**Pilot Protocol for Death Ascertainment and Adjudication in LLFS**

The pilot protocol details the steps we will take in order to test whether death adjudication on a larger scale will be feasible and possible in the LLFS. It will consist of a National Death Index (NDI) search, obtaining death certificates, obtaining medical records for a subset of deaths. Additionally modifications to the current LLFS consent, HIPAA waiver, and IRB issues are discussed.

## National Death Index Search:

An NDI application will need to be submitted to obtain information on deaths. The NDI Plus application will enable us to obtain information on state of death, date of death, death certificate number, and ICD-9/ICD-10 codes from the death certificate. It will be most cost effective to perform this search one time, for deaths from all field sites (estimate of ~$500 total for all sites). The DMCC will submit the application, and data will be returned to them. The NDI is updated through 2012.

## Obtaining Death Certificates:

At the Pittsburgh site, which has 226 deaths through 2012, we will obtain death certificates from PA, WV, and OH, as well as other open access states in which deaths occurred. This will cover the majority of the 226 deaths. PA is a closed access state, which requires an application to obtain death certificates; however, we have previous experience with this at Pitt. WV and OH are open access states, thus no application is needed to obtain death certificates. The rationale for limiting to PA and other open access states for this pilot is that other states in which Pitt deaths occurred may be closed access, so for the purposes of expediting the pilot study, we will not fill out additional applications for those closed access states.

## Obtaining Additional Medical Records Associated with Deaths:

In a subset of the deaths for which we obtain death certificates at the Pittsburgh site, we will determine the feasibility of obtaining additional medical records, which may include hospital records, nursing home records, hospice records, decedent interviews, etc. Further decisions on the number of deaths in this subset, and exact records obtained will be determined after death certificates are obtained. From previous studies, we estimate only ~15% of the deaths may occur in the hospital, thus we will also obtain hospitalization records from within 30 days of a death event. Decedent interviews have been performed in LLFS and this information is available. (However, information on where a hospitalization occurred was not collected on the decedent interviews.)

## Adjudication of Deaths:

We will have a panel of 3 investigators at Pitt to adjudicate cause of death. A final report of death will be generated for each death, and the Health ABC study template will be followed. The panel and areas of expertise for these investigators will be determined at a later date, after death certificates are obtained.

**Modifications to Informed Consent and IRB:**

The following text (from the LIFE Study consent) needs to be added to the LLFS informed consent for Exam 2:

"We will ask you to provide written permission to contact your physician/health care provider for a copy of your medical records if you report an illness or hospitalization during your study participation and/or to discuss any health related concerns that may arise during the study. We will only contact your health care provider with your permission."

AS WELL AS:

***"Will this research study involve the use or disclosure of my identifiable medical information?***

"This research will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g. physician's office) records. This information that will be recorded will be limited to information concerning your health status and hospitalizations. This information will be used for the purpose of tracking your health status for the duration of the study. No identifiable information will be placed in your medical record unless you specifically request that we send identifiable study results to your health care provider."

Additionally, at Pitt to obtain medical records associated with deaths, we will need to invoke the death waiver to obtain these records without an authorization. We have not previously tested this at the PITT IRB, and are not aware whether the Pitt IRB has previous experience with this in any other study. This is Pitt-specific, and other sites will need to check with their local IRBs on what needs to be done once we move this beyond the pilot phase.

**Timeline:**

We estimate a total of 6-9 months before we can test the feasibility of obtaining medical records or other records associated with deaths. This estimate is based on first needing to submit the NDI application, waiting for approval, and obtaining this information from the NDI. This is also based on the time it will take to obtain IRB approval for pilot and prospective records collection at Pittsburgh. Additionally, once the application for death certificates is submitted to the state of PA, it will be 3 months before death certificates arrive at Pittsburgh. Once this takes place, then we can commence obtaining medical and other records for the subset of deaths at Pitt.

Modification of Forms to Ascertain Hospitalizations and Fatal Events

Strategy: The Panel 5 Medical History Forms (new and return), Panel 16 Annual Follow-Up Telephone Contact Questionnaire, and Panel 18 Decedent Proxy Interview contain questions about hospital admissions. All questions omit the name of the facility where the subject was admitted, which is necessary for future retrieval of medical records. The Panel 5 and 16 forms ask general questions about hospitalizations without targeting specific conditions, while the Panel 18 decedent interview asks diagnosis-specific questions. Asking diagnosis-specific questions helps with participant recall, and also provides the sites with disease information that helps with requesting the appropriate documentation from the hospital. Therefore, the strategy is to modify the detailed questions in the decedent form to obtain the extra hospital information, and then apply those modified questions to the other 3 forms.

Panel 18 Decedent Proxy Interview: Questions related to overnight hospitalizations are Q4c (coronary heart disease), Q5c (cerebrovascular disease), Q6c (congestive heart failure), Q7c (cancer), Q8c (pneumonia), Q9c (fracture), and Q10c (all other overnight hospitalizations not already described. The current format of questions Q4c-9c is:

*Date of hospitalization: __ __ / __ __ / __ __ __ __*

Change to:

*Date of admission: __ __ / __ __ / __ __ __ __ Date of discharge: __ __ / __ __ / __ __ __ __*

*Name of Hospital: _____*

*City, State: _____*

Rationale: Many hospitals require very specific dates, so providing a date range and length of stay increases the chance of identifying the correct admission. The name and location of the hospital will enable retrieval of records.

There are 3 fields in Q10c for other hospitalizations, and the current format of Q10c is:

*Date of hospitalization: __ __ / __ __ / __ __ __ __*

*Reason for hospitalization: _____*

Change to:

*Date of admission: __ __ / __ __ / __ __ __ __ Date of discharge: __ __ / __ __ / __ __ __ __*

*Diagnosis at Discharge: _____*

*Name of Hospital: _____*

*City, State: _____*

Rationale: In addition to the changes in the diagnoses-specific questions, the term ‘reason for hospitalization’ has been changed to ‘diagnosis at discharge’ to prompt the subject to provide a disease that was diagnosed rather than a symptom that brought the person to the hospital. For example, the subject may report, ‘I was having difficulty breathing,’ as the reason for admission but may report a wide range of diagnoses at discharge that would require very different parts of a medical record to adjudicate (ie. Pneumonia, heart failure, pneumothorax, allergic reaction, etc.)

Location of death is currently asked as Q20:

*Did (name) die in a hospital (do not include emergency room, hospice, nursing home or rehabilitation facility)?*

*1-yes*
*0=no*
*D=don’t know*
*R=refused*

Change to:

*What was the exact date of death: __ __ / __ __ / __ __ __ __*

*What was the location of death?*

*1=Hospital inpatient*

*Hospital name: _____*

*City, State: _____*

*Date of admission: _____*

*2= Emergency room*

*Hospital name: _____*

*City, State: _____*

*3= Nursing Home/Rehab Facility*

*Facility name: _____*

*City, State: _____*

*4=Inpatient Hospice*

*Facility name: _____*

*City, State: _____*

*5=Residence*

*City, State: _____*

*6=Other*

*Describe (include city and state):*

_____

Rationale: Better ascertainment of location and date of death is needed to obtain medical records and death certificates. The interviewer may ask the proxy if a copy of the death certificate could be sent to the study.

Panel 5 New and Return Medical History Form: Hospitalizations are ascertained by Q4a-c. It is assumed that the 'New' version will no longer be needed. For the 'Return' form, the questions are:

*Have you been hospitalized overnight since [insert date of last administration of last telephone follow-up]?*

| | |
|---|---|
| *1-yes* | |
| *0=no* | *Go to Q5* |
| *D=don't know* | *Go to Q5* |
| *R=refused* | *Go to Q5* |

Change to same format as Decedent Proxy Interview by asking individual disease-specific questions on CHD, CVD, CHF, cancer, pneumonia, and fracture, then ask for all other hospitalizations. Include for each 'yes', name and location of hospital, dates of admission and discharge, and for the 'other hospitalization question', the diagnosis at discharge.

Rationale: Using specific disease-related questions will trigger recall and assist in the requesting of the appropriate medical record documentation for each condition.

Panel 16 Annual Follow-Up Telephone Contact Questionnaire: Hospitalizations are ascertained by Q3a-c. The same changes using the disease-specific stem questions and general other hospitalization questions described in Panel 5 should replace the current questions in Panel 16.