Manual 18

TICS Substudy

April 23, 2013

Study website - **http://www.cscc.unc.edu/aricncs/**

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1. Overview

The purpose of the TICS substudy is to provide better characterization of non-examined persons for whom a TICS (Telephone Interview for Cognitive Status) interview was obtained. As there is no specific hypothesis specified for this study, sample size calculations are based on estimation of the correlation between TICS and other measures of cognitive function, e.g. the MMSE (Mini-Mental State Exam - assumed to be ~.70).[1] Sample sizes required to achieve specified 95% confidence interval widths for the Spearman correlation coefficient are provided for a range of planning estimates of the correlation.

Planning estimate of ρ	Confidence Interval Width		
	0.1	**0.2**	**0.3**
0.5	975	246	111
0.6	746	189	86
0.7	503	129	60
0.8	269	72	36

A sample size of 132 would appear to strike a balance between obtaining a reasonable estimate and work-load feasibility. As the TICS refusal rate has been high, Field Centers (FCs) will contact participants until they reach the required sample size. Refusals will be noted to allow assessment of the refusal rate and representativeness of the sample. To ensure representation from all FCs and even distribution of the workload, the sample will be stratified by FC. The TICS will therefore be completed for 33 participants at each FC, randomly sampled from those who have been selected to Stage 2 and attended the visit.

2. Sampling List

The Coordinating Center will produce four lists, one for each Field Center, of participants who have been selected to Stage 2 in the six months prior to creation of the list and have any data entered in the PNE form (Stage 2 physical and neurological exam). The lists will be randomly permuted. Field Center staff will contact participants in order until 33 participants have completed the TICS. Refusals will be tracked as described below. To maintain the random sample, it is critical that the participants are contacted in order. To clarify, the first 33 participants on the list may be contacted in any order. Beyond that, the number of participants contacted should not exceed the number of refusals. (e.g. do not contact #35 on the list until at least two participants have refused the TICS). FCs should be aware that a small number of participants completed the TICS then went on to complete the clinic visit. These participants may have been sampled for the TICS substudy. It is not necessary to complete a second TICS for these participants – please confirm before contacting a sampled participant that the TICS has not already been entered into the DMS. If a TICS was completed prior to creation of the sampling list, it will be noted on the list.

All calls should be completed within three months of distribution of the list.

3. Administration of the TICS and Data Entry

Ideally, the TICS should be administered by the same staff administering TICS for the main study (certification for new staff is described below).

Data entry instructions and a recruitment script are included in the TICS QxQ. The TICS form should be completed for every participant who agrees to complete the TICS. If a participant is contacted and refuses, the TICS form should be set to permanently missing. The TICS form may be set to permanently missing upon three failed contacts. No data entry is required for participants who are not contacted.

4. Certification

Field Centers desiring to train additional staff in the TICS protocol may utilize a local expert to train and certify. Local certification should include demonstrated proficiency in the administration and scoring of the TICS, including observation of 2 certification assessments (where adherence to script and accurate scoring is appropriately demonstrated). The CC should be notified when a new staff member has been certified.

5. Reporting

The CC will add a table to the weekly management report tracking progress of the TICS substudy.

[1] Fong, TG, Fearing, MA, Jones, RN et al. The Telephone Interview for Cognitive Status: Creating a
crosswalk with the Mini-Mental State Exam. Alzheimers Dement. 2009 November 5(6): 492–497.