Manual of Operations for CHS Streamlined Death Investigation and Adjudication

I. Introduction

As of 11/30/2015, CHS field centers discontinued investigation of deaths because the CHS Events grants ended. Telephone surveillance calls are being continued for 3 years which will identify new deaths in the remaining cohort. Review of obituaries by local staff will also identify new deaths along with new CMS data searches. In addition to the newly identified deaths, there remains a backlog of deaths prior to the end of the Events grant that were never investigated by the field centers. The CHS All Stars ancillary study has great interest in continuing the investigation of the survivor cohort as they continue aging into their 90s and older, and will support a streamlined version of previously used Events methods, as outlined below.

Based on the known backlog of uninvestigated deaths at each site, and an estimated crude rate of 43.4% mortality over the next 3 years, the projected number of cases per site to investigate over the next year is shown in the table below.

	# Alive as at Yr28 call	Current Backlog of Deaths by Site	# of Deaths in Active Subjects only	Estimated New Deaths in Current Year	Total Estimate of Deaths Requiring Investigation	Current Deaths to Investigate as of 8/16/2016
Wake	137	37	19	20	39	24
Davis	156	27	24	23	47	24
JHU	77	8	7	11	18	2
Pitt	133	4	3	20	23	11
Total	503	76	53	74	127	61

II. Changes from Prior Events Investigation Protocol

The procedures to investigate and adjudicate Events have been streamlined significantly. There will be no investigation of morbid events. We anticipate using CMS data in the future to identify hospitalizations. There are no data abstraction forms and no data entry. There will not be any local adjudication, and the final adjudication will be handled by investigators in Pittsburgh. There will not be any mailing of documents to the coordinating center. All support documents will be scanned, redacted, and labelled in Adobe, and uploaded to a secure website at the coordinating center.

As of 8/31/2017, the procedures to follow have been streamlined further. These changes will be noted in italics. The original and streamlined procedures as described in the table below:

Original Protocol	Streamlined Protocol
Investigate all morbid and fatal events	Investigate fatal events only
Collect multiple medical record support documents depending on cause of death	*As of 8/31/2017, no medical records will be collected*
Collect death certificate with cause of death	No change
Collect narrative interview with proxy for out of hospital deaths	Collect narrative interviews with proxy for ALL deaths, replacing final telephone surveillance call.
Abstract medical record onto forms, and data enter into system	No abstraction or data entry
Local and central adjudication	No local or central adjudication. Cases will be forwarded and classified by Pittsburgh All Stars investigators
Redaction/sterilizing of PHI from death certificate and medical record paper documents	Redaction/sterilizing of PHI from death certificate and medical record using Adobe after documents are scanned
Packets with abstraction forms and support documents mailed to CC	Packets with cover page uploaded to secure site at CC.

III. Identification of Deaths to Investigate

Each field center will be provided by the coordinating center with 2 lists of all outstanding deaths from their site not yet investigated (ID, acrostic and date of death). These lists will be sent to the field centers at the beginning of every month. One list will be deaths in 'active' subjects, and the other list will be deaths in Code 30/refusals. The lists will include backlogged deaths from prior to the Events grant ending, and new deaths identified since that time. As more deaths are identified during the surveillance calls and through CMS data, they will be added to the list.

IV. Investigation of Deaths

Deaths in active subjects - For each death on the 'active subject' list, field centers will obtain 2 components of the completed packets (*As of 8/31/2017, no medical records will be collected*):

1. Death certificate with cause of death
2. Narrative interview with proxy (ALL deaths). *As of 8/31/2017, no narrative interview should be attempted for deaths PRIOR to 2014. For deaths 2015 and moving forward, narrative interviews should be attempted with proxies for all deaths in active subjects (not Code 30/refusals), regardless of location of death. This includes deaths in acute care hospitals, nursing homes, hospices and at home.*

Death certificate – using standard procedures from the original protocol, obtain a copy of the death certificate with cause of death. This can be obtained from the local, county or state vital

records office, or from the family, at the field center's discretion. A non-certified copy is fine, only a photocopy is needed.

Narrative interview –contact someone close to the participant familiar with the course of events leading up to the death. Ask for a description of what happened to the subject, and include information about **symptoms, diagnoses, timing, and any other info that will supplement** the death certificate, and will add to the picture of what occurred. *As of 8/31/2017, narratives should be completed for all deaths in active subjects (not Code 30/refusals) for deaths 2015 and more recent. No narratives need to be completed in deaths prior to 2015. The narrative should be a paragraph the enables the reviewer to understand the physical and cognitive status of the subject, the disease(s) that lead up to the death, if the subject was undergoing some kind of treatment, if there had been a recent hospitalization and what it was for, and if the death was sudden and unexpected or if it was anticipated.*

A. Deaths in Code 30/Refusals – For each death on the 'Code 30/Refusal' list, field centers will obtain only the death certificate with cause of death.

V. Uploading Documents to Coordinating Center

Once the documents are collected, a cover page (end of MOP) should be completed to identify the case and indicate which documents are included in the packet. If a specific document is not included, there should be an explanation as to why it is not attached.

Packets should be in the following order:

1. Completed cover page
2. Death certificate
3. Narrative interview

The packet should be scanned to a .pdf file, using a file name of the study ID number and the acrostic. For example, for Mary Jane Jones with ID number 7012345, the file name will be ***7012345 JONEMA.pdf***. If the subject has no middle initial and you cannot use the * symbol in the file name, use the + instead.

Once the paper file is scanned, the electronic file should be opened. Adobe is easy software to use, and has both a labelling and redacting feature. Adobe Acrobat DC Professional is the current version. The instructions here are for Adobe Acrobat X Pro which may be a bit old, but many versions are available as well as other software that can be used for this purpose.

Each electronic file must be labelled using either the 'header' or 'footer' feature, with the same name as you named the file (ID number and acrostic) on every page. Go to TOOLS, select PAGES, select HEADER & FOOTER, add HEADER & FOOTER. Change the font size to 16-18 so it is easily readable, and select the location of the header or footer depending on where there is open space on most pages so it is not on top of other writing. Some documents have a lot of writing at the bottom and it is easier to see a header high up, while others have a lot of information at the top and there is more free space on the bottom. Once the location is selected, press OK at the bottom and file name will be on every page.

One the file is labelled on every page, the file must be redacted or 'de-identified'. Go to TOOLS, select PROTECTION, select MARK FOR REDACTION. Use your mouse to drag the cursor and place boxes around the identifying information. Go through the entire document page by page,

and place boxes around all patient and family names, day and month of birth, all medical record, insurance and social security numbers, phone numbers and addresses, room numbers. DO NOT redact names of facilities (hospitals or nursing homes), dates of treatment, physician names. Once you have gone through the entire document, select APPLY REDACTIONS. Black boxes will cover the identifying information. Then save the file to a secure location using only the file name (ID and acrostic but remove the 'redacted' that is automatically placed in the file name).

Once the file is labelled, redacted and saved, it should be uploaded to the secure website at the coordinating center.

To login to the secure upload site (OneDrive) click on the following link:
https://login.microsoftonline.com/login.srf?wa=wsignin1.0&whr=uw.edu&wreply=https:%2F%2Fuwnetid-my%2Esharepoint%2Ecom

Site usernames to log on are as follows:

Wake Forest: chs3wfu
Davis: chs4ucd
Hopkins: chs5jhu
Pittsburgh: chs6pitt

(Passwords will be provided separately by email.) After logging in, click on "Shared with me", and then click on "CHS Events". The folders you have access to will show (each site will only have access to their own site's folder; the CC, Diane and Anne will have access to all the folders).
Files can be uploaded via drag-and-drop into the appropriate FC folder. (To move a file using drag-and-drop, right click on the file and holding down the button, move the file to the upload folder. Detailed instructions can be found in this YouTube tutorial:
https://www.youtube.com/watch?v=XvNn6xGK7GI)
When done uploading files, select the drop down menu from your site's name from the upper right corner. Select "Sign out".

The Events Coordinator at the Coordinating Center will generate the History Reports for deceased participants, create a .pdf file for each, and upload to the website. Files will use the same naming convention of IDNO and acrostic, but will add an extension of "HX" to identify the document as the History form, for example, ***7012345_JONEMA_HX.pdf***.

VI. Death Adjudication

Uploaded files will be accessed by Pittsburgh investigators, Dr. Anne Newman, a long-time CHS investigator, geriatrician/epidemiologist, and by Ms. Diane Ives, epidemiologist, CHS events coordinator, and an experienced CHS adjudicator, who will review the support documents and classify the underlying cause of death. In addition to the support documents provided by the field centers, the coordinating center will generate the standard reports used in the prior central adjudications that list all the hospitalizations and adjudicated outcomes for each subject. This will provide some background history on the subject to supplement the medical record, death certificate and narrative. The mortality review form used by the cardiac adjudication committee will be completed, and data entry will occur in Pittsburgh.

VII. Invoicing

As of 8/31/2017, field centers agreed to continuing mortality investigating using this additional streamlining (dropping medical record collection) by using existing funds for surveillance call activities to cover costs.

VIII. Queries

Any questions related to the MOP or procedures should be directed to Diane Ives at the University of Pittsburgh (412.383.1890, ivesd@edc.pitt.edu) or Mary Lou Biggs PhD at the University of Washington (206-897-1945, mlbiggs@uw.edu).

CHS Death Packet Cover Page

Study ID: __ __ __ __ __ __ __ Acrostic: __ __ __ __ __ __

Date of Death: __ __ / __ __ / __ __ __ __

Submitted by: _____ Upload Date: __ __ / __ __ / __ __ __ __

Status: ☐ Active ☐ Code 30/Refusal

All pages should include ID number and acrostic, and should be redacted/sterilized for all identifiers (names of subject and family members, home addresses and phone numbers, social security numbers, month and day of birth, medical record and insurance numbers, etc.)

Attachments:

1. Death Certificate with cause of death:

   ☐ Attached

   ☐ Not attached – reason:

2. Narrative with proxy describing circumstances, symptoms, medical issues resulting in death (please type):

   ☐ Attached

   ☐ Not attached – reason:

Comments: