

VOICE-C PTID

SH #

Today's Date

--	--	--	--

--

--	--

--	--	--

--	--

dd

MMM

yy

**Social Harms Report (SH)**

*Instructions: This form is to be completed for any VOICE-C participant who reports a social harm. Interviewer complete items 1-2.*

1.	Describe the social harm event  _____ _____ _____
	<input type="checkbox"/> Declined to answer

2.	What type of social harm is this event? <i>(mark all that apply)</i>	<input type="checkbox"/> Physical <input type="checkbox"/> Emotional <input type="checkbox"/> Financial <input type="checkbox"/> Other, specify: _____
----	--	---

**Participant Questions. To be asked to participants by interviewer.**

3.	Do you think this situation is resolved?	<input type="checkbox"/> Yes go to item 5 <input type="checkbox"/> No <input type="checkbox"/> Declined to answer
----	--	---

4.	What would help to resolve this situation?	 _____ _____ _____ <input type="checkbox"/> Declined to answer
----	--	--

5.	Did this event include unwanted disclosure of study participation?	<input type="checkbox"/> Yes <input type="checkbox"/> No, <b>go to item 7</b> <input type="checkbox"/> Declined to answer
----	--	---

6.	To whom (was there unwanted study participation disclosure)?	 _____ _____ _____ <input type="checkbox"/> Declined to answer
----	--	--

7.	Please tell me what impact this situation has had on your quality of life.	<input type="checkbox"/> A minimal disturbance that had no significant impact. <input type="checkbox"/> A moderately upsetting disturbance, but did not have a significant impact. <input type="checkbox"/> A major disturbance that had a significant impact. <input type="checkbox"/> Declined to answer
----	--	---

## Social Harms Form (SH-1)

**Purpose:** This form is used to record social harms reported by participants during their VOICE-C participation *that are related to VOICE-C study participation or procedures*.

**General Information/Instructions:** This form is only completed if a social harm is reported, therefore this form is not required for every participant, or at any specific visit.

**Overall instructions:** Enter the PTID in the top left corner of every page of this form and initial and date the bottom right of every page. The date the form is completed (not the date of the social harm) should be completed at the top of page 1, as well as the social harm number. The SH number should be assigned sequentially for each individual PTID. Items 1-2 are to be recorded by the Interviewer based on participant description or report and the action taken. Items 3-8 are to be asked to the participant and response categories may be read aloud.

### Item-specific Instructions:

Item	Instruction
1	Describe the social harm event in as much detail as possible, including onset and outcome (if applicable) dates, location, individuals involved, action taken, treatment or care sought, etc.
2	The interviewer is to make an assessment of the type of social harm the described event is: physical, emotional, financial and/ or other. An event may have implications on all of the above.
Items 3 - 8	These questions are to be asked directly to the participant by the interviewer. This form will not be translated, so the interviewer should translate if needed. Response categories may be read aloud for categorical questions.
3	This item is to reflect the participant's (not the interviewer's) impression as to whether the social harm event is resolved.
4	Record in CAPITAL LETTERS the participant's impressions of what would resolve this situation. Ask this question and record responses here even if the participant reported the situation as resolved in item 3.
5	Record if the social harm was a result of, or resulted in unwanted disclosure of VOICE-C study participation to another person or group of people
6	Specify who learned of VOICE-C study participation. Record relationships (i.e. MOTHER, HUSBAND), not names.
7	Record how the participant perceives this social harm (and related disclosure about study participation, if applicable) event to have impacted his/her quality of life.

--	--	--	--

---

8.	Other participant comments:	<hr/> <hr/> <hr/> <input type="checkbox"/> Declined to answer
----	-----------------------------	--

**Action Taken. *To be completed by interviewer.***

9.	Referrals made ( <i>mark all that apply</i> ): <input type="checkbox"/> VOICE counselor (Groups 1 and 2 participants only) <input type="checkbox"/> Other, specify: _____ <input type="checkbox"/> No referrals needed
----	---

**Comments:** *Initial and date all comments.*

---

---

---

---

---

---

## Social Harms Form (SH-2)

### Item-specific Instructions:

Item	Instruction
8	Prompt the participant to add any other comments about the event that you have not asked or already discussed. If s/he has no further comments write "NONE."
9	Record all referrals made in response to this social harm.
Comments	Interviewer should write any other information about the social harm in this section that is not already captured on the form. All comments should be initialed and dated. Follow-up information about the SH obtained at a later date should be recorded in this section.