

5.0 Data Management

This chapter describes the procedures for all data management tasks for the 1999 NLTCs Supplemental Studies. The data management tasks were the primary responsibility of the Data Manager, however, the Project Director had an integral role in data receipt and cleaning, preparing data files to be loaded into CATI, monitoring response rates and TSD production, and the fiscal monitoring of the incentive and phlebotomy payments to the subcontractor. Data Management tasks included monitoring the Telephone Survey Department (TSD), verification of specimen receipt to the lab, alignment of specimen receipt with consent form receipt, reconciliation of incentive and phlebotomy payments to the subcontractor with regard to completed and payable appointments, and assignment of all cases to final status codes.

5.1 Data Receipt and Preparation

Data files containing the sample subjects were received on diskette from the Center for Demographic Studies at Duke by the Project Director. The Statement of Work defined the data file formats and required variables. Each file included the respondents' names, unique ID numbers, and other demographic information, in addition to the respondents' telephone numbers and addresses. This data was taken from the Core Interview conducted by the Census Bureau for Duke and the NLTCs.

Upon receipt of the sample subject files, RTI formatted the data to facilitate loading it into the CATI interview system. The data, as received, could not be directly formatted and loaded into CATI because there were significant amounts of key data missing (telephone numbers and addresses), as well as significant data errors, such as miscoded state information. All of the data files received from Duke required extensive data cleaning and tracing to prepare them for use in the CATI interview system.

5.2 Monitoring TSD Response Rates and Production

Interviewers from the Telephone Survey Department (TSD) made telephone calls for all four of the Supplemental Studies. These calls included scheduling appointments for Venipuncture, conducting surveys for Kin and NOK, and reminding subjects to return specimens. Daily Frequency Reports for each substudy were emailed from TSD to the Project Director detailing the number of subjects remaining to be called, number of refusals, and the number of completed cases for the previous day, week, and duration of the project. These reports were utilized to monitor response and production rates. Frequency Reports identified problems in TSD, such as subjects not being worked or high refusal rates, and notified the Project Director when TSD needed additional subjects to be loaded into the CATI system to keep production moving. This monitoring system allowed the Project Director, Telephone Survey Manager and TSD to work closely to improve efficiency and production.

5.3 Monitoring TSD Status Code Reports

TSD interviewers scheduled phlebotomy appointments, reminded participants to submit their specimens to the lab, and administered the Venipuncture, Kin and NOK questionnaires. Based on the outcome of the call (i.e., completed interview, refusal, etc), the Telephone Interviewer (TI) assigned each participant a status code.

RTI programmers compiled the status codes for all participants of each study, and submitted weekly reports to the Data Manager. Each report contained the respondent name, ID number, status code, and the date the status code was assigned. These reports were utilized to update the status codes of participants in the control systems.

For some respondents, the TSD status code was not in agreement with the project control system. In order to correct the disparities, the Data Manager developed a TSD Discrepancy Report (*Exhibit 5-1*) that documented the differences in the TSD report and project control system. The report listed the ID number of the participants in question, as well as their status codes and status dates from both the TSD report and the project control system. The Discrepancy Report was distributed to the Telephone Survey Manager and TSD for further clarification of the assigned status or to update their system. Typically, the Discrepancy Report contained sample members that had called project staff to decline participation, but it also included respondents that were either deceased or in poor health. Most of the respondents listed on the Discrepancy Report were removed from the active CATI call list.

The development of the Discrepancy Report led to the discovery of errors in the CATI system. Several respondents that were loaded into the CATI became suspended in “110 – Attempt Preload” status. This code is utilized after the initial load into the CATI system and is quickly replaced once a case has been worked for the first time. In this case however, respondents were not accessible to the TI and were, therefore, not moved from this status. The Discrepancy Report also alerted project staff to an error in the Venipuncture appointment scheduler. A few respondents were reported by TSD as “295 – Complete” who had no corresponding appointment documented in the output table. Upon further investigation, project staff discovered that when two TIs worked cases from the same site at the same time, the scheduler allowed both interviewers to set an appointment for the same time slot. Upon completion of the second call, the first appointment was overwritten. For example, the first TI set an appointment for Biloxi at 10:00 a.m. on March 15. The second TI set an appointment for Biloxi at the same time and date and concluded the call two minutes later. The appointment set by the first TI was overwritten in the appointment output table, there was no record of the first appointment other than the "Complete" code, and TSD was unaware of the problem.

5.4 Verification of Specimens Received

The receipt of blood specimens at the lab within 24 hours of collection was critical to the success of the Venipuncture study. RTI project staff employed several techniques to ensure timely receipt of the specimens. These included monitoring the subcontracting nurses and tracking the specimen shipments through Federal Express.

After completion of a blood draw, each nurse was responsible for contacting an Interim supervisor and providing key information. The information included the respondent ID number, status of the draw (i.e., complete, short stick, refusal, reschedule), and the Federal Express Airbill Number of the biospecimen shipment. The Interim supervisor emailed this information to the Biospecimen Manager daily in an Excel spreadsheet. The Interim supervisor was also responsible for sending this information to Chuck Ogburn at the lab in order to alert him of the specimens to arrive the next day. On a daily basis, the Biospecimen Manager compared this spreadsheet to the appointment scheduler to verify completion of each scheduled appointment. All discrepancies or missed appointments were reported immediately to an Interim supervisor.

Exhibit 5-1. Venipuncture Discrepancy Report

ID	Control status num	Control System Status Text	CATI Status Num	CATI Status Text
V33383	201	Appointment Scheduled	110	ATMPT PRELOADS
V17141	201	Appointment Scheduled	115	ATMPT DA/FD INF
V39371	201	Appointment Scheduled	260	UNABLE TO LOC
V40476	420	Refusal	110	ATMPT PRELOADS
V20244	420	Refusal	120	NEED DA
V33567	420	Refusal	235	REMAIL LETTER
V09365	420	Refusal	260	UNABLE TO LOC
V03046	420	Refusal	260	UNABLE TO LOC
V37395	440	Language Barrier	102	
V29224	450	Deceased	110	ATMPT PRELOADS
V33171	450	Deceased	115	ATMPT DA/FD INF
V27615	450	Deceased	230	REF-NO ACTION
V30207	450	Deceased	260	UNABLE TO LOC
V34352	450	Deceased	270	UNAVAIL FOR DUR
V29699	450	Deceased	272	INCAPABLE
V41813	450	Deceased	285	FIN LANG--SPAN
V34761	515	Short Stick	262	TIME EXHAUSTED
V32929	520	Specimen Received (next day)	260	UNABLE TO LOC
V40334	520	Specimen Received (next day)	285	FIN LANG--SPAN
V30681	540	Specimen and Consent Form received	110	ATMPT PRELOADS
V36359	540	Specimen and Consent Form received	230	REF-NO ACTION
V01240	540	Specimen and Consent Form received	253	NOT PREV STUDY
V29292	540	Specimen and Consent Form received	255	DECEASED
V28121	540	Specimen and Consent Form received	260	UNABLE TO LOC
V41095	540	Specimen and Consent Form received	270	UNAVAIL FOR DUR
V36748	540	Specimen and Consent Form received	281	FIN REV-REV'D
V32873	540	Specimen and Consent Form received	286	FIN LANG--OTH
		completes with no set appointment		
V26513	125	Pending Appointment Call	296	COMPLETE-FM N/A
V41324	127	Appointment Call Attempted (No Answer)	295	COMPLETED INT
V35215	127	Appointment Call Attempted (No Answer)	295	COMPLETED INT
V31044	127	Appointment Call Attempted (No Answer)	295	COMPLETED INT
V34054	128	Appointment Call - Scheduled Call Back	295	COMPLETED INT
V30897	128	Appointment Call - Scheduled Call Back	295	COMPLETED INT
V00313	128	Appointment Call - Scheduled Call Back	295	COMPLETED INT
V35140	128	Appointment Call - Scheduled Call Back	295	COMPLETED INT

The University of Washington lab staff sent the Biospecimen Manager a daily list of specimens received. The Excel spreadsheet contained the respondent ID number, Federal Express Airbill number, date specimen was drawn, date specimen arrived, and total volume of blood collected (ml). On a daily basis, RTI project staff imported the spreadsheet into the control system and compared it to the one sent by Interim. Missing specimens were promptly tracked through Federal Express utilizing the Airbill number.

Several specimens arrived at the University of Washington more than 24 hours after the sample was collected. The delay was the result of collecting blood in remote areas of the U.S. with limited shipping capacity. In all of these instances, the nurse refrigerated the blood overnight prior to shipment the next day. Federal Express misplaced only one specimen in the course of shipping bloods. One specimen was misrouted after an earthquake in California shut down the airports for a few hours.

In addition to reporting blood samples received, the University of Washington lab staff sent the Biospecimen Manager a complete list of buccal cell samples received for the Venipuncture, Buccal Cell, and Kin Studies. On a weekly basis, lab staff emailed an Excel spreadsheet that contained the ID number and date the buccal specimen was received. RTI project staff imported the spreadsheet into the appropriate control system.

5.5 Specimens Received vs. Consent Forms Received

In order to process and store an individual's specimen at the laboratory, a signed consent form must be on file at RTI. On a monthly basis, the Data Manager compared the list from the University of Washington of respondents with a specimen at the lab to a list of the respondents with a signed consent form in-house. Nurses that failed to return the phlebotomy paperwork were notified and asked to return it as soon as possible. In a few instances, nurses returned paperwork that did not reach RTI project staff. In those instances, an additional consent form was sent to each respondent along with a letter stating that the specimen could not be used until RTI had received a copy of the signed consent form. A similar procedure was used for Buccal Cell and Kin samples. Respondents that had not submitted a signed consent form for release of their buccal specimens were sent a similar letter and an additional consent form.

5.6 Reconciling the Phlebotomy Incentive Money and Nurse Payments

Venipuncture respondents were given a \$50 incentive for their participation. The nurses paid participants cash upon completion of the blood draw. In order to expedite the process of getting nurses into the field, RTI issued Interim a partial payment of the total amount expected to be paid in incentive money prior to the first scheduled blood draw. That amount proved to be adequate to cover the cost of the \$50 incentive per draw for the entire study. Interim issued the incentive money to the nurses on a weekly basis, as needed based on the number of appointments scheduled. During the appointments, nurses asked participants to sign the **Incentive Receipt (Appendix E)** and select the box documenting their acceptance or refusal of the incentive money. One copy of the **Incentive Receipt** was returned to RTI with the rest of the phlebotomy paperwork. At the conclusion of the study, the Project Director was able to determine the difference between what had been paid to Interim prior to the start of the study and what had been paid directly to participants.

Payments to Interim for the nursing visits also required record reconciliation. The daily blood draw record sent to RTI by the Interim supervisor was also used to determine the total number of phlebotomy appointments payable which was then compared to the quarterly Interim invoices. Not all phlebotomy appointments resulted in a payable appointment. For example, some appointments were canceled prior to the nurse visiting the home. However, if a respondent refused participation while the nurse was visiting his home, the refusal was regarded as a payable appointment. The Biospecimen Manager classified each appointment as payable or not, and this documentation was then utilized to determine which payable appointments were still outstanding due to Interim invoice delays. The documentation also alerted the Project Director to appointments that appeared more than once on separate Interim invoices.

5.7 Case Finalization

At the end of the data collection period, all cases that had not been previously assigned to final codes were appropriately moved. The final codes include, but are not limited to, complete, deceased, refusal, incapable, language barrier, and unable to locate. In order to finalize the few remaining cases, RTI project staff had to call some respondents and/or review the TSD Trace Report. The Trace Report documented every attempt to contact each participant by phone, including occasions when no contact was made (i.e., reached an answering machine). The Trace Report documented the reasons for the delay in finalizing a case. In some instances, a TI had yet to recontact a case he was trying to convert from a refusal or was waiting until a specific date to recontact a case because the respondent was out of town. The Data Manager used this information to finalize all respondents on a case-by-case basis. The Data Manager also utilized the Trace Report to verify that TIs assigned the correct status code to individuals coded as incapable. The Data Manager selected 20 percent of the respondents coded as incapable and verified that they had been correctly coded. A sample page of the Trace Report is displayed in *Exhibit 5-1*.