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

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

2. Onset date: 00/00/00

3. Reported at visit: 

4. Social harm code: 

Social Harm Codes: See case for definitions:
- Personal Relationships
- Medical/Dental
- Military/Other Government Agency
- Travel/Immigration
- Health Insurance
- Other
- Employment
- Life Insurance
- Housing
- Education
- Domestic Violence, bullying, coercion
- Animal Abuse
- Financial
- Substance Abuse
- Substance Use
- Suicide
- Self-harm
- Incest
- Child Abuse
- Other
Questions?