



Social Harms

MTN 005

Study-Specific Training

What is Social Harm?

- Non-medical adverse consequences of study participation, including:
 - Difficulties in personal relationships
 - Stigma or discrimination from family or community
- Social harms can be related to:
 - Personal Relationships
 - Travel/Immigration
 - Employment
 - Education
 - Medical/Dental
 - Health/Life Insurance
 - Housing
 - Military/Government Agency
 - Other



Before Study Initiation

- Study team should discuss what issues are most likely to be encountered by participants
- Create a plan for how issues will be handled
- Define staff roles and responsibilities
- Describe these roles, responsibilities, and procedures in site-specific SOPs

Identifying Social Harms



- Participants may report harms spontaneously to study staff
- Participants may respond to staff questions
- Study staff may directly observe social harms

Strategies for Documenting Harms

- Actively listen to the participant's description of the problem and ask questions to obtain as much detail as possible about their perceptions of:
 - Severity of the harm,
 - Cause(s) of the harm,
 - Effects/consequences of the harm

Follow-Through



- Take all possible actions to try to address the problem, per the plan agreed upon with the participant.
- As with medical adverse events, follow all problems to resolution.
- Provide referrals as needed to other organizations, agencies, and service providers that may be able to help address the problem.

Examples



- The male partner of a participant, randomized to the IVR Group, finds out about the study product. He gets angry, pushes her, and then ends the relationship.
- Is this a Social Harm?

Examples



- A participant has been having financial difficulty and is evicted from their home during the study. They don't have alternative accommodations.
- Is this a Social Harm?

Documentation



- Chart notes
 - Complete, detailed notes
 - Who, when, what , how, why, results, action plan, including referrals
 - Track through resolution, at later visits
 - Was plan executed, was plan/ referral effective, are additional actions required, etc.
- Social Harm Log

Social Harm Log

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

Social Harm Log (SH-1)

SAMPLE DO NOT FAX
TO DATAFAX



Note: Number pages sequentially
(01, 02, 03) for each participant.

Page

MTN005 IVR Ring (148)

SH-1 (151)

Participant ID

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Social Harm Log

Site Number Participant Number Chk

1. Concisely describe the serious or unexpected social harm experienced by the participant:

2. Onset date:
dd MMM yy

3. Reported at visit:

4. Social harm code:

Social Harm Codes: See back for definitions.

01 Personal Relationships	05 Medical/Dental	09 Military/Other Government Agency
02 Travel/Immigration	06 Health Insurance	10 Other
03 Employment	07 Life Insurance	11 Harassment, bullying, coercion
04 Education	08 Housing	

Questions?

