SOCIAL AND BEHAVIOURAL SCIENCES RESEARCH FOR HEALTH

9.0 The context of health research using methods from the social and behavioural sciences is often different from clinical, biomedical and public health research. Social and behavioural sciences include, but are not limited to, anthropology, sociology, psychology, philosophy, political science, economics, history, communications and education. Many of these research initiatives are relevant in the mid to long term for knowledge production, science and society. Such research efforts will also have scholarship value besides relevance for policy and programme development, providing a deeper understanding of explanatory factors. Moreover, social science research informs policy-making activities about the various facets that can be considered to ensure that social equity and intersectionality of populations are accounted for. Sometimes such studies are done as a precursor to the execution of major IR and programme evaluation projects. Similarly, community behavioural studies or formative research on cultural and geographical contexts are conducted before introduction of new interventions and refinement of existing ones. Thus, depending upon the context, social science studies can also have immediate and immense relevance to development and refinement of programmes and policies. To be judicious and ethical in understanding and assessing human behaviour, the details of symbolic communication of culture, which includes a group's skills, knowledge, attitudes, values and motives, have to first be understood as they influence a participant's response to research. Ethical relativism applies to moral diversity among different cultures and societies. In the Indian context, this is evident due to multi-religious, caste, class, endogamic, gender and geo-ethnic variations which are important characteristics of society that need to be considered in socio-behavioural research proposals. In view of the above, ECs should be aware of the challenges that may be encountered in the process of conducting such studies.

9.1 Some key features

9.1.1. Conventional social science research on health underscores the importance of bringing contemporary contexts to biomedical and health research.

9.1.2. It has now emerged as a cross-cutting area of enquiry relevant to almost every type of

medical, biomedical, clinical and health research such as clinical trials, epidemiological research, programme evaluations, implementation research, genetics, research on disaster and conflict contexts.

9.1.3. The principles of social science research ethics, with rights and responsibilities of the different stakeholders including participants, researchers, reviewers, publishers, etc., are similar to those for biomedical and public health research.

9.1.4. There are, however, specific ethical issues involved in social and behavioural sciences studies as given in Box 9.1.

Box 9.1 Ethical issues in social and behaviour sciences studies

1. Risks are non-measurable and dynamic in nature and therefore might be misconstrued as no/minimum risk research.
2. PI's obligations related to data sharing, incidental findings and post-research benefits to the study population would need to be reviewed by the EC on a case-by-case basis, and prior approval from the EC should be obtained for any exemptions.
3. What would constitute ancillary care during such research needs to be carefully considered on a case-by-case basis by the EC.
4. As part of the research protocols, socially, legally, medically and technically unacceptable practices and behaviour may be discovered, documented, or observed. While researchers are not required to interrupt such behaviours to determine the truth, they must document these in the research findings and appropriately disseminate the findings for the larger social good.
5. While maintaining the privacy and confidentiality of the respondent's identity, researchers have an obligation to report the extent or the patterns of behaviour, such as suicidal tendency or infanticide, to the concerned authorities.

9.1.5 Ethical challenges are more pronounced in collaborative research (national or international) due to possible inequity of expertise and knowledge access between partnering institutions and researchers, and funding relationships. See section 3.8.3 for further details.

9.1.6 Appropriate experts/expertise of EC members in the social and behavioural sciences domain are an essential aspect to address the above challenges.

9.2 Addressing the ethical challenges

9.2.1 Design and conduct of the study is important for a meaningful outcome in social and behavioural research. See Box 9.2 for further details.

Box 9.2 Consideration for appropriate design and conduct of study

1. Like any other research, the researchers must ensure that the proposed studies are scientifically sound, built on an adequate prior knowledge base, and are likely to generate valuable information.
2. In socially stratified groups and communities, researchers must spend time to become conversant with cultural norms and practices in order to develop strategies to build trust and negotiate power in ways that do not put research participants at risk.
3. In some types of research within communities, appropriate interpreters would be required. They need to be carefully selected, keeping in mind the hierarchies existing in the context. A local person from the same village in which the research is to be conducted should not be used as an interpreter. Instead, an interpreter should be chosen from some other nearby village so that her/his vulnerability and perceived threat from other participants can be mitigated. Institutions should develop or have SOPs for handling deteriorating situations, including a pre-tested communication plan.
4. The information about these norms/practices should be collected from reliable and multiple sources including multiple persons/groups, which should be mentioned in detail. This knowledge should be considered while deciding the group of participants and style of interview/investigation. However, the final decision about recruiting the participant should be based on the participant's and her/his family's opinion about norms/practices. These issues become particularly pertinent in cases of research that involve patriarchal or restrictive communities.
5. Field work challenges for research team – Research team members may sometimes be subjected to unforeseen situations which may involve trauma, humiliation and threats of violence. Training should be given to the research team to meet such challenges.

9.2.2 Ethical review

There are some unique features of social and behavioural sciences research which need to be considered by the EC on a case-by-case basis. See Box 9.3 for further details.

Box 9.3 Considerations by the EC for ethical review

1. Social and behavioural sciences research approaches are not always positivist and, therefore, articulation of a hypothesis may not be possible at the beginning of the research. Instruments/documents are developed during the course of the research; are reflective; and may keep changing as the research progresses. The EC must be kept informed about these changes and appropriate re-consent taken from participants.
2. The researcher must take prior permission from the EC with justifiable reasons for audio/video recording of participants' interviews.

9.2.3 Risk assessment

Participants of research in behavioural and social science face the potential of being exposed to significant and unique harm which may not be limited to physical harm. The researchers, research team and EC must recognize the cultural context and associated harm related to dignity as well as social and informational harm. This will avoid hurting or transgressing rights of the participants/community.

- **Harm to dignity** is likely to occur when individuals are not treated as persons with their own values, preferences, and commitments, but rather as mere means not deserving of respect. This is also sometimes classified as another form of negligence. It may result in individuals feeling hurt, humiliated, excluded, dismissed or unfairly treated.
- **Psychological and emotional harm** may result from participating in a study where memories of traumatic experiences such as disasters (natural or otherwise), violence, conflict, abuse, assault and other such conditions need to be revisited by the participants. This may also affect and compound the vulnerabilities of participants already experiencing post-traumatic stress disorder (PTSD).
- **Social harm** is a non-medical adverse consequence of study participation, including difficulties in personal relationships and stigma or discrimination from family or community. Social harm can be related to personal relationships, travel, employment, education, health, housing, institutions (government/non-government) and others.
- **Informational risk** is the potential for harm from disclosure of information about an identified research participant to others. For much of social and behavioural research, informational risk is one of the primary risks.

9.2.4 Risk mitigation

Measures should be employed to minimize potential risks and their negative impact, such as short- and long-term adverse impacts on participants of studies on abortion, sexual abuse and other sensitive subjects. These measures should be incorporated into research methods, with special reference to hierarchies that exist in the social context where the research is undertaken.

9.2.5 Community engagement

While devising methods and interpreting observations, researchers should engage potential participants and communities in a meaningful participatory process

that involves them in an early and sustained manner in the design, development, implementation and monitoring of research, and in the dissemination of its results.

9.2.6 Informed consent

Human participants in a proposed research study must be informed about the nature of the research project, and researchers/research teams must obtain their voluntary consent prior to their participation in the study. The different types of informed consent processes in social and behavioural sciences research are provided in Box 9.4.

Box 9.4 Informed consent in social and behavioural sciences research on health

1. **Community consent/gatekeeper consent/individual consent:** Individual informed consent has to be taken after obtaining the permission of gatekeepers, such as community heads or leaders/ culturally appropriate local authorities/healthcare providers/institutions or organizations responsible for community welfare or their appointed advocates. Consent procedures must respect local cultural customs, however, community traditions do not substitute for individual consent unless a waiver has been granted.
2. **Participant consent:** Researchers must develop culturally appropriate ways to communicate information necessary for adherence to the standard required in the informed consent process.
3. **Selective withholding of study information:** ECs may permit selective withholding of information/hypothesis of the study in the consent form for achieving overall social and public good, without influencing the outcome of the study. On completion of the research, the participants should be de-briefed, if applicable. Authorized deception as described in section 5.11 is also applicable here.
4. **Participant refusal:** Often the power differences between participants and researchers in India make it difficult for people to explicitly refuse to participate. Researchers should be alert to cultural symbols of refusal, such as body language, silence, monosyllabic replies, or restlessness that communicate discomfort. They must not persist with the research under these circumstances.
5. **Relational autonomy:** Individuals are socially embedded wherein the person's identity is shaped by social determinants, such as caste, class, ethnicity and gender. Therefore, the participant may not be autonomous in decision making. Right to autonomy must be understood in relation to substantive equality of opportunity, sufficient social support and conditions for self-respect. Accordingly, concerns about social justice must be central to any adequate conception of individual autonomy. The EC may take into account this context with due diligence regarding the vulnerable status of prospective participants during review, for example, a woman asking her husband or family before giving consent.
6. **Waiver of informed consent:** If the research has important social and public health value and poses no more than minimal risks to participants, the EC may waive the requirement for individual informed consent if it is convinced that the research would not be feasible or practicable to carry out without a waiver, for example, research on harmful practices. See section 5.7 for further details.

9.2.7 Privacy and confidentiality

Privacy and confidentiality of research participants should be considered while selecting sites for data collection, choosing sensitive research areas, specific contexts and settings. In some circumstances participants become more vulnerable in research because of heightened psychological, social, physical or legal risks. Breach of confidentiality in these types of research may cause serious harm to vulnerable participants. It is important to protect study participants from potential future risks and harm by establishing culturally sensitive and context specific safeguards.

9.2.8 Duty to disclose sensitive information

As mentioned in Box 9.1, researcher(s) may come across certain facts detrimental to a participant's self or others, such as suicidal tendency/ideation, notifiable diseases. In such a situation, researchers have a responsibility to disclose this information to relevant persons/authorities to save life or prevent damage contemplated by the participant. Measures to be taken in such instances are given below:

- If there is a high likelihood of getting sensitive incidental findings during the research process, then the ways to handle these at individual, family and community levels should be discussed and mentioned in the protocol.
- Researchers and the EC should have a basic understanding of the legal provisions in the related area. Persons with the necessary domain knowledge and experience can be special invitees to EC meetings.

9.2.9 Studies Using Deception

Deception occurs when researchers provide false or incomplete information to participants for the purpose of misleading them so as to achieve the study objectives and for larger public good. Research employing any type of deception should undergo full committee review.

Research involving any kind of deception should:

- pose no more than minimal risk;
- not adversely affect the welfare and safety of the participants;
- be conducted only when the research cannot be carried out without deception;
- have an adequate plan for debriefing the participants after completion of the study, if appropriate;
- disseminate results of research to the participants, if applicable; and
- be carefully reviewed by the EC.

Box 9.5 Types of deception

1. **Active deception:** Selective withholding of the information/hypothesis of the study in the consent form along with giving incorrect information for achieving public good without influencing the outcome of the study, for example, psychology, neuro-behavioural, behaviour intervention study.
2. **Incomplete disclosure:** If research involves incomplete disclosure but no deception.
3. **Authorized deception:** Unlike in active deception, participants are informed that they would be deceived prior to the research but the nature of the deception will not be disclosed or research will not be described accurately or some procedures will be deceptive. Such revelation provides the participants an opportunity to decide whether or not to participate on these terms.

9.2.10 Safety of participants

Support systems, such as access to counselling centres, rehabilitation centres, police protection, etc., should be in place when research is on a sensitive issue, such as mental health, gender based violence and social exclusion and discrimination.

9.2.11 Safety of research teams in the field

The safety of the research team is the responsibility of the institution, sponsors and local authorities, particularly in research on sensitive topics or in sensitive research settings since there would be a possibility of the researcher or research team being subjected to disturbing instances while conducting the research. Besides providing safety, including insurance coverage, and giving training to the researcher or research team to meet such challenges, setting up community advisory boards could be helpful to ease the situation.

9.2.12 Qualitative research

The knowledge gathered through qualitative research is interpretative based on the observation and its analysis by the researcher or research team which is socially constructed at individual and socio-cultural levels.

- Informed consent is very often dynamic in nature and negotiable. When written consent may not be possible, other means could be used and documented.
- The EC may look at issues that pertain to the design involving researcher–participant relationships, informed consent process and conduct of the research.
- Preliminary activity of observation for preparing notes, before actually initiating research based on the observation, need not be submitted for EC's review.

However, any ethical issues arising even during that preliminary phase, before actual collection of data, should be included in the research proposal for review by the EC.

- On some occasions/in some observational research the EC may approve waiver of consent, provided mechanisms for maintaining privacy and confidentiality are justified.
- In collaborative research, it is desirable to establish a rapport with the community to be engaged in research through the gatekeepers or community advisory boards.
- Sharing raw data and notes with repositories, researchers, peer community, institutions, and funders is increasingly becoming a requirement for transparency in research.
- Sharing raw data including audio-visual material should protect confidentiality of the individual and research setting by sufficiently processing data to mask identifiers before sharing.
- Researchers have a duty of disclosure to share research findings in aggregated form and relevant information in a user-friendly format with community leaders, gatekeepers and communities without disclosing individual identities. They must also share these findings and relevant information with the participants.