4.0 Data Collection Operations

This chapter describes the procedures for all data collection tasks for the 1999 NLTCS Supplemental Studies. Data collection duties were shared by RTI project staff, RTI Telephone Interviewers, and subcontracting nurses. Details on the procedures used for each study including site assignment, telephone interviews, reporting, and quality control efforts are discussed.

4.1 Venipuncture Substudy

4.1.1 Site Assignment Procedures

Duke staff were responsible for providing the sample members for the Venipuncture Substudy and for sending contact information about the selected sample members to RTI. Sample members were 65 to 89 years of age. RTI project staff loaded all information for the sample members into a database including the unique case identification number (ID) assigned to each case. Once respondents were loaded into the database, they were assigned to geographic regions, waves, and sites in order to manage the volume of specimens to the lab.

Sample members were divided into regions, sites, and waves based on their places of residence. Respondents were divided into four geographic regions: South, West, North Central and North East. ***Exhibit 4-1*** lists the states contained in each region. Site assignments were made based on county of residence and proximity to an Interim HealthCare, Inc. franchise or subcontracting office. Interim provided RTI with a list of offices across the country (***Appendix D***), and sample members were assigned to preliminary sites. Approximately 40 sample members did not reside in an area served by Interim HealthCare or their contracting offices. Alaska and Hawaii residents were excluded from the phlebotomy portion of the Venipuncture Substudy because FedEx could not guarantee next day delivery of the blood samples to the University of Washington.

Exhibit 4-1. Geographic Regions For National Long Term Care Survey Supplemental Studies

NC		NE		S		W	
IA	MN	CT	NJ	AL	NC	AZ	OR
IL	MO	DE	NY	AR	OK	CA	SD
IN	NE	MA	PA	FL	SC	CO	UT
KS	OH	ME	RI	GA	TN	ID	WA
MI	WI	NH	VT	KY	TX	MT	WY
				LA	VA	NV	
				MD	WV		
				MS	WASHINGTON DC		

Final site assignments were made with the aid of the Geographic Information System (GIS). The address of each sample member as well as the address of each Interim franchise and contract office was loaded into the GIS. The GIS provided a visual representation of these locations on a map of the United States (***Exhibit 3-3***). Each sample member was represented by a red triangle, an Interim franchise office was indicated with a blue dot, and a contract office was represented by an aqua dot. In order to assign sample members to an Interim office, particularly if more than one office was located in a specific county, the distance between the office and sample

member's residence was calculated. It was standard for a nurse to drive 30 miles one way, so a circle with a radius of 30 miles typically represented a site, with the Interim office as the center (***Exhibit 3-4***). There were 135 designated sites.

Exhibit 4-2. Venipuncture Sample Wave List

ID:	Office Name	Address:	City:	State	Zip:	Total	Region
23	Daytona	2701 S Ridgewood Ave, Ste C4	Daytona	FL	32119	8	S
23a	St. Augustine	252 Southpark Cir E	St. Augustine	FL	32086	6	S
23b	Palm Coast	Nine Pine Cone Dr, Suite 103	Palm Coast	FL	32137	6	S
24a	Vero Beach	1965 42nd Ave #1	Vero Beach	FL	32960	6	S
26	Clearwater	13501 Icot Blvd, Suite 114	Clearwater	FL	33760	17	S
27	Inverness	210 Montgomery St	Inverness	FL	34450	20	S
28	Miami	8405 NW 53rd St, Suite A102	Miami	FL	33166	27	S
28a	Sunrise	1601 Sawgrass Corporate Pkwy, 1st	Sunrise	FL	33323	37	S
29	Sarasota	3920 Bee Ridge Rd Bldg H, Suite M	Sarasota	FL	34233	27	S
65	Northridge	9651 Reseda Blvd	Northridge	CA	91364	81	W
53	Portland	Division Plaza, 2410 SE 121 Ave	Portland	OR	97216	25	W

The University of Washington lab could accommodate the receipt of 150 blood specimens per week. In order to meet the weekly quota restrictions, the start dates of blood collection for the four regions, and the sites contained in them, were staggered. Each region was divided into groups. The South, being the largest, was divided into eight groups; the West was divided into four groups; the North East was divided into five groups; and the North Central was divided into four groups. Groups of one region were then paired with groups of another to form one wave. This was done in an attempt to limit the number of sample members contained in one wave to 250. (With an expected response rate of 60 percent or less, 250 sample members at most will yield 150 blood specimens.) ***Exhibit 4-2*** contains a sample wave list for groups of the South and West. The South Group is made up of nine sites that cover 154 sample members, and the West Group contains 106 respondents and two sites. ***Exhibit 4-3*** contains the Wave number, regional group number, number of sites contained in each wave, number of phlebotomists utilized, number of sample members allocated to a particular wave, and the blood collection start date.

Exhibit 4-3. Summary of Venipuncture Waves

WAVE #	Wave Contents by Region		# SITES	# PHLEBS	# PARTICIPANTS	DATE
1	S Group 1	W Group 1	11	13	259	January 29
2	S Group 2	W Group 2	11	11	248	February 5
3	S Group 3	W Group 3	11	12	251	February 12
4	S Group 4	W Group 4	15	15	247	February 19
5	S Group 5	NE Group 1	15	15	258	February 26
6	S Group 6	NE Group 2	11	12	248	March 5
7	S Group 7	NE Group 3	12	12	248	March 12
8	NE Group 4	NC Group 1	9	11	248	March 19
9	NE Group 5	NC Group 2	8	11	247	March 26
10	NC Group 3		17	18	246	April 2
11	NC Group 4	S Group 8	15	15	191	April 9

4.1.2 Tracing

Approximately 534 cases or 20 percent of the Venipuncture sample members had inadequate contact information. Addresses and/or phone numbers were either missing or incorrect, so RTI project staff sent these cases to the Tracing Operations Unit (TOPS). TOPS specializes in locating new contact information for lost study subjects. The tools they use to provide updated information include the death index, Department of Motor Vehicle records, and address and telephone updates. TOPS has also access to proprietary databases, such as credit bureaus, and collateral sources. Collateral sources include relatives, neighbors, the Social Security Administration, and State Bureau of Vital Statistics. TOPS provided RTI project staff new contact information for 190 cases. In addition, they alerted project staff to 34 deaths and 20 participation refusals.

4.1.3 Participant Recruitment

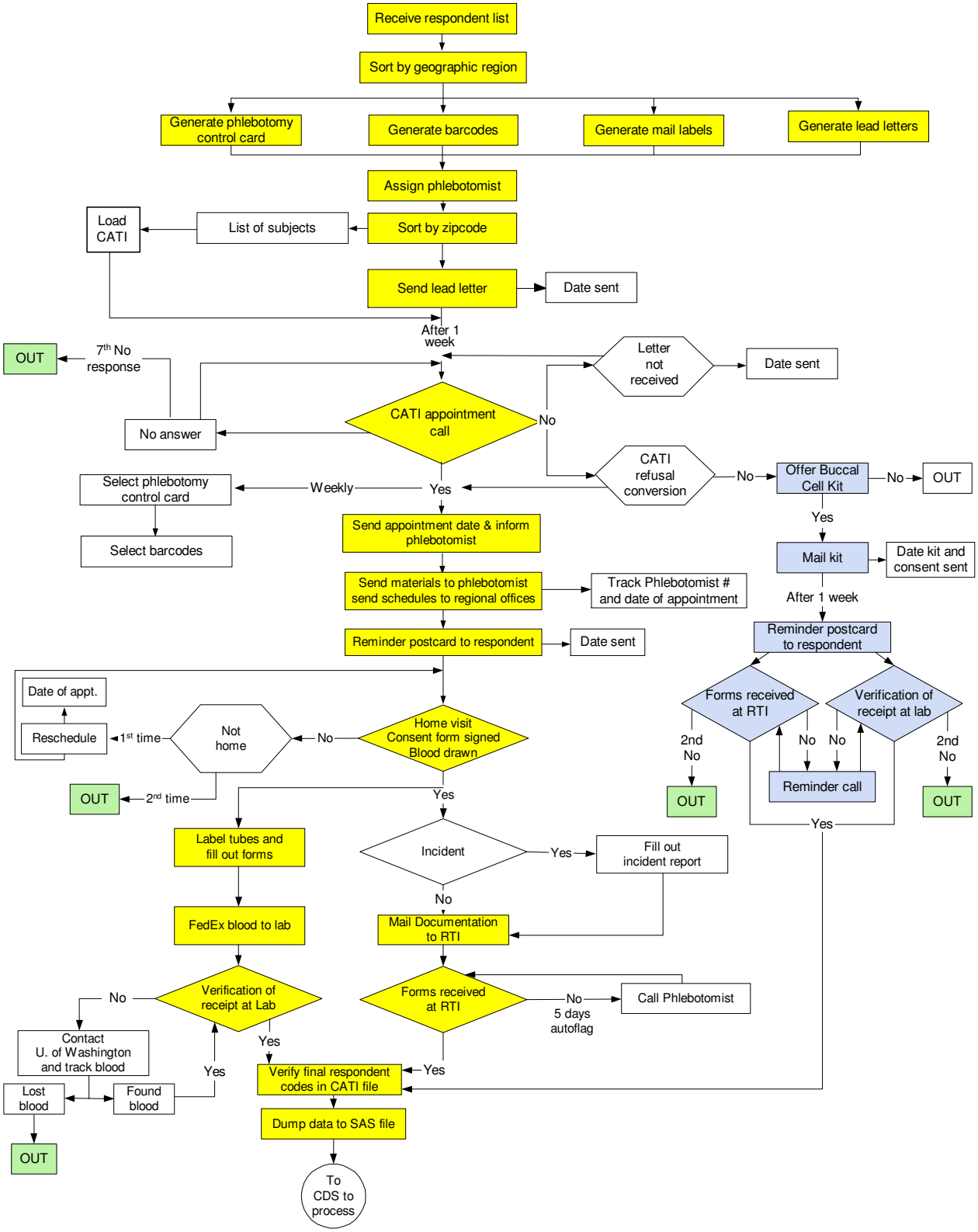
All sample members were sent an introductory lead letter and brochure describing the study and inviting them to participate. Copies of the lead letter and brochure are displayed in ***Appendix B***. Lead letters were sent out in waves in order to limit the number of appointment calls and, therefore, limit the number of specimens sent to the lab in a given week. One week after the lead letters were mailed, RTI's Telephone Interviewers (TIs) called sample members to elicit their participation and schedule an appointment for a blood draw. TIs logged phlebotomy appointments in the scheduler that was discussed in *Section 3.1.2*. TIs made appointments in two-hour blocks from 8 am to 8 pm, Monday through Thursday. Appointments were not scheduled on Friday since laboratory staff were not available on Saturday to receive the specimens. Participants that scheduled phlebotomy appointments were sent a reminder postcard that contained the appointment date and time as well as a toll-free number to call to reschedule or change the time of an appointment. The reminder postcard is included in ***Appendix E***.

4.1.4 Preparation for Phlebotomy Appointments

Data Preparation (DP) Unit staff completed several tasks in preparation for the phlebotomy appointments. DP staff labeled all phlebotomy forms with patient-specific barcodes. Each barcode contained the sample member's ID number followed by a form specific suffix. For example, each consent form was labeled with a barcode that contained an ID number followed by "CF". Project staff then assembled participant specific packets for each scheduled blood draw. A participant packet included all barcode labeled phlebotomy forms for a particular case in addition to the map generated by the Geographic Information System that is displayed in ***Appendix F***. Project staff sent participant packets to the nurses via Federal Express at least seven days prior to the appointment.

DP staff also assembled and shipped all necessary phlebotomy supplies to the nurses prior to their first scheduled appointment. Phlebotomy supplies included supplies needed for venipuncture, such as needles and Vacutainer tubes, as well as supplies needed to pack and ship the blood. A toolkit, packed with enough supplies for five blood draws, was also included in the supply shipment to the nurses. The toolkit provided nurses with a neat, professional-looking mechanism to carry the numerous phlebotomy supplies, including the biohazard container, from appointment to appointment. A diagram of the venipuncture study work flow is included in ***Exhibit 4-4***.

Exhibit 4-4. Venipuncture Study Work Flow



4.1.5 Nurse Visit

RTI project staff sent nurses their phlebotomy appointments via email and/or fax at least seven days in advance. Nurses were trained to notify the Biospecimen Manager immediately if a participant packet had not arrived at least three days prior to the appointment. They were also trained to notify RTI project staff if they were in need of additional supplies prior to an appointment. Upon receipt of the participant packet, the nurse checked the enclosed **Phlebotomy Control Card** against her schedule to ensure that the appointment date and time were consistent. The nurse also verified that the barcode labeled forms matched the ID number of the participant. The **Phlebotomy Control Card** and other phlebotomy forms are included in ***Appendix E***.

Upon arrival at the participant's home, the nurse obtained informed consent. The participant was asked to read and sign the **Consent Form** prior to having his blood drawn. The **Consent Form** contained the purpose of the study, study procedures, benefits and risks of participation, an assurance of confidentiality, and the participant's rights as a study participant. It also provided the participant with a toll-free number to call in order to receive additional information. The participant's signature on the **Consent Form** documented his willingness to participate. After the nurse obtained consent, she signed the **Consent Form** and gave the participant a copy for his records. The consent form is included in ***Appendix E***.

The nurse obtained three tubes of blood from the participant in the standard manner. She wrote the date and time each tube was filled on the Vacutainer label and affixed the barcode labels. Each tube was labeled with a barcode of the particpant's ID number. After the specimen collection and labeling were complete, the nurse paid the participant the $50 incentive and completed the **Incentive Receipt Form**. The participant signed the Incentive Receipt documenting that he/she had either accepted or refused the $50 incentive. The nurse gave the participant a copy of the Incentive Receipt for his records and thanked him for his participation.

4.1.6 Shipping the Specimen and Paperwork

Nurses were trained to pack and ship the blood specimens according to International Air Transport Association (IATA) Packing Instruction 650 for non-dangerous goods. Specimens were packed in ziplock bags with absorbent material. They were then shipped to the lab inside a sealed styrofoam container placed in a cardboard box. A gel pack was also placed inside the styrofoam container to regulate the temperature inside the box and protect the specimens. Nurses completed and sent a copy of the **Shipping Manifest** with the specimen. Specimens were shipped to the lab by Federal Express courier for Priority Overnight, Weekday delivery the day they were drawn. RTI supplied the nurses with pre-printed Federal Express labels to expedite the shipping process.

Nurses were also responsible for completing and returning the phlebotomy paperwork to RTI. The phlebotomy forms, such as the **Phlebotomy Control Card** and **Incident Form,** captured specific information regarding the collection and shipment of specimens for each participant, including any unusual details or incidents that could be of significance when considering the assay results. Nurses also returned a copy of the participant's **Consent Form**, **Incentive Receipt**, and **Shipping Manifest**. The **Shipping Manifest** contained the Federal Express tracking number and was used in the event a shipment did not arrive at the lab as expected. Nurses returned these forms to RTI in a pre-addressed Tyvek envelope sent to them in the participant packet.

4.1.7 Refusal Conversion to Buccal Cell Collection

In order to increase the participation rate, venipuncture sample members who declined to have blood drawn were asked to donate buccal cells. Respondents declined to have a blood sample taken primarily because they were afraid to let a stranger into their homes. They also refused to have blood taken for purposes other than diagnostic tests. RTI project staff sent buccal cell collection kits to all respondents that refused venipuncture. Kits were also sent to sample members that were not served by an Interim office and to respondents that agreed to venipuncture but did not have specimens successfully drawn (short sticks).

4.1.8 Assessment of Capacity

Sample members that were initially deemed to be ineligible due to incapacity were recontacted to assess capacity and in some cases, elicit participation in either the venipuncture or buccal cell components of the study. Due to the age of the study sample, many subjects were reported to be mentally or physically incapable of participation. RTI project staff developed criteria for capacity based on the National Bioethics Advisory Commission Recommendations regarding Research Involving Persons with Mental Disorders that may Affect Decisionmaking Capacity [1].

RTI developed four classification categories. Individuals were classified first as either physically or mentally incapable. Individuals characterized as physically incapable were then divided into groups based on their ability to participate with or without assistance, and individuals classified as mentally incapable were divided into groups based on their ability to order their daily activities or their inability to do so. Examples of physical incapacity included severe arthritis, a stroke that negatively effected motion, and terminal illness. Alzheimer's Disease, a stroke that impaired decision-making ability, and dementia were conditions associated with mental incapacity. Physically impaired individuals that could "swish and spit" with assistance were asked to participate. Similarly, individuals with the mental capacity to make choices, as to cereal, clothing, etc., were asked to participate. All other sample members were classified as incapable and were not further contacted.

RTI project staff made every effort to engage the prospective subject in the informed consent process. We attempted to develop and present material relevant to the project to help the cognitively impaired to understand the research through the use of a simplified consent (less complex language and less words) and visual instructions. In addition, for subjects with fluctuating or limited decision making capacity, we used concurrent consent by a family member or friend chosen by the subject. These family members were asked to sign a **Proxy Consent Form**, in addition to the subject signing the **Simplified Consent Form**. The **Simplified Consent Form** and **Proxy Consent Form** are included in ***Appendix G***.

4.1.9 Receipt of Specimens at University of Washington

The University of Washington laboratory staff notified the Biospecimen Manager daily to report the ID numbers of the specimens received. ID numbers for specimens received were entered into an Excel spreadsheet and sent to RTI daily. In addition, Interim Healthcare supervisors contacted the Biospecimen Manager daily to report the number of appointments completed and/or rescheduled, recount the number of specimens collected, alert

RTI staff to any incident, and report the Federal Express tracking numbers for the specimens shipped. RTI staff were able to track any late shipment to the lab, update the appointment scheduler to reflect any changes or missed appointments, and document individuals that refused venipuncture when the nurse arrived or who were short sticks (i.e., unable to have blood drawn due to rolling veins, dehydration, etc).

4.1.10 Receipt of the Phlebotomy Forms

Nurses returned the phlebotomy forms to RTI using the pre-addressed first class Tyvek envelopes included in their participant packets. RTI project staff entered the phlebotomy forms into the database on a weekly basis. Because the forms were labeled with barcodes, they were easily scanned into the database with a wand. RTI staff verified that all consent forms contained the signature of the participant. In addition, staff documented the refusal or acceptance of the $50 incentive to facilitate the accounting process.

4.2 Buccal Cell Substudy

4.2.1 Wave Assignment Procedures

Duke staff were responsible for providing the sample members for the Buccal Cell Substudy and for sending contact information about the selected sample members to RTI. Sample members were 80 to 100+ years of age. RTI project staff loaded all information for the sample members into a database including the unique case identification number (ID) assigned to each case. Once respondents were loaded into the database, they were assigned to waves in order to manage the volume of specimens to the lab. The University of Washington lab could accommodate the receipt of 150 buccal cell specimens per week. In order to avoid exceeding the weekly quota, the start dates of buccal collection for the 1891 sample members were staggered in waves as shown in ***Exhibit 4-5***. The table contains the mailout dates for the lead letter, buccal cell collection kit and reminder postcard, as well as the dates of the reminder phone call made by the Telephone Survey Department (TSD).

4.2.2 Tracing

Approximately 249 cases or 9 percent of the Buccal Cell sample members had inadequate contact information. Addresses and/or phone numbers were either missing or incorrect, so RTI project staff sent these cases to TOPS. TOPS specializes in locating new contact information for lost study subjects. TOPS provided RTI project staff new contact information for 71 cases. In addition, they alerted project staff to 18 deaths and 2 participation refusals.

4.2.3 Buccal Cell Collection Kit Assembly

Data Preparation (DP) Unit staff, under the supervision of Project Staff, completed several tasks as part of the assembly of buccal cell collection kits. DP staff labeled all consent forms and questionnaires with patient-specific barcodes. Each barcode contained the sample member's ID number followed by a form specific suffix. For example, each consent form was labeled with a barcode that contained an ID number followed by "CF". DP

staff also labeled the buccal cell collection vials with patient-specific barcodes. To complete the task, DP staff wore gloves to prevent transferring their DNA to the vials and contaminating the tests. DP staff assembled the remaining items for the buccal cell kits, and RTI project staff inserted the $10 incentive so that the kits could be shipped to the respondents.

Exhibit 4-5. Summary of Buccal Cell Waves

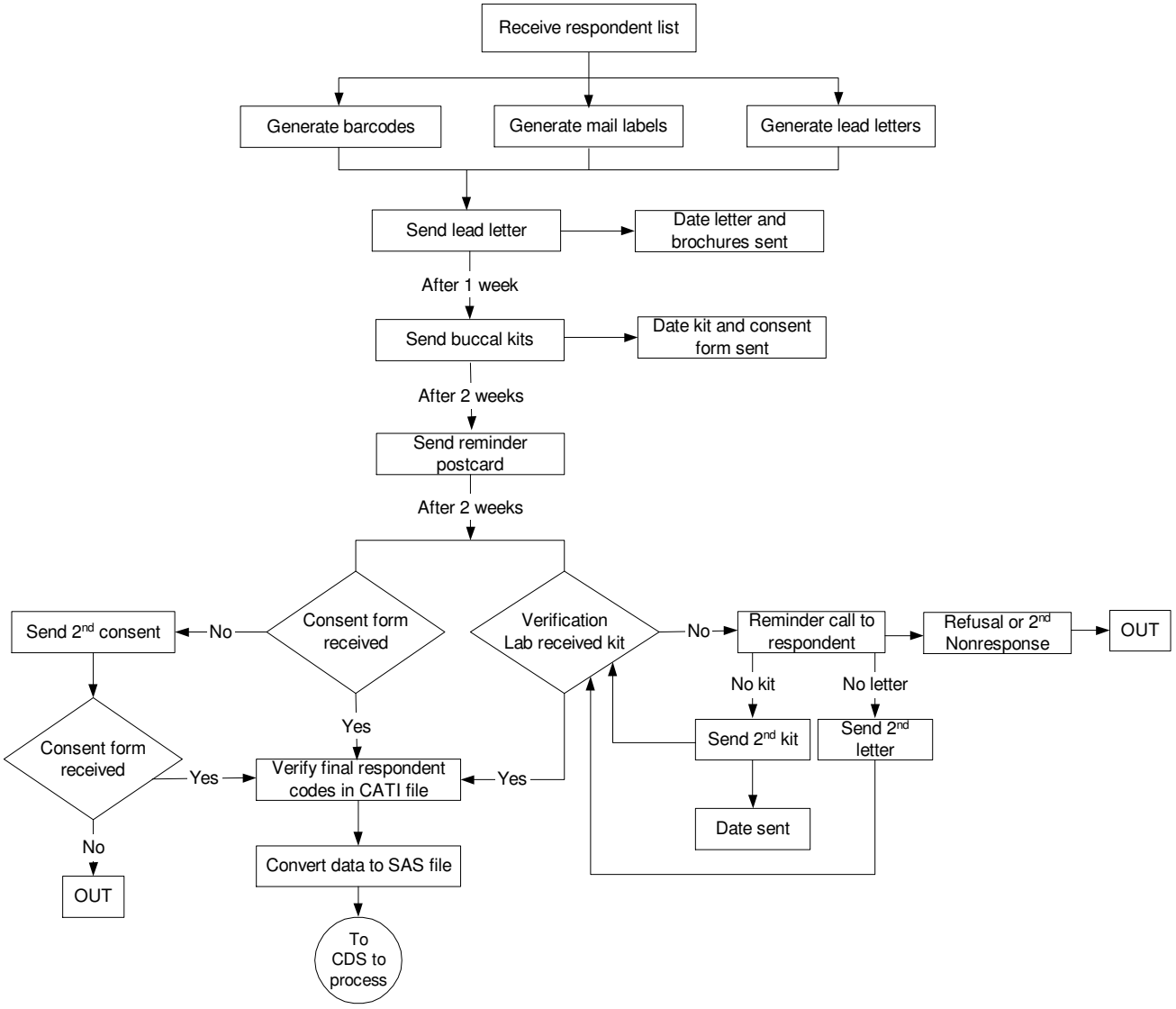
Start	Stop	#	Lead Letter	Mail Kit	Reminder Postcard	Reminder Call
B00115	B02279	1	10/11/00	10/16/00	10/23/00	11/1/00
B02285	B04720	2	10/16/00	10/23/00	10/30/00	11/6/00
B04729	B07095	3	10/23/00	10/30/00	11/6/00	11/13/00
B07100	B09207	4	10/23/00	10/30/00	11/6/00	11/13/00
B09239	B11017	5	10/30/00	11/6/00	11/13/00	11/20/00
B11042	B13456	6	10/30/00	11/6/00	11/13/00	11/20/00
B13458	B15750	7	11/6/00	11/13/00	11/20/00	11/27/00
B15755	B17801	8	11/6/00	11/13/00	11/20/00	11/27/00
B17820	B19924	9	11/13/00	11/20/00	11/27/00	12/4/00
B19964	B22245	10	11/13/00	11/20/00	11/27/00	12/4/00
B22261	B24414	11	11/20/00	11/27/00	12/4/00	12/11/00
B24425	B37313	12	11/20/00	11/27/00	12/4/00	12/11/00
B37441	B41943	13	11/27/00	12/4/00	12/11/00	12/18/00

4.2.4 Participant Recruitment

All sample members were sent an introductory lead letter and brochure describing the study and inviting them to participate. Copies of the lead letter and brochure are displayed in ***Appendix B***. Lead letters and buccal cell collection kits were sent out in waves in order to limit the number of specimens sent to the lab in a given week. One week after the lead letters were mailed, RTI Project Staff mailed buccal cell collection kits to the sample members. The buccal cell collection kit included instructions for collecting the sample, both written and visual (***Appendix G***), the necessary supplies for collecting and shipping the specimen to the lab, **Consent Form**, *Questionnaire regarding Childhood and Parents*, and $10 incentive. The **Consent Form** is displayed in ***Appendix H***.

One week after the collection kits were mailed, reminder postcards were sent to the respondents who had failed to return buccal cell kits. The reminder postcard is included in ***Appendix I***. TSD interviewers placed reminder calls to sample members whose specimens did not arrive at the lab or who failed to notify project staff of their refusal. During the reminder call, TIs identified sample members that needed an additional collection kit. Additional kits were needed to replace collection kits that had been misplaced by change of address, accidentally discarded, or were missing items, such as the Scope mouthwash. ***Exhibit 4-6*** is a diagram of the work flow for the Buccal Cell Study.

Exhibit 4-6. Buccal Cell Study Work Flow



4.2.5 Assessment of Capacity

Sample members that were initially deemed to be ineligible due to incapacity were recontacted to assess capacity and in some cases, elicit participation. Due to the age of the study sample, many subjects were reported to be mentally or physically incapable of participation. RTI project staff developed criteria for capacity based on the National Bioethics Advisory Commission Recommendations regarding Research Involving Persons with Mental Disorders that may Affect Decisionmaking Capacity. This process was thoroughly discussed in *Section 4.1.8*.

Physicallly impaired individuals that could "swish and spit" with assistance were asked to participate. Similarly, individuals with the mental capacity to make choices, as to cereal, clothing, etc., were asked to participate. All other sample members were classified as incapable and were not further contacted.

RTI project staff made every effort to engage the prospective subject in the informed consent process. We attempted to develop and present material relevant to the project to help the cognitively impaired to understand the research through the use of a simplified consent (less complex language and less words) and visual instructions. In addition, for subjects with fluctuating or limited decision making capacity, we used concurrent consent by a family member or friend chosen by the subject. These family members were asked to sign a **Proxy Consent Form**, in addition to the subject signing the **Simplified Consent Form**. The **Simplified Consent Form** and **Proxy Consent Form** are included in ***Appendix H***.

4.2.6 Receipt of Specimens at University of Washington

The University of Washington laboratory staff notified the Biospecimen Manager weekly to report the ID numbers of the specimens received. ID numbers for specimens received were entered into an Excel spreadsheet and sent to the Biospecimen Manager.

4.2.7 Receipt of the Consent Forms and Questionnaire

Sample members returned the consent forms and *Questionnaire regarding Childhood and Parents* to RTI using the business, pre-addressed first class envelopes included in their collection kits. RTI project staff entered the consent forms into the database on a weekly basis. Because the forms were labeled with barcodes, they were easily scanned into the database with a wand. RTI staff verified that all consent forms contained the signature of the participant. RTI project staff also keyed questionnaire data into the database.

4.3 Kin Substudy

4.3.1 Receipt of Sample from Duke

Duke staff were responsible for providing the sample members for the Kin Substudy and for sending contact information about the selected sample members to RTI. The sample members, siblings of the 1999 NLTCS respondents, were identified in the Duke file by the 1999 NLTCS respondent's unique identifier. Each sample member did not have unique identifiers of their own. RTI project staff loaded all information for the sample members into a database and assigned a unique case identification number (ID) to each case based on their 1999 NLTCS sibling's unique case number. A suffix was added to the original respondent's ID number for each sibling. For example, "0052101" and "0052102" were assigned to the two siblings of original respondent "00521". The name of the 1999 NLTCS participant (sibling) was included in each Kin sample member's record for recruitment purposes.

4.3.2 Tracing

Approximately 2443 cases or 52 percent of the Kin sample members had inadequate contact information. Addresses and/or phone numbers were either missing or incorrect, so RTI project staff decided to send these cases to the TOPS. TOPS specializes in locating new contact information for lost study subjects. TOPS provided RTI project staff new contact information for 604 cases. In addition, they alerted project staff to 56 deaths and 21 participation refusals.

4.3.3 Buccal Cell Collection Kit Assembly

Data Preparation (DP) Unit staff completed several tasks as part of the assembly of buccal cell collection kits. DP staff labeled all consent forms and questionnaires with patient-specific barcodes. Each barcode contained the sample member's ID number followed by a form specific suffix. For example, each consent form was labeled with a barcode that contained an ID number followed by "CF". DP staff also labeled the buccal cell collection vials with patient-specific barcodes. To complete the task, DP staff wore gloves to prevent transferring their DNA to the vials and contaminating the tests. RTI project staff assembled the remaining items for the subject-specific buccal cell kits and inserted the $10 incentive so that the kits could be shipped to the respondents.

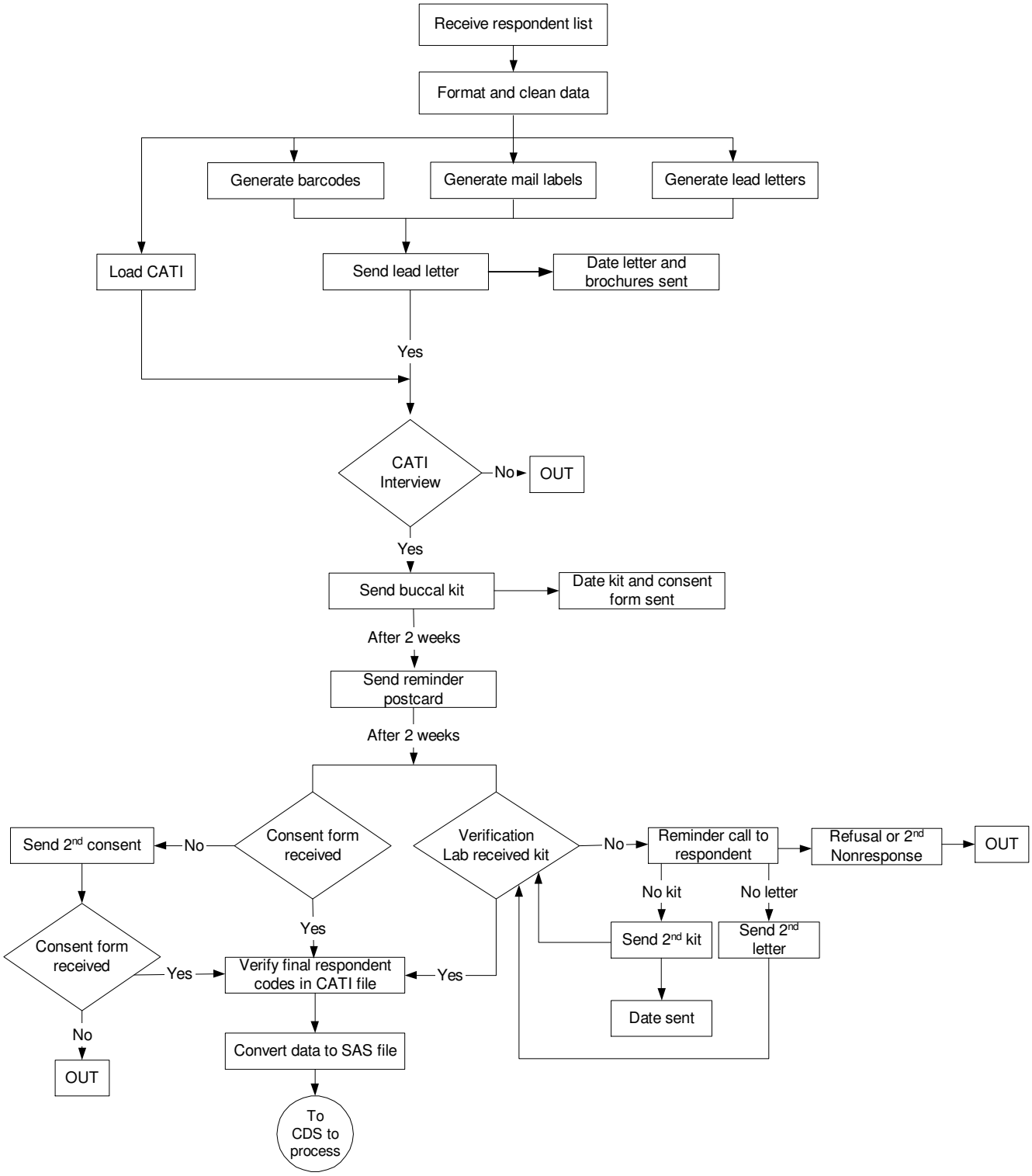
4.3.4 Participant Recruitment

All sample members were sent an introductory lead letter and brochure describing the study and inviting them to participate. Copies of the lead letter and brochure are displayed in ***Appendix B***. One week after the lead letters were sent, TSD interviewers called sample members to elicit their participation. Participation included the completion of the 25-minute telephone questionnaire regarding health and functioning. Proxy interviews were conducted in the event that a sample member was hard of hearing or incapacitated. All participants that completed the interview were asked to submit a buccal cell specimen.

Prior to the interview, the TI explained to the subject that participation in the study included providing verbal informed consent and completing the telephone questionnaire. The TI read the consent to the subject over the telephone. Each sample member was given the opportunity to ask questions prior to giving consent to participate. The TI also provided the telephone number of the Data Manager and an RTI IRB contact in the event that a participant had further questions about the study or his rights as a study participant.

One week after the completed interview, RTI project staff mailed the sample member a buccal cell collection kit. The buccal cell collection kit included instructions for collecting the sample, both written and visual (***Appendix G***), the necessary supplies for collecting and shipping the specimen to the lab, **Consent Form**, *Questionnaire regarding Childhood and Parents*, and $10 incentive. The **Consent Form** is displayed in ***Appendix J***. A diagram of the work flow for the Kin Study is presented in ***Exhibit 4-7***.

Exhibit 4-7. Kin Study Work Flow



4.3.5 Receipt of Specimens at University of Washington

The University of Washington laboratory staff notified the Biospecimen Manager weekly to report the ID numbers of the specimens received. ID numbers for specimens received were entered into an Excel spreadsheet and sent to the Biospecimen Manager.

4.3.6 Receipt of the Consent Forms and Questionnaire

Sample members returned the consent forms and *Questionnaire regarding Childhood and Parents* to RTI using the business, pre-addressed first class envelopes included in their collection kits. RTI project staff entered the consent forms into the database on a weekly basis. Because the forms were labeled with barcodes, they were easily scanned into the database with a wand. RTI staff verified that all consent forms contained the signature of the participant. RTI project staff also keyed questionnaire data into the database.

4.4 Next-of-Kin Substudy

4.4.1 Receipt of Sample from Duke

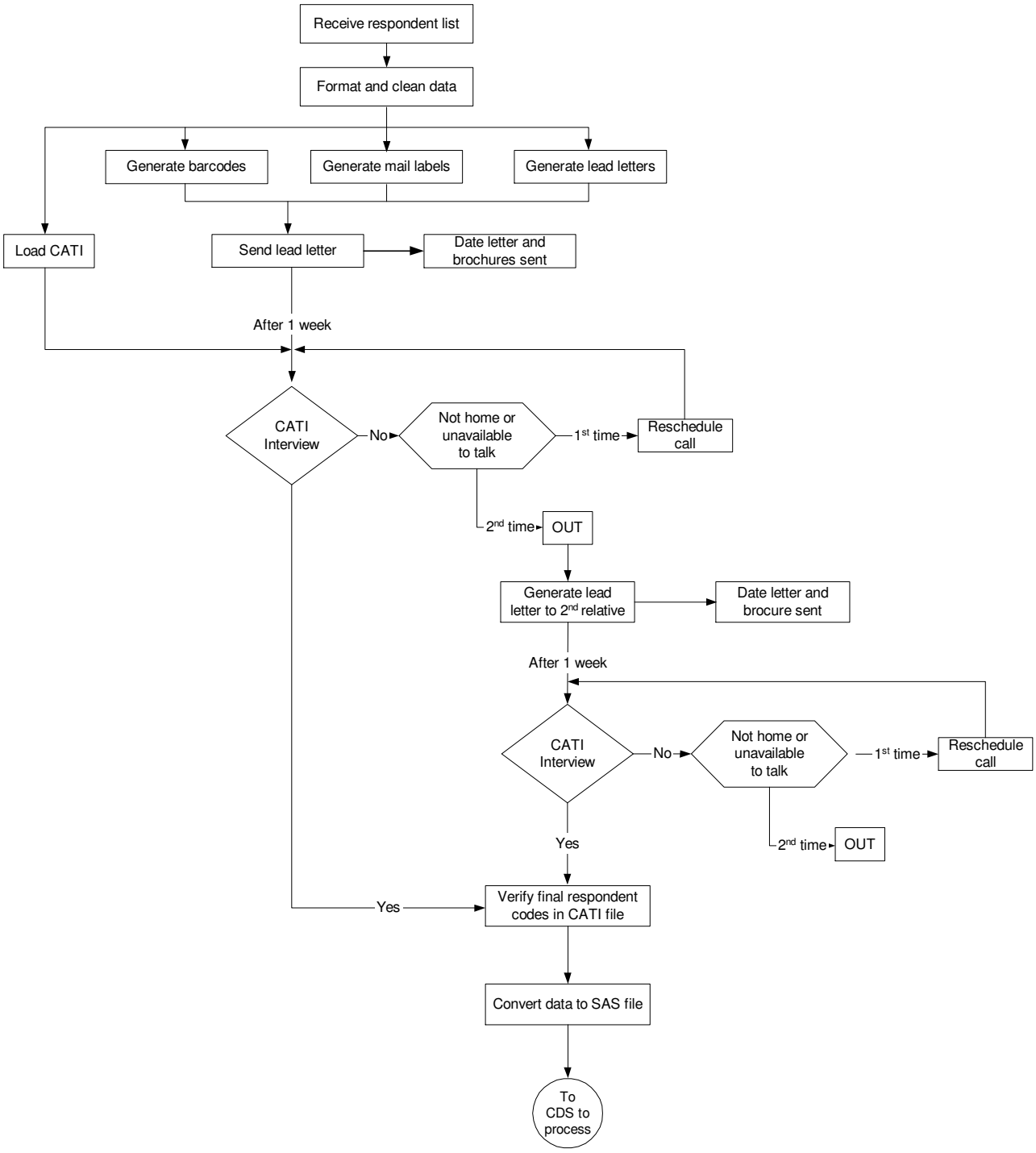
Duke staff were responsible for providing the sample members for the Next-of-Kin (NOK) Substudy and for sending contact information about the selected sample members to RTI. RTI project staff loaded all information for the sample members into a database. The database was constructed to store contact information for two relatives of each deceased subject. Unlike the other studies, the unique case-identification number (ID) was assigned to the deceased and not the NOK sample members. If the Telephone Survey Unit was unable to contact the first relative, the name and phone number of the second contact appeared for the Interviewer's use. Sample members with missing or incorrect contact information were not sent to TOPS.

4.4.2 Participant Recruitment

All sample members were sent an introductory lead letter and brochure describing the study and inviting them to participate. Copies of the lead letter and brochure are displayed in ***Appendix B***. One week after the lead letters were sent, TSD interviewers called sample members to elicit their participation. Participation included the completion of the 25-minute telephone questionnaire regarding the deceased subject's care immediately prior to death. The questionnaire collected data that included the cause of death, place of residence prior to death, and the utilization of institutional care, such as a nursing home. In the event that the first relative could not be contacted or was unable to participate, the second relative was contacted to complete the interview.

Prior to the interview, the TI explained to the subject that participation in the study included providing verbal informed consent and completing the telephone questionnaire. The TI read the consent to the subject over the telephone. Each sample member was given the opportunity to ask questions prior to giving consent to participate. The TI also provided the telephone number of the Data Manager and an RTI IRB contact in the event that a participant had further questions about the study or his rights as a study participant. The work flow plan for the Next-of-Kin Study is presented in ***Exhibit 4-8***.

Exhibit 4-8. Next-of-Kin Study Work Flow



References

1. National Bioethics Advisory Commission (Dec 1998). Research Involving Persons with Mental Disorders that may Affect Decisionmaking Capacity.