

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

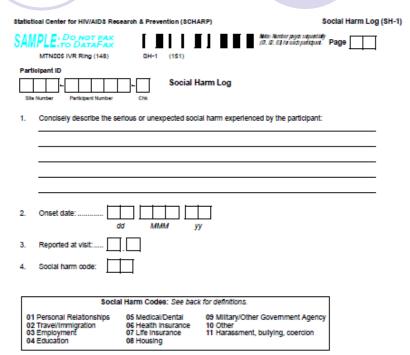
 A participant has been having financial difficulty and is evicted from their home during the study. They don't have alternative accommodations.

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







Questions?

