.aspx>
- b. Remove booklet cover
 - i. If blank, place in respective site's "Blank Covers" folder
 - ii. If there are comments, place in respective site's "(State) Covers" folder
- c. Cut off stapled end of booklet guts with paper trimmer or scissors
- d. Separate survey and consent sections
- e. Batch surveys in groups of no more than 5 (110 pages) within the same site
- f. Log into Scan Station
 - i. Click 'New batch'
 - ii. Check make sure:
 1. Details>Job = 'GPC Breast Cancer'
 2. Process>Source = the name of the scanner you are using (For the scanner in 2136 WL, this would be 'Canon DR-6050C TWAIN')
 3. Process>Settings: '200 DPI Duplex'
 4. Process>Feeder: 'Front & Back'
 - iii. Load the batch you intend to scan
 - iv. Click 'Start'
 - v. Click 'OK' when the batch is done.
 - vi. Confirm that multiples of 22 pages were scanned for surveys, and multiples of 6 pages for consents. If not you may need to delete pages before accepting the batch.
 - vii. Check to see if any page images were rotated when scanned – if so you may need to discard and rescan the batch or rescan pages
 - viii. Wait until the status of the batch proceeds past 'Evaluating' to "Ready for Correction" before logging out of Scan Station
- g. Write the batch number on a post-it and affix to the front of the batch.
- h. If the survey process needs to be paused at this stage, surveys should be placed in the "To Be Processed" cabinet on the "Scanned" pile waiting to be filed

6. FILING

- a. File materials (in order by Study ID) into respective folders, by site

7. VERIFYING

- a. Reserve the TeleForm Scan Station software at <https://sharepoint.uiowa.edu/sites/cph/teleform/layouts/15/start.aspx#/SitePages/Home.aspx>
- b. Log into Verifier
- c. Select “Batch management dialog”.
- d. Batches with the status of ‘Ready for correction’ are ready for correction.
- e. If any such batch contains one or more counts in the ‘nonform’ column, contact Brian to let him know – disregard this batch for now. This typically means that there was a problem with how a page was scanned. The page needs to be manually verified or rescanned.
- f. Right click or double click on a batch.
- g. Use the controls below and verify the form.

To Do This	Press Key(s)
Change a suspect character to an alphabetic character	A through Z
Change a suspect character to a numeric character	1 through 9, 0
Change a suspect character to a special character	@, #, \$, %, and so on.
Accept the “best guess” replacement character and move to the next questionable character	ENTER, =
Select all characters in the current field	SHIFT + ENTER
Insert a new line in a multi-line Image Zone	CTRL + ENTER
Move to the next field	TAB
Move to the previous field	SHIFT + TAB
Switch between Insert and Overstrike mode	INSERT

- h. Select “Image management dialog” to view the form and individual fields in it as verified.
- i. Once a form has been corrected, the status should change to ‘Ready to be committed’. Committing a form writes the data to the database and the PDF images to a network folder. Right click on the batch and select ‘Commit’.
- j. Once committed, the survey and consent form data should be written to [ph-db].[GPC Breast Cancer Survey] and PDF images of both should be created at \\TeleForm Data\HERCe\Breast Cancer\Scanned Images\