



# SOL-INCA2

## Eligibility and Recruitment (IER)

### QxQ

7/11/2025

### Introduction

The Eligibility and Recruitment (IER) form is designed to capture information about eligibility and informed consent for all participants approached for the SOL-INCA2 ancillary study. **Q0a-Q3** may be completed before the INCA2 visit.

### Procedures

The IER form can either be updated directly in CDART or completed on paper and keyed into CDART. A video tutorial depicting the data entry process is available online at <https://sites.csc.unc.edu/hchs/SOL-INCA>.

### Recording Responses

For each question, enter or select the appropriate response.

#### ADMINISTRATIVE INFORMATION

**Q0a.** Enter the date the form was initially completed.

**Q0b.** Enter the Staff ID of the person who completed the form.

**Q0c.** Update as necessary to reflect the participant enrollment status.

0 = Ineligible → Selected when a participant identified as eligible in CDART is determined to no longer be eligible. This includes:

- Participant lives outside the field center radius
- Participant lives outside of the country
- Participant lives in a nursing home or other care facility
- Participant is incarcerated
- Participant is unable to come to the field center due to mental or physical disability, but is outside the radius for field center transportation or home visit

1 = Eligible but not interested → Selected when a participant identified as eligible in CDART indicates they are not interested in the study. This includes:

- Participant is sick or caring for a sick relative (and home visit is not an option)

2 = Eligible and interested → Selected when a participant identified as eligible in CDART indicates they are interested in the study.

#### A. APPOINTMENT

**Q1.** Enter the scheduled appointment date for obtaining consent and completing neurocognitive testing. This is typically the same as the Visit 3 appointment date.

**Q2.** Indicate whether the participant will be attending the appointment with a proxy who will sign the consent form. In most cases, the proxy will also serve as an informant.

**Q3.** Indicate whether the participant will be attending the appointment with an informant who can answer questions about the changes in the participant's memory and abilities to do daily activities. This may be a proxy or another individual who attends the appointment with the participant.

**Q3a.** Indicate whether the neurocognitive testing appointment will occur at the field center or in the participant's home.

## B. CONSENT

**Q4.** Enter the date the participant was presented with the consent form. This is typically the same as the Visit 3 appointment date.

**Q5.** Indicate whether the proxy version of the consent form was utilized to obtain consent.

**Q6.** Enter the final consent status of the participant.

0 = Refused to participate → Selected when a participant or proxy that expressed interest in the study did not agree to participate in the study.

1 = Agreed to participate → Selected when a participant or their proxy agreed to participate and signed the corresponding informed consent document.

**Q7.** Indicate whether the participant or their proxy agreed to audiotaped interviews. If the participant agrees to audiotaped interviews, they will be asked to reconfirm verbally before the recording begins. In this case, do not update the IER. The IER CDART form should reflect what is recorded on the signed INCA2 informed consent document.

**Q8.** Indicate whether the participant or their proxy agreed to an MRI scan. If the participant agrees to an MRI scan, they may be invited to participate in the MRI component of the INCA2 study at a later date. They may still refuse to participate in MRI or withdraw consent for MRI at any time even if they consented here. Refusal or withdrawal after initially consenting will be recorded in a separate form. The IER CDART form should reflect what is recorded on the signed INCA2 informed consent document.

**Q9.** If the participant or their proxy modifies consent for the study, enter the most recent date on which consent was modified. There is no need to modify the IER form if the participant withdraws consent for audiotaped interviews or MRI scan.

## C. NEUROCOGNITIVE TESTING

**Q10 – Q12.** Enter the date, start time, and stop time during which the neurocognitive tests were administered.

**Q13.** Indicate whether the participant had any physical impairments and/or disabilities that may have affected neurocognitive testing (for example, hearing, visual, motor).

**Q13a.** If Q13=1 (Yes), note the specific physical impairment/disability here.

**Q14.** Indicate whether a field center-provided hearing assistive device was used with the participant at any point during the neurocognitive exam.