	<b>Title:</b>	<b>In-Home Check-in Procedures SOP</b>		
	<b>Version Date:</b>	2017-FEB-09	<b>Document Number:</b>	SOP_DCS_0053
	<b>Effective Date:</b>	2017-MAY-15		
<b>Data Collection Site (DCS)</b>	<b>Version:</b>	3.2	<b>Number of Pages:</b>	5

### 1.0 Purpose:

The purpose of this document is to provide a standardized approach to welcoming a participant at the start of an in-home interview, as well as to ensure that all preparatory information is conveyed to the participant clearly and accurately.

### 2.0 Scope:

This document is to be used by In-Home Interviewers to welcome participants at the start of in-home interviews and to ensure that all preparatory information is conveyed to the participants clearly and accurately.

### 3.0 Responsibilities:

In-home Interviewers are responsible for performing the procedures as described in the current and approved version of this standard operating procedure.

### 4.0 Related Documents:

- **MAN\_GEN\_0207** – Beartooth F1, V2.0 Interviewer and + Technical Manual
- **MAN\_DCS\_0224** – Accommodations Guidance Manual
- **MAN\_GEN\_0223** – Proxy Process Guidance Manual
- Proxy Process Script
- **SOP\_DCS\_0064** – Collecting Measurements Manually & Manual Data Entry – DCS

### 5.0 Definitions:

Not applicable

### 6.0 Equipment:

- Laptop computer (fully charged);
- Mouse;
- Headphones with microphone;
- Signature pad; and,
- Personal cellular phone.

### 7.0 Supplies:

- Pen & paper;
- CLSA ID badge;
- GPS or Google map of the surrounding area;

- Proxy Information Package (for participant 70 & older);
- Proxy Consent (for participant 70 & older);
- CLSA Brochure;
- CLSA FAQ (printed from website);
- Paper copy of the Proxy Process Script;
- Participant DCS Visit Instructions; and,
- Paper copy of the In-Home Questionnaire.

## 8.0 Procedure Steps:

**Step 1:** In Home Interviews are booked using Beartooth\_f1, refer to *MAN\_GEN\_0207 – Beartooth F1, V2.0 Interviewer and + Technical Manual* for more details.

### Beginning the in-home interview

**Step 2:** When greeted at the participant's home, thank the participant for allowing you to come to their home. Ask the participant where they would like to conduct the interview.

- Ensure that the participant answers all of the questions (e.g., yes, no, don't know, refuse). A spouse or partner may be present, but it is preferred that the participant and the interviewer have some privacy while completing the interview to avoid distractions.
- If interviewing a participant with special needs, then refer to the **Consenting & Enrolling Participants with Special Needs** section below.

**Step 3:** In Onyx click on **Appointments of the day**.

**Step 4:** Find the participant's name in the list and click on **Receive**.

**Step 5:** Ask the participant to verify the following information and check it with the information in the computer system. Correct the information if the participant reports an error:

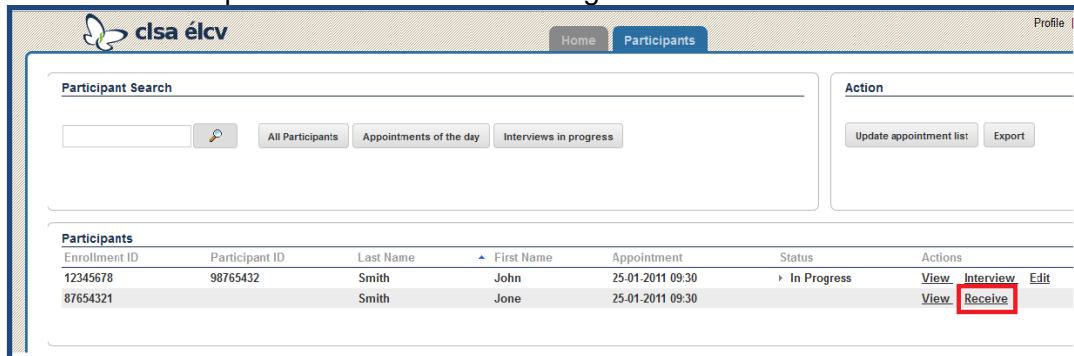
- Participant's name;
- Date of Birth;
- Address (check- corrections must be made in Beartooth\_f1); and,
- Phone.

The screenshot shows a web-based form for volunteer registration. The header includes the logo for 'cisa élcv' and navigation tabs for 'Home' and 'Participants'. The form title is 'Volunteer Registration'. The fields are as follows:

- First Name \*: Wilma
- Last Name \*: Flintstone
- Birth Date \*: 21-Apr-1964
- Gender \*: Female
- group.Address section:
  - Street: [empty]
  - City: [empty]
  - Province: [empty]
  - Country: [empty]
  - Postal Code: [empty]
- Phone: [empty]

**Step 6:** In the next of kin section, verify that the participant does not need to provide the name, address or phone number of their next of kin but instead should provide information for a contact person, preferably someone who doesn't live with them.

**Step 7:** Scroll down and press **Generate ID** on the right side



**Step 8:** At the Participant Tab in Onyx, look for the Participant's name and select **Interview** in the "Actions" in that row.

**Step 9:** Inform the participant that they will be asked to do the following during the interview:

- Answer questionnaires;
- Complete general health and memory tests.

**Step 10:** The interviewer must ask if the participant has any questions. If the participant doesn't have any additional questions, begin the consent process.

**NOTE: Consenting was done during Consenting verification at the time the interview was booked but** adults must be presumed capable of making decisions unless the opposite has been demonstrated. If you have any concerns that the participant has any form of cognitive impairment:

- Initiate the proxy script to ascertain if the participant would like to use a proxy.
- If the proxy script is not available to open in Beartooth, be sure to carefully note their answers to the questions in the script on the accompanying *ARF\_GEN\_0223 – Proxy Script Admin Report Form*.
- A copy of the ARF should be sent to the NCC in the vapor shipper, refer to the **Paper CRF Entering, Maintenance & Filing** section of *SOP\_DCS\_0064 - Collecting Measurements Manually & Manual Data Entry – DCS*.

**Step 11:** Provide the participant with a copy of the DCS visit instructions and review it with them.

**Step 12:** If the participant is 70 or older, and has not already established a proxy, they will have been sent a proxy information package with their reminder letter. If the participant has indicated that they want to identify a proxy, provide them with a copy of the proxy consent. Explain that the staff will go through the proxy consent with them at the DCS visit.

### **Participants with Special Needs**

Accommodation strategies will be employed as necessary, according to the details provided in the *MAN\_DCS\_0224 - Accommodations Guidance Manual*. Be sure to note any details about accommodations that the participant may need in Special notes in Beartooth\_f1 so that DCS staff can be aware of things the participant may need during the DCS visit.

### **Blind Participants**

- Inform the participant that they are welcome to bring a guide person or a guide dog to their site visit. If neither of the above options is available and the participant has a cellular phone, a DCS staff member can greet them at the cab/bus upon arrival and assist them into the DCS. Alternatively the participant could call the DCS upon departure, provide an expected time of arrival at the DCS and a staff member can meet them out front at the prescribed time.
  - Ensure that the participant is aware that although the guide person is allowed to guide them throughout the DCS, the guide person is unable to participate in the interview process.
- Note the blindness of the participant in Beartooth to ensure that DCS staff contact the participant and make special arrangements, where required, to assist the participant into the DCS.
- Other impairments can also be noted in Beartooth\_f1.

### **Illiterate Participants**

- Note illiteracy in Beartooth, ensuring that DCS staff are made aware of it and are prepared to read all written documents to the participant throughout the DCS visit.

### **Participants in Wheelchairs**

- Inform the participant that they are welcome to bring a person to assist them with mobility through the DCS, if required. If the participant has a cellular phone, a DCS staff member can greet them at the cab/bus upon arrival and assist them into the DCS. Alternatively, the participant could call the DCS upon departure, provide an expected time of arrival at the DCS, and a staff member can meet them out front at the prescribed time.
  - Ensure that the participant is aware that the person assisting with mobility is allowed to guide them through the DCS, but that they are unable to participate in the study process.
- Note the participant's impairment in Beartooth\_f1 to ensure that DCS staff contact the participant and make special arrangements for assistance at DCS visits if required.

## **9.0 Documentation & Forms:**

- **ARF\_GEN\_0223** – Proxy Script Admin Report Form

## **10.0 References:**

- The Declaration of Helsinki
- Good Clinical Practice (GCP) Guidelines
- Personal Health Information Protection Act ([PHIPA], Ontario only)

**F1 Revision History:**

<b>New Version #</b>	<b>Revision Date</b>	<b>Revision Author</b>	<b>Content Approval</b>
3.2	2017-FEB-09	Lorraine Moss	Mark Oremus
<b>Summary of Revisions</b>			
Remove - Step 13, describing the process for presenting the HIN-extended consent to the participant. Added the HIN-extended Consent to the list of Supplies. Updated information regarding changes to Beartooth_f1 version 2. Removed reference to completing consent verification on paper until new software is ready			
<b>New Version #</b>	<b>Revision Date</b>	<b>Revision Author</b>	<b>Content Approval</b>
3.1	2016-MAY-19	Lorraine Moss	Mark Oremus
<b>Summary of Revisions</b>			
Added Step 13, describing the process for presenting the HIN-extended consent to the participant. Added the HIN-extended Consent to the list of Supplies.			

FOLLOW-UP