

1.0 Introduction

This report describes the design, implementation, and operational results of the Functional and Health Changes of the Elderly Supplemental Studies for the 1999 National Long Term Care Survey, or NLTCS. The four Supplemental Studies included the Venipuncture Study, Buccal Cell Study, Kin Survey, and Next-of-Kin (NOK) Survey. The Venipuncture and Buccal Cell Studies involved the collection of DNA samples from 1999 NLTCS participants. The Kin and NOK Surveys entailed a telephone interview with siblings and kin of 1999 NLTCS participants. Participants in the Kin Survey were also asked to submit a buccal cell sample for genetic analysis. The focus of this document is to describe the field procedures used, highlight strengths and weaknesses of the procedures, report operational results, identify barriers encountered during the conduct of the Supplemental Studies, and provide recommendations for future iterations of the studies. The 1999 NLTCS Supplemental Studies were conducted by Research Triangle Institute (RTI) under contract to Duke University from 2000 to 2002.

1.1 Background and Overview of the NLTCS

The NLTCS, sponsored by the National Institute on Aging (NIA), is a national survey of Medicare beneficiaries in 173 primary sampling units (PSUs). The NLTCS is comprised of longitudinal respondents, who are interviewed with each iteration, and new respondents, who are added to replenish the sample so that it represents the entire U.S. population over age 65. The NLTCS consists of questions regarding respondent mental and physical health and well being. Duke University's Center for Demographic Studies (CDS) managed the 1982, 1984, 1989, 1994, and 1999 waves of the NLTCS. Dr. Kenneth Manton was the Principal Investigator for the NLTCS, and Dr. Larry Corder was the Senior Investigator. The Census Bureau conducted each iteration of the NLTCS Core Interviews, and RTI was retained by Duke University to conduct the 1999 NLTCS Supplemental Studies.

The goal of the 1999 NLTCS was to obtain disability and mortality data from aged Medicare beneficiaries nationwide and link that data to earlier NLTCS. The 1999 NLTCS, with cross-sectional and longitudinal sample components, was used to evaluate changes in age and gender specific chronic disability rates 1982 to 1999, assess correlates of age and gender specific disability, and discover how changes in chronic disability relate to mortality observed at late ages 1982 to 1995. The 1999 NLTCS also examined how changes in body mass index and nutrition relate to activity levels and disability as assessed in the NLTCS over time, evaluated changes in higher functional levels in aged individuals from 1994 to 1999, and examined the relation of disability and mortality changes to changes in Medicare service use from 1982 to 2000.

The results of the NLTCS have major scientific and health policy significance. The NLTCS can be used to longitudinally track changes in the health and functioning of individuals in a nationally representative sample of persons age 65 and over. The results can be used to determine the nutritional status of the aged and its effects on cognition and disability. Also, NLTCS data can be utilized to track changes in Medicare home health and skilled nursing facility use. Consistent with the earlier practice with the 1982 to 1994 NLTCS, the 1999 NLTCS files and data on Medicare service use, mortality and relevant documentation will be linked to the earlier NLTCS and made available to researchers of the aging community.

1.2 Overview of the Functional and Health Changes of the Elderly Supplemental Studies

RTI, as a subcontractor to Duke University, assisted Duke's CDS by conducting four supplemental studies with 1999 NLTCs participants. The Functional and Health Changes of the Elderly Supplemental Studies included the Venipuncture Study, Buccal Cell Study, Kin Survey, and NOK Survey. RTI's responsibilities included protocol development, questionnaire revision, CATI questionnaire programming, retaining phlebotomy subcontractors, data and biospecimen collection, data processing, and reporting activities for all components of the supplemental studies.

The Functional and Health Changes of the Elderly Supplemental Studies will help determine the heritability of disability and health problems. Blood and buccal cell samples were collected in order to assess the effects of apolipoprotein (APOE) polymorphisms on dementia, cognitive impairment, and circulatory disease and the effects on selected genetic markers (e.g., within the WRN gene) of human longevity syndromes and their relation to physical function. Elderly siblings of the 1999 NLTCs participants were interviewed in order to examine the correlation of disability and longevity traits for persons with different biological relations. The combination of data from NLTCs respondents and their siblings provides enough statistical power to evaluate hypotheses on the prevalence of chronic disease in biologically related individuals. Data from the supplemental studies will also be used to further the research into the costs of health care among the elderly.

1.2.1 Overview of the Venipuncture Study

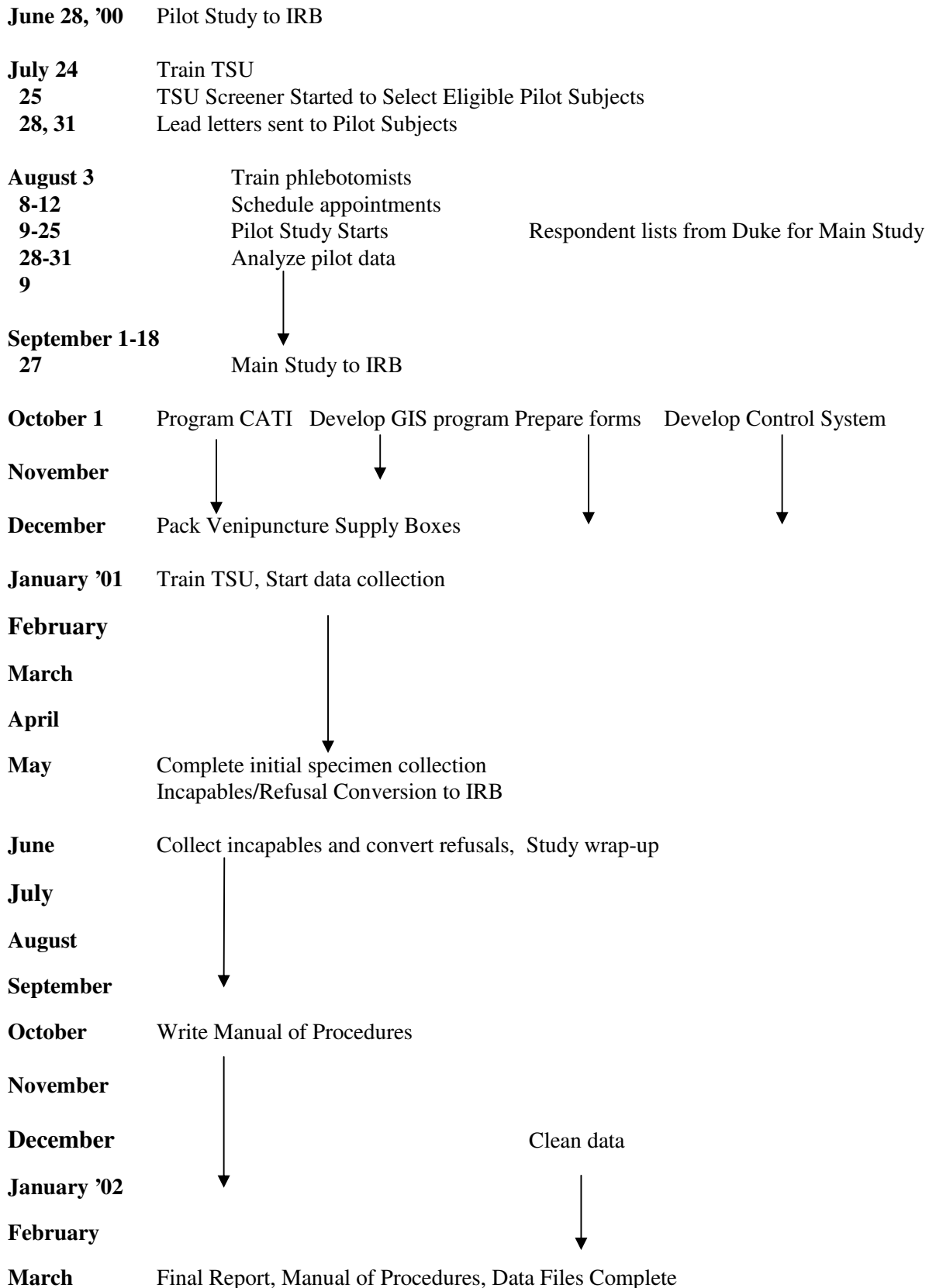
The purpose of the Venipuncture Study was to collect blood samples from 2,000 NLTCs participants, aged 65-89, living in 145 PSUs across the U.S. Blood collection was restricted to individuals less than 90 years of age to minimize participant burden on the extreme elderly. A pilot study was conducted in the summer of 2000 to test the effect of two levels of incentive payment on participation rate, and blood collection began nationwide in February 2001.

RTI sent a lead letter and study brochure to sample members prior to contacting them by telephone to elicit participation. Once the sample member agreed to participate, the telephone interviewer set a blood draw appointment. Subcontracting nurses traveled to the participant's home, obtained written consent, obtained the blood sample by venipuncture, and paid the fifty dollar incentive. Three vials of whole blood (20 ml total) were collected from each respondent and shipped overnight to the University of Washington. Sample members that refused venipuncture were asked to submit buccal cell samples.

1.2.2 Venipuncture Study Timeline

The project timeline is included in *Exhibit 1-1* to graphically present the chronological order of study tasks. Activities on the timeline are fully described later in this report.

Exhibit 1-1. TIMELINE: National Long Term Care Survey - Functional and Health Changes of the Elderly Venipuncture Substudy



1.2.3 Overview of the Buccal Cell Study

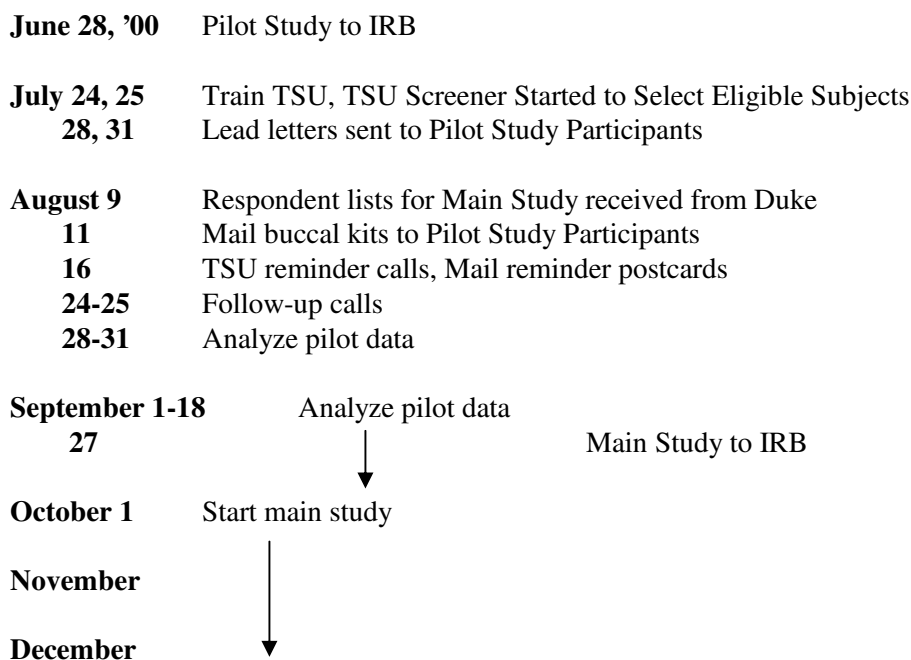
The purpose of the Buccal Cell Study was to collect buccal cell samples from 1,500 NLTCS participants, age 80 and older, living in 173 PSUs across the U.S. A pilot study was conducted in the summer of 2000 to test the DNA yield obtained from the 'swish and spit' method of buccal cell collection and to test the effect of two reminder procedures for obtaining buccal cell samples through the mail. Half of the sample members received a reminder postcard for submitting their specimen; the other half received a reminder telephone call. Buccal cell collection began nationwide in October 2000.

RTI sent a lead letter and study brochure to sample members requesting their participation in the Buccal Cell Study. One week later, a buccal cell collection kit, complete with consent form, ten-dollar incentive, and instructions, was sent to each sample member. Sample members were asked to swish two teaspoons of Scope mouthwash around in their mouths to collect their cheek cells for genetic analysis. Collected samples were sent Priority Mail to the University of Washington. Two weeks after the mailing of the buccal cell collection kit, sample members who had not returned their specimens were sent a reminder postcard. One week after the reminder postcards were mailed, telephone interviewers called sample members that had failed to return a sample or communicate their refusal and elicited their participation.

1.2.4 Buccal Cell Study Timeline

The project timeline is included in *Exhibit 1-2* to graphically present the chronological order of study tasks. Activities on the timeline are fully described later in this report.

Exhibit 1-2. TIMELINE: National Long Term Care Survey – Functional and Health Changes of the Elderly Buccal Cell Substudy



January '01	Fix technical problems
February	Clean data, plan for refusal conversion
March	Begin remails to newly located subjects
April	↓
May	Data back from Tracing
June 11	Begin study wrap-up
27	Incapables and Refusal Conversions to IRB
July	Begin remails to incapables and refusal conversions
August	↓
September	Out of field
October	Clean data
November	↓
December	↓
January '02	Begin Manual of Procedures (MOP)
February	↓
March	Final Report, Manual of Procedures, Data Files Completed

1.2.5 Overview of the Kin Survey

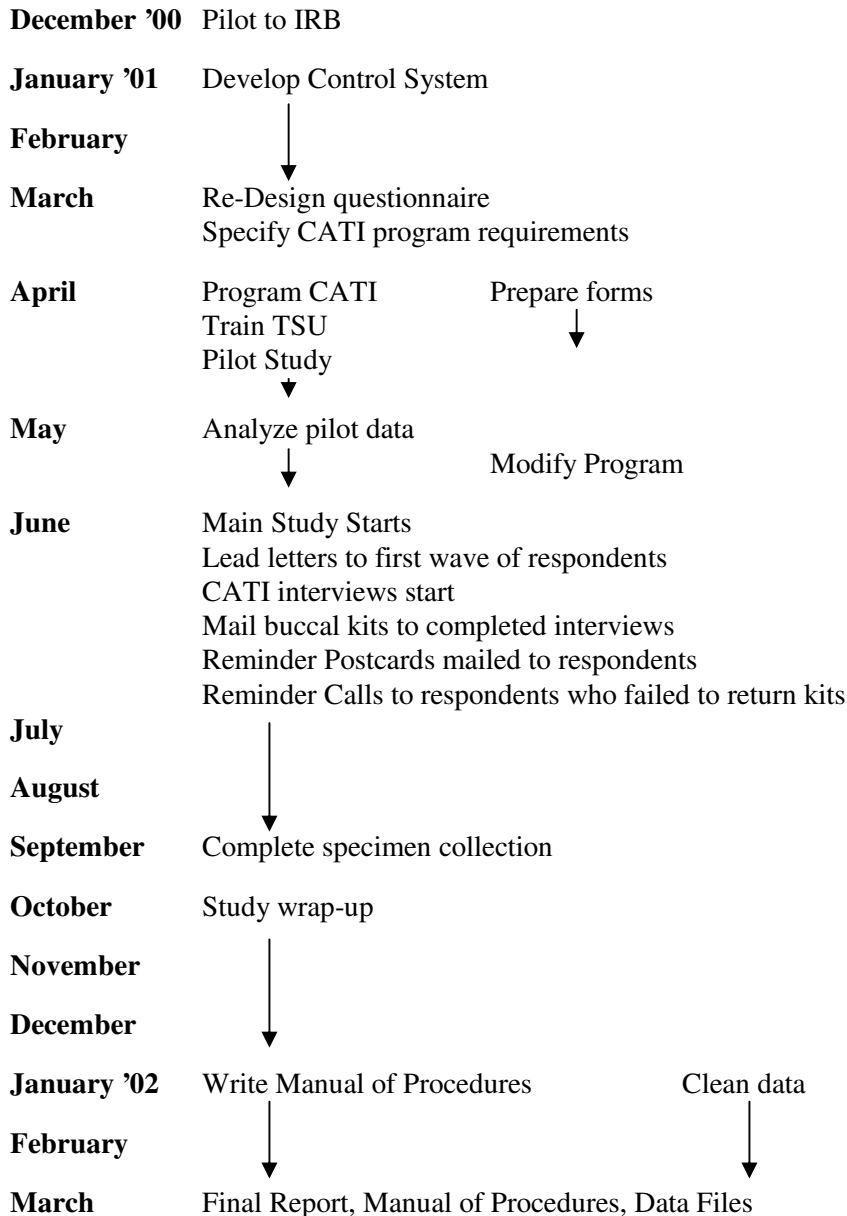
The purpose of the Kin Survey was to interview and collect buccal cell samples from 3,500 siblings of NLTCs participants, living in 95 PSUs across the U.S. A pilot study was conducted in the spring of 2001 to test procedures and to assess participation rates for both the telephone interview and buccal cell collection. The main study began nationwide in June 2001.

RTI sent a lead letter and study brochure to siblings of the NLTCs participants requesting their participation in the Kin Survey. One week later, a telephone interviewer contacted sample members to obtain participation in the survey or establish a proxy, if necessary. Participants completed a 25-minute interview to assess their health and functioning. At the conclusion of the interview, participants were asked to provide a buccal cell sample for genetic analysis. Buccal cell collection kits were mailed according to the procedures developed for the Buccal Cell Study.

1.2.6 Kin Survey Timeline

The project timeline is included in *Exhibit 1-3* to graphically present the chronological order of study tasks. Activities on the timeline are fully described later in this report.

Exhibit 1-3. **TIMELINE: National Long Term Care Survey – Functional and Health Changes of the Elderly Kin Substudy**



1.2.7 Overview of the Next-of-Kin Survey

The purpose of the Next-of-Kin (NOK) Survey was to interview 450 family members of 1999 NLTCs

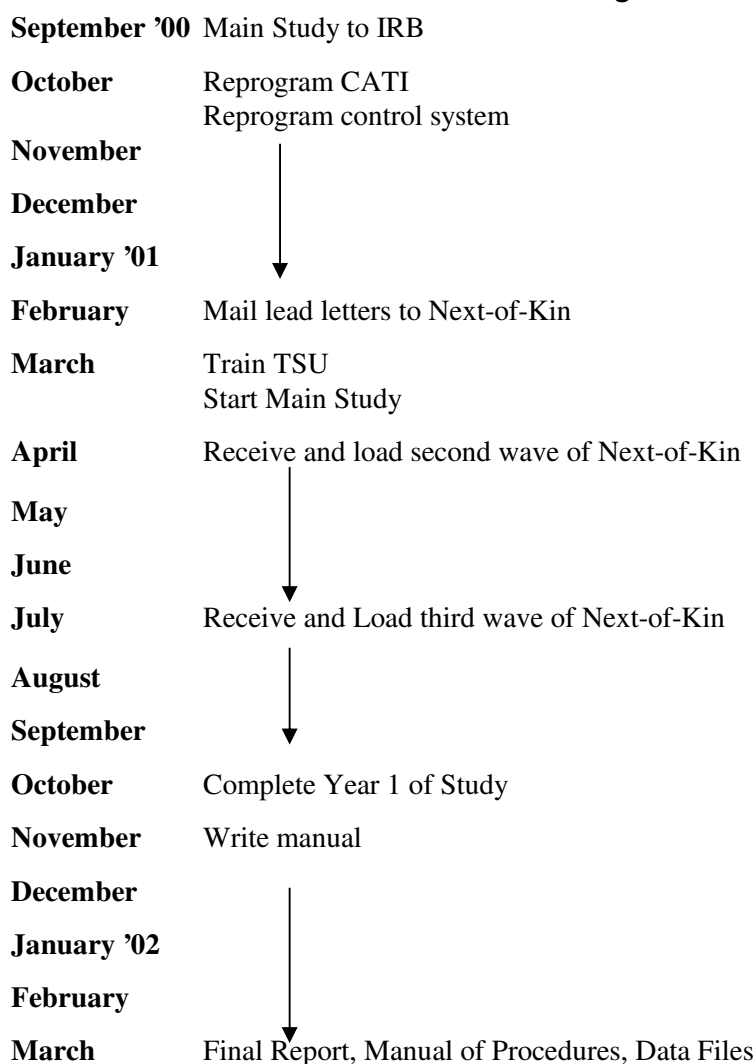
participants who had died since the Core Interview. A pilot study was conducted in 1997-1998 to evaluate the procedures, instruments and related materials, and response rates for the NOK Survey. The main study began nationwide in the spring of 2001.

RTI sent a lead letter and study brochure to the next-of-kin of deceased 1999 NLTCs participants requesting their participation in the NOK Survey. One week later, a telephone interviewer contacted sample members to obtain participation in the survey by providing information on the deceased subject’s health and medical care immediately prior to death. Participants completed a 25-minute interview that included the causes of death, place of residence prior to death, and use of institutional care, such as nursing homes or hospitals.

1.2.8 Next-of-Kin Survey Timeline

The project timeline is included in *Exhibit 1-4* to graphically present the chronological order of study tasks. Activities on the timeline are fully described later in this report.

Exhibit 1-4. TIMELINE: National Long Term Care Survey – Functional and Health Changes of the Elderly Next-of-Kin Substudy



1.3 Institutional Review Board Approval

The RTI Committee for the Protection of Human Subjects (or IRB) reviewed the 1999 NLTCS Venipuncture and Buccal Cell Pilot Studies on June 28, 2000. The pilot study for Kin was reviewed on December 20, 2000. The Venipuncture and Buccal Cell Main Studies were reviewed by the IRB on September 20, 2000. The main study for Kin was reviewed on April 17, 2001, and the main study for NOK was reviewed on October 18, 2000. Respondents deemed to be mildly or moderately physically or mentally incapable were approved for inclusion in the Venipuncture and Buccal Cell Studies on May 23, 2001. Issues raised by the IRB were addressed by the RTI Project Director, and the studies were approved for implementation. In addition to RTI's IRB approval, the 1999 NLTCS supplemental studies were reviewed and approved by the Duke IRB. All of the Supplemental Studies were re-approved by RTI's IRB during annual reviews of the projects.

1.4 Summary of Supplemental Studies Results

1.4.1 Venipuncture

There were 1988 eligible subjects in the data files submitted to RTI from Duke's Center for Demographic Studies. Sixty percent of the eligible sample donated a biospecimen for genetic analysis. Almost half of the biospecimens were buccal cell specimens not blood. Buccal cell collection was offered as an alternative to venipuncture as many of the respondents did not object to genetic analysis but did object to the invasive venipuncture procedure or to having a stranger in their homes. More comprehensive presentation of the results are presented in Chapter 6.

1.4.2 Buccal Cell

The Buccal Cell Study had 1186 eligible subjects aged 80 to 100+ years. The subjects were mailed buccal cell kits for biospecimen collection. Fifty percent of the sample returned a sample for genetic analysis. A significant percentage of this population was not physically or mentally capable of donating a biospecimen.

1.4.3 Kin

There were 2,397 eligible subjects in the data files submitted to RTI from Duke's Center for Demographic Studies. Sixty percent of the subjects completed an interview, 5% of the interviews were proxy interviews for incapable respondents. Seventy percent of the respondents who completed an interview returned a biospecimen for genetic analysis. There were 386 sets of siblings among the genetic samples. Set sizes ranged from sets of two to sets of six siblings.

1.4.4 Next-of-Kin

RTI received 664 potential next-of-kin subjects of deceased NLTCS respondents. Relatives were very cooperative and willing to complete the interview, yielding an 82% response rate.
