

# Strategy for Risk/Harm Minimization around Integrated Biological and Behavioural Assessment (IBBA)

## 1. Background:

This document describes situations in which members of the key population may encounter harm that occurs because of their participation or during the time of their participation in the IBBA and how the Avahan IBBA survey team and/or the programme team will respond to minimize the effects of such harms. These harm response services are essential to spell out so that community members affiliated with the programme and programme staff knows what actions they can and should take to mitigate the harm. The harm response plan was developed with input from the Avahan programme partners so as to be consistent with those procedures followed by the programme if similar incidents were to occur to key population members who access services.

## 2. Community Preparedness:

One of the key means to avoid harm during the time of the IBBA is to inform and prepare the community (essentially representatives from the KP groups and other stakeholders) and gain their confidence. In preparation for the IBBA, there is a need to mount a carefully planned process for

- providing information about the survey to the community,
- understanding and addressing their concerns,
- obtaining their input on implementing the survey in a community-sensitive manner
- establishing community monitoring and advisory structures (at the district level) to ensure any adverse events are addressed properly with knowledge of community members on board either for monitoring or advisory in nature.

A separate document describes in detail the process of community preparation. In brief, the community will be accessed through existing social structures and opinion leaders identified by others in the community. Through the process of conducting the IBBA with the community, questions or issues may arise that cannot be addressed without further consultation. Other issues that arise may be beyond the control of the survey team (e.g. cooperation of police or the programme partner). The IBBA team involved in community preparation will be prepared to deal with issues in such a manner that the subjects are made aware - without raising any expectations that the survey team or program cannot subsequently deliver.

## 3. Rights of Participants

Protecting the rights and welfare of those who participate in research is a fundamental tenet of ethical research and needs to be one of the corner stones of the IBBA methodology. Some key aspects of the IBBA protocol have been put in place to protect these rights:

- A proper understanding of the whole process and procedure of IBBA and informed consent is obtained from the participant.
- Participation is voluntary and will not affect individuals' ability to access services

- Individuals can choose to stop participating in the survey at any time, or can decline to answer specific questions or give specific specimens as they choose.
- Although names are recorded on the consent form, this will not be linked to any information or samples that are given and complete confidentiality will be maintained.
- The steps involved in the survey are described in clear language before consent to participate in the survey is obtained.
- Behavioral information given by individuals and biological specimen and test results of the individuals will not be shared with programme staff or other members of the community.
- Persons who report STI symptoms or have positive syphilis test results will be offered free treatment.
- Treatment of existing STI will be given to participants in the study
- Survey staff will be trained to administer the survey in a respectful and ethical manner to prevent violation of respondents' rights.

The survey team recognizes that key populations need additional protection in research since they are more vulnerable as human participants than others. The IBBA should be designed to encourage the participation, while protecting their rights and welfare.

#### **4. Monitoring and Addressing Adverse Events**

Efforts to reduce adverse events will be made by the survey team. However, if an adverse event occurs (possible occurrences are described in the subsequent section), the following steps will be taken to identify and address them:

##### **4.1 Monitoring adverse events**

Both passive and active methods for being aware of adverse events are put in place:

- 1) Reports of adverse events can be made by individuals or their designated agents; and
- 2) The local community advisors (community monitoring and advisory boards) should conduct key informant interviews in areas where the survey has been completed and the team has gone to understand the perception of IBBA, and attempt to identify any problems that have been experienced.

##### **4.2 Persons who can make complaints of adverse events**

Reports of harms that occur during the IBBA can be given by persons who participated in the survey/work near the recruitment points, or by other persons on behalf of such persons. Reports can be filed with any member of the survey team (including the community liaison officer); NGO/Avahan programme staff; or designated community monitors.

##### **4.3 Tracking redressal of adverse events**

Persons who receive reports should appropriately document the complaint using a standardized form (see the Adverse Event Report Form), including the following information:

- The date of the adverse event
- The date of the report
- The nature of the harm experienced/extent of harm experienced
- The name/description of the person who committed the harm
- A method for contacting the person who experienced harm
- The person to whom the complaint was made and their contact information

#### 4.4 Process for reviewing complaints

Members of the survey team should submit reports of adverse events to the team supervisor or appropriate higher authority. All reports from the team supervisor, community monitoring board, NGO/Avahan programme staff, or others, should be sent to the district field coordinator. The district field coordinator will ensure that all reports are shared with the community advisory board at their meetings. If a serious adverse event is reported, it should be submitted to the advisory board immediately. Serious adverse events (refer to Adverse Event Reporting Definitions) will be reviewed by the community advisory board, a plan for corrective action devised, and initial action taken within 24 hours of receiving report. Adverse event and corrective action should be reported to ethical committee as stipulated. Immediate methods of redressal will be documented in the Adverse Events Report Format with long term response as recommended by Ethical committees, follow up meetings from the Advisory board, or the IBBA team documented in the Adverse Events Resolution Format.

Grade I and Grade II reports should be reported to the community advisory board on a weekly basis. Immediate action steps by the IBBA field team should be documented on the Adverse Event Report form. If action taken by the survey team does not adequately address the harms, corrective action by the community advisory board is issued. The district field coordinator should report all serious adverse events to the PI of the study immediately. Other reports of adverse events can be submitted on a weekly basis to the PI. The PI will submit Serious Adverse Events Reports (Grade III) to the Ethical Committee within three days of receiving the report. Grade II Reports will be submitted to the Ethical Committee on a monthly basis and Grade I reports on a quarterly basis.

### 5. Types of Harms/Adverse Events and Recommended Steps of Redressal

Example of possible harm or risk	Steps to redress those harms/risks	Who will monitor proactively
<p>1. Participant is emotionally disturbed by questions that are asked.</p>	<p>Interviewer should observe participant closely to determine whether participant should pause or stop interview.</p> <p>Participants who appear or report being disturbed should be offered a referral to a nearby counsellor. Participants who are very upset should be given counselling on the spot (by an on-call counsellor)</p> <p>Arrangements for on-call counsellor and use of local nearby counsellor should be ensured by district field coordinator as part of field logistics.</p>	<p>Interviewer is first level. Team supervisor should monitor for such situations.</p>
<p>2. Survey team member(s) is/are disrespectful toward participant or potential participant</p>	<p>All survey team members undergo training for appropriate behaviour in the field and sensitization of working with key populations.</p> <p>Team supervisors will investigate situation to determine what was said/done that offended a participant.</p> <p>Survey team members who are found to be disrespectful will be reprimanded and removed from field work. Such individuals will undergo additional sensitivity training.</p> <p>The community monitor board will determine whether person should be allowed to return to field work.</p>	<p>All survey team members observe body language and facial expressions of participants for signs of having taken offence.</p> <p>Community monitors conduct key informant interviews in survey sites following field work to determine how community perceives the field teams.</p>

Example of possible harm or risk	Steps to redress those harms/risks	Who will monitor proactively
<p>3. Survey team member(s) breaches confidentiality/privacy/anonymity of participant (e.g. name is shared, interviewer discusses participant's behaviour during questionnaire are discussed with others, data are removed from secure area, etc.)</p>	<p>All survey team members undergo training about maintaining confidentiality and techniques to maintain anonymity of participants. Survey team members will sign a confidentiality agreement. Survey team members who are found to have breached confidentiality will be fired from project and incident will be reported in employee file.</p>	<p>Team supervisor should monitor whether team members are discussing specific participants during off hours.</p>
<p>4. Survey team member sexually harasses or propositions participant or potential participant.</p>	<p>All survey team members undergo training of appropriate field behaviour and consequences of sexual harassment. Team member accused of sexual harassment will be suspended from field work. Survey team members who are found to have sexually harassed a participant will be fired from project. If harassment occurs, the entire survey team will halt work and meet with community stakeholders to discuss incident and receive feedback about how to regain community trust.</p>	<p>Team supervisor and district field coordinator will start investigation within 4 hours of the report and issue status to state field coordinator. All reports of such incidents will be sent to the community advisory board and highest levels of Research Agencies/ICMR Institutes/FHI management within 24 hours of report.</p>
<p>5. Survey team member/s physical violence at the hand of survey team members or survey staff</p>	<p>All survey team members undergo training of appropriate field behaviour and consequences of physical or sexual violence. Team member accused in such cases of physical or sexual violence will be suspended from field work. Team member found to be directly involved in such cases of physical or sexual violence will be fired. If harassment occurs, the entire survey team will halt work and meet with community stakeholders to discuss incident and receive feedback about how to regain community trust.</p>	<p>Team supervisor and district field coordinator will start investigation within 4 hours of the report and issue status to state field coordinator. All reports of such incidents will be sent to the community advisory board and highest levels of Research Agencies/ICMR Institutes/FHI management within 24 hours of report.</p>
<p>6. Participant experiences unnecessary pain (e.g. multiple pricks, rough treatment, incompetent phlebotomist, etc.) during blood draw.</p>	<p>Phlebotomists are well trained (including practicum experience) to draw blood efficiently while minimizing pain, and to reduce anxiety of patients by explaining. Phlebotomists who are causing pain to people will be removed from field work and undergo retraining.</p>	<p>Community liaison officer is available to act as a witness during blood draw if requested by participant.</p>
<p>7. Participant feels weak or giddy after giving biological specimens.</p>	<p>Specimen collection site will be equipped to have persons to rest (e.g. chairs or mats and cushions, etc.) and offer refreshments (e.g. juice, biscuits, etc.). Participants who feel weak will be asked to rest quietly and take some refreshments until they feel well. The medical officer will examine the patient to determine if there is other problem.</p>	<p>Phlebotomists and medical officer should observe participants after blood draw. Incidents should be noted in log.</p>

Example of possible harm or risk	Steps to redress those harms/risks	Who will monitor proactively
7 Medical officer or phlebotomist are not following appropriate procedures for universal precautions (e.g. not using clean equipment, or changing gloves between patients)	All survey team members are given training about universal precautions to be used during survey. Staff not following procedures for universal precautions will be removed from the field teams and undergo re-training. After re-training, personnel will be observed closely by medical officer for first three days after returning to work. If personnel continue to violate universal precautions procedures they will be removed from the project.	All team members should observe to ensure universal precautions are followed. medical officers will observe field work and report problems.
8. Survey team members put undue pressure/coerce potential respondents to participate or continue with survey, including giving biological specimens when respondent declines.	All survey team members will undergo training about respecting respondents rights to decline or discontinue at any point during the survey. Field supervisors will be trained not to unduly pressure field workers to meet targets. Persons who are found to put undue pressure on potential respondents will be removed from field work. Other members of the field team (without supervisor) will have a group discussion and re-training to determine whether this is a broader problem or pressure from supervisor is contributing to problem. Group discussion and issues will be discussed with team supervisor.	Community monitors will conduct key informant interviews to determine whether this is a problem. District field coordinator will facilitate group discussion/ re-training of field team and discuss findings with team supervisor.
9. Survey team members create visibility for key populations in recruitment sites.	All survey team members undergo training to be inconspicuous in the field and not attract attention to key populations. All site lists will be kept strictly confidential with survey teams (not shared with other stakeholders). Specific schedules of survey teams (sites and timings) will not be shared with other stakeholders. Team supervisors organize team members so they are not visible in recruitment areas. Teams that create visibility stop field work and undergo retraining with feedback from community consultants. Plans and strategies for reducing visibility in recruitment sites are developed with community consultants.	District field coordinator should monitor recruitment work. Community monitors observe or conduct key informant interviews to determine if this is a problem.

<b>Social, economic and political risks or harm</b>		
10. Police raids or increased harassment by police, local residents, local rowdies.	Document events systematically as they are reported to the programme (using the web-based reporting system)	NGOs
11. Eviction of key population members from place of residence or work by police, district administration, or local residents	National and state level: To advocate with the state administration to ensure that such police action is stopped, or action is taken against rowdies	Avahan, with the collaboration of SACS and NACO
	District level: To lobby with district administration to stop police action immediately, or take immediate steps against rowdies	SLP and respective NGOs
	State and national level media advocacy to alert media about police harassment of key population members	Avahan and Media advocacy partners
	In each district, legal aid cells or KP friendly advocates/ lawyers to be contacted beforehand to provide legal support to KPs in case of arrest or harassment	SLP and NGOs
	Advocacy with local residents to negotiate safety of key population members	SLP, local key population collectives
	Develop a community fund to provide compensation for loss of work due to arrest or police harassment	Local key population collectives
	Develop policies for using the DIC to provide temporary shelter in case of eviction or serious harassment	NGOs, local key population collectives
	12. Disclosure of identity of participants as key population members, which may lead to increased stigma, harassment, eviction or conflict within the family of the key population member	<b><i>In addition to provisions mentioned above,</i></b> Psycho-social counselling
Family counselling		NGOs
To link up individual key population participant experiencing such harm, to key population collectives, support group, self-help groups		NGOs, local key population collectives
13. Disclosure of sensitive, confidential or defamatory data pertaining to individual key population participant or the particular group in media	To prepare press note templates, sensitive to key population rights and issues	Advocacy partners, Avahan, SLP, and NGOs
	At national and state level to advocate against unethical media practice related to key populations and other marginalised populations	Avahan and advocacy partners

## 5. Compensating for Harms

Despite all precautions, some research participants (subjects) might be harmed. Subjects who are harmed as a direct result of research should be cared for and compensated. This is simple justice. However for those who might endure harm while participating in the IBBA, it might at times be very difficult to separate injuries traceable to the IBBA from those that stem from the underlying social conditions or context. Decisions on compensation for harm should be made in consultation with committee designated by PI.