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Introduction Guidelines

1. Observe professional standards for managing and conducting scientifically rigorous research at all stages of the study.
2. Respect and safeguard the rights of free will, privacy, confidentiality, and well-being of research participants and minimize the burden of study participation to the greatest extent possible, adhering to both ethical and legal obligations toward participants.
3. Obtain informed consent from every research participant.
4. Develop protocol for interviewers and other project members to use to protect respondent identifying data and survey data.
5. Develop procedures and obtain voluntary informed consent for any additional data collection activities.
6. Maintain sensitivity to cultural and social differences.
7. Report research findings and methods and provide appropriate access to study data.
8. Institute and follow appropriate quality control procedures.
9. Consider whether there are any other ethical issues resulting from design decisions, particularly when technology is used.
10. Document materials and procedures related to the ethical conduct of the study and ethics committee review.

References

Appendices: [A](#) | [B](#) | [C](#) | [D](#) | [E](#)

Further Reading

Introduction These guidelines focus on ethical concerns arising from the use of human subjects for research in multinational, multicultural, or multiregional surveys, which we refer to as '3MC' surveys. The guidelines define human subject research as the "...systematic collection or analysis of data...in which human beings (i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment (ii) become individually identifiable through investigators' collection, preparation, or use of biological material or other records". There is no lack of source material on ethical guidelines for human subject research (see for a review: International efforts to protect the rights of human subjects involved in research are predominately rooted in the ethical principles established by the Declaration of Helsinki. The Declaration of Helsinki, originally adopted by the World Medical Association in 1964 and most recently revised in 2008, defines the ethical responsibilities of physicians to their patients and to the subjects of biomedical research. It asserts the principle of informed consent from research subjects and the protection of individual subjects' well-being over any anticipated benefits of the research to science and society. The principles of the Declaration of Helsinki have been extended to include social science human subject research. The Belmont Report, issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, underpins the regulation of human subjects research in the United States. It advances three key fundamental ethical principles for the conduct of all research involving human subjects: respect for persons, beneficence, and justice. Application of these principles requires careful consideration of the selection of research subjects, informed consent, and an assessment of potential risks and benefits to research subjects and to society. The Belmont Report has influenced research ethics in many parts of the world. Professional organizations, such as the American Association for Public Opinion Research (AAPOR), the European Society for Market Research, and the International Statistical Institute (ISI), have also developed ethical codes and guidelines for their members. The ethical codes of these professional organizations define the norms and responsibilities for survey researchers in relation to respondents, as well as to clients or sponsors, the public, and other researchers. In addition to these self-regulatory measures, many countries have legislation in place that affects human subject research (e.g., data protection legislation and requirements for ethics review boards). Whether working in familiar surroundings or in new contexts, researchers must make sure they are informed about, and comply with, relevant legislation. When working in other countries or locations, researchers may need to comply not only with local requirements, pertinent to the place where they are collecting data, but also with their own country's requirements. A compilation of laws, regulations and guidelines from over 130 countries has been prepared by the [U.S. Office for Human Research Protections](#). As might be expected, there is considerable overlap in the principles contained in the various ethics codes, professional

association guidelines, and government regulations. This section attempts to consolidate their common elements, as to highlight concerns particular to 3MC surveys, including cross-national variation in laws and regulations relevant human subject research and cultural differences that affect the conduct of ethical research across cultures. Beyond professional codes of ethics, is useful to consider the ethical framework or philosophy that guides the research, eng sensitivity toward research participants and their social contexts . And, it is important to note that the way in which researchers, as well as survey interviewers, perceive ethics, is situated in their own cultural context. suggests that ch research problem is itself an ethical decision. It is important to recognize that researchers may confront tradeoffs bet ethical principles and that there is no one ethical principle that overrides all others. For example, maintaining sensi cultural differences by having other family members present during the interview may conflict with ethical obligati protect confidentiality and to minimize error in respondent reporting. For further information on the ethical principl presented here, please see the listing of ethics codes, declarations, guidelines, and other resources for researchers co 3MC human subject research that is provided in [Further Reading](#).

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Guidelines Goal: To ensure that all members of participating research teams follow widely accepted standards for e professional, and scientific conduct from the design of the study through implementation, dissemination, and reporti

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1. Observe professional standards for managing and conducting scientifically rigorous research at all stages of study. *Rationale* Researchers have a responsibility not only to protect participants from the risks of harm associated participation in the research but also to adhere to ethical management practices and to conduct research that meets tl scientific standards of their field. The reader is referred here to other sections in these Guidelines which provide use guidance on meeting scientific standards for the design, implementation, analysis, and documentation of 3MC surve ***Procedural steps***

1.1 Understand and adhere to the best practices of survey methodology.

1.1.1 Clearly and objectively lay out the study's major research questions for internal use in guiding the development of the study.

1.1.2 Ensure that a survey is the most appropriate method to use to answer the research questions.

1.1.3 Adhere to ethical business practices in bidding, contracting, and project management. These include tl following:

- Honestly describing the organization's expertise in a bid.
- Disclosing if a survey project is being carried out on behalf of multiple clients or is using subcontractor
- Meeting contractual obligations.
- Ensuring agreement by both parties on any changes to contractual obligations.
- Maintaining good relations between the coordinating center and research organizations involved in the
- For additional detail, see [Tenders, Bids, and Contracts](#).

1.1.4 Disclose sources of financial support or relevant relationships that have the appearance of or potential constitute a conflict of interest.

1.1.5 Fulfill ethical responsibilities to employees (e.g., fair hiring practices, an objective performance evalu process, and a commitment to employee safety). See [Data Collection: Face-to-Face Surveys, Guideline 1](#) guidance on the survey organization's responsibility to protect the well-being and safety of its interviewi

1.1.6 Train staff on the importance of ethics and scientific rigor in research involving human subjects, as dis in the remainder of this chapter.

- 1.1.7 Ensure that interviewers are aware of their ethical and responsibilities (e.g., in the United States, interviewers are obligated to report evidence of child abuse).
- 1.1.8 Instruct interviewers on the limits of their ethical responsibilities (e.g., when they should provide information about local health resources or contact a clinical psychologist or social worker assigned to the project, rather than attempting to provide medical assistance or mental health support services themselves).
- 1.1.9 Equip staff involved in design, data collection, and analysis with appropriate skills to perform scientific and rigorous research.
- 1.1.10 Follow best practices in survey design, data collection, and post-survey processing as described in the following chapters:
 - [Survey Design and Organizational Structure](#)
 - [Survey Quality](#)
 - [Tenders, Bids, and Contracts](#)
 - [Sample Design](#)
 - [Questionnaire Design](#)
 - [Adaptation](#)
 - [Translation](#)
 - [Instrument Technical Design](#)
 - [Interviewer Recruitment, Selection, and Training](#)
 - [Pretesting](#)
 - [Paradata and Other Auxiliary Data](#)
 - [Data Collection](#)
 - [Data Harmonization](#)
 - [Data Processing and Statistical Adjustment](#)
 - [Data Dissemination](#)
- 1.1.11 Employ appropriate tools and methods of analysis.
- 1.1.12 Make interpretations of research results that are consistent with the data.
- 1.1.13 Be clear and honest about how much confidence can be placed in the conclusions drawn from the data.
- 1.1.14 Report research findings, even if they are not in line with the researcher's hypothesis.
- 1.1.15 Monitor possible ethics violations, such as interviewer falsification or plagiarism, during the design, data collection, and analysis phases.
- 1.1.16 Consider both cost and error implications of decisions that are made in the design, implementation, and analysis phases of the research study and the relationship that these decisions have with ethical considerations.
- 1.1.17 When possible, conduct methodological studies to inform understanding of the cost and quality implications of survey design decisions for the benefit of future studies and the scientific research community. Most of the methodological research on ethics and other survey design considerations has been conducted in Western cultures. Additional research is needed in non-Western societies.
- 1.2 Understand and adhere to relevant professional codes of ethics regarding survey research.
 - 1.2.1 In the United States, the primary organization representing survey researchers is the American Association of Public Opinion Research (AAPOR), which obligates its members to adhere to its code of ethics.

1.2.2 There are two international survey professional organizations, each of whom prescribes principles of practices for organization members:

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1.2.3 See for a more exhaustive list of existing professional and trade associations and codes of standards.

1.3 Observe general standards of scientific conduct as well as standards mandated by study countries themselves

1.3.1 Countries have different methods to assess adherence to ethical standards.

- In the United States, institutions generally have an Institutional Review Board (IRB) which assesses the protocols proposed for protection of human subjects and is approved by the [U.S. Department of Health Human Services](#).
- Institutions in many other countries are subject to country-specific regulations as well. See the 2017 edition of the International Compilation of Human Research Standards [here](#) for laws, regulations, and guidelines of human subjects protection in over 100 countries as well as from a number of international and regional organizations.

1.3.2 When developing an ethical protocol for a cross-cultural survey, consider using the standards catalog and vocabulary for market, opinion, and social research.

1.3.3 Do not engage in scientific misconduct, including:

- Revealing the identity of research participants.
- Generalizing results beyond the study's target population, or otherwise misrepresenting the sample design to select respondents.
- Plagiarism, falsification, or fabrication in proposing, performing, reviewing research, or in reporting research results.
- Fundraising, selling, or canvassing under the guise of research.

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2. Respect and safeguard the rights of free will, privacy, confidentiality, and well-being of research participants; minimize the burden of study participation to the greatest extent possible, adhering to both ethical and legal obligations toward participants. *Rationale* The social researcher's responsibility to respect the human rights of study participants is universally prescribed in ethics codes and guidelines such as the Declaration of Helsinki and the Belmont Report, and monitored by ethics review boards in countries where such boards exist. In addition, the collection of accurate data depends upon the cooperation of respondents: individuals are more likely to agree to participate in a study and provide complete, accurate information if they feel that they can trust the research organization. Finally, a positive experience regarding the research interaction encourages participation in future research. *Procedural steps*

2.1 Observe the principles embodied in the Belmont Report. The Belmont Report is based upon three unifying principles for using any human subjects for research: respect for persons, beneficence, and justice. The United States Department of Health and Human Services uses these three principles to form the basis of their regulations to protect human subjects. The principles are used below to organize the different aspects of ethical obligations that researchers must consider.

2.1.1 **Respect for persons:** Protecting the autonomy of all people and treating them with courtesy and respect, allowing for informed consent. Researchers must be truthful and not engage in fraudulent claims.

- Encourage participation in the research study only in ways that avoid personal harassment, while recognizing appropriate ways to minimize non-response through acceptable means of contact (see [Guideline 3](#)). This includes limiting the number of times that an interviewer visits a household to attempt to obtain sample participation.
- Be respectful and honest with survey respondents (e.g., be honest about the length of the interview, any incentives being offered, and the purpose of the study).
 - points out that it is not always possible “to be completely open to all participants” (p. 154) without overwhelming the listener. Furthermore, the definition of honesty and the way in which honesty is expressed vary according to culture.
- Adapt the study protocol as needed to protect the rights of vulnerable populations—that is, populations with diminished autonomy resulting from age, cognitive impairment, or imprisonment, such as children, the elderly, prisoners, the mentally impaired, and members of economically and otherwise disadvantaged groups. Use special consent procedures (e.g., obtaining consent from a parent or family member) or other appropriate modifications. See [Guideline 3](#) for further information about obtaining informed consent.

2.1.2 Beneficence: The philosophy of 'do no harm' while maximizing benefits for the research project and minimizing risks to the research subjects.

- Use existing data whenever possible; do not collect new data unnecessarily.
- Keep respondent burden as low as possible by ensuring that each question in the survey maps to a specific research goal, balancing the need for information against the effort that is required to complete additional questions, asking questions in a way that is easy for respondents to answer (see , , and for guidance), and when sensitive or otherwise demanding information is required, devising ways to help respondents provide it without undue burden. For example, part of the interview could be self-administered if there is concern that respondents might be uncomfortable providing responses to an interviewer. See [Data Collection: Face-to-Face Surveys, Guideline 4](#) and [Data Collection: Telephone Surveys, Guideline 3](#), as well as [Data Collection: Self-Administered Surveys](#), for a discussion of self-administered modes of data collection.
- Determine whether asking respondents to provide information on specific topics could bring harm or potential repercussions to them and do not include questions on those topics.
 - Alternatively, disclose the probability and magnitude of a risk of harm and let competent adult participants decide whether to provide the information. Respect for persons means allowing people to choose for themselves while providing extra protection to those with limited autonomy.
 - If the information gathered by sensitive questions is necessary for the research goals, consider conducting a series of questions to define a latent construct, rather than asking a direct question.
- Consider carefully whether the requested information may be seen as private, threatening or embarrassing to the population interviewed, and implement techniques to minimize unease.
 - In mental health studies, provisions are often made to provide suitable support for respondents or interviewers who experience emotional distress (for example, some form of emotional or psychological support service or provision of a resource list). A resource list may be made available to all participants or only those who demonstrate emotional distress. In addition, interviewers in these studies should complete specialized training on how to handle interviewing on sensitive topics.
 - Also, recognize that cultures differ in what topics can be discussed and how they can be discussed.
- Some study designs permit the use of a proxy interview, which is an interview with someone other than the person about whom the survey information is sought, such as the parent or spouse. If the study design uses a proxy interview, then consider the sensitivity of the requested information and assess whether it would be appropriate to ask a person other than the respondent for sensitive information in a proxy interview.
 - If proxy interviews are used, create and adhere to a clearly defined set of rules concerning who can act as a proxy respondent. Consider whether the use of a proxy interview requires the consent of the target respondent. If the target respondent has indicated any unwillingness to provide information, do not obtain the information from a proxy instead. Take care not to affect the relationship between the proxy and target respondent.

- 2.1.3 **Justice:** Ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly; fair distribution of costs and benefits to potential research participants—and equally.
- Do not exclude minority groups, native populations, or aboriginal peoples in the sample, unless it is appropriate to do so. Examples include exclusion of respondents living in certain areas of a country because of height security concerns and increased risk to interviewers, exclusion of respondents living in very remote areas because of budget constraints, and exclusion of respondents because of language barriers and the prohibitive cost of additional translation and administration of the survey.
- 2.2 In addition to ethical obligations, consider the legal obligations to research participants. These obligations vary depending on the country of the researchers, the country of the research participants, and the country from which the source of funding originates.
- 2.2.1 In the United States, the legal foundation for protection of human subjects of research, including survey respondents, is the Research Act of 1974 (P.L. 93-348, July 12, 1974). This Act led to the development of the Regulations of the Protection of Human Subjects of Research, which require universities and other institutions receiving federal funds to establish Institutional Review Boards (IRBs) to safeguard the rights of research volunteers. See the following page on the United States Office of the Federal Register website [here](#) for updates and revisions to the U.S. federal policy for the protection of human subjects.
- 2.2.2 In Canada, all research involving human subjects must adhere to the ethics policy put forth by the Pan-Canadian Research Ethics (Government of Canada, 2014).
- 2.2.3 In Australia, human subjects research is regulated by the Human Research Ethics Committees (see [here](#)).
- 2.2.4 While human subjects research is not regulated by a single entity in the European Union, the EU does have regulations designed to safeguard the confidentiality of personal data (see [here](#)).
- 2.2.5 Many other countries around the world have similar research ethics policies and regulations. It is an individual researcher's responsibility to identify the appropriate policies in the respective country or countries.
- 2.3 If appropriate, obtain a Certificate of Confidentiality (CoC) or other legal document for protection from the requirement to release the identity of a respondent in a legal proceeding. In the U.S., CoCs are issued by the National Institutes for Health (NIH) and other Department of Health and Human Services (DHHS) agencies and are generally issued for data that are sensitive, such as mental health or sexual or illegal behavior. Certificates of confidentiality are only issued for research projects that:
- 2.3.1 Collect personally identifiable, sensitive information (see [here](#)).
 - 2.3.2 Are approved by an Institutional Review Board (IRB) operating under a Federal Wide assurance (FWA) issued by the DHHS Office of Human Research Protections ([OHRP](#)) or with the approval of the FDA.
 - 2.3.3 Are on a topic that is within the HHS health related research mission.
 - 2.3.4 May receive federal funding (not required but issuance is at the discretion of the issuing agency).
 - 2.3.5 Store research data in the United States.
 - 2.3.6 Are allowable under federal regulations.
 - 2.3.7 Make clear to respondents the extent to which confidentiality is protected.

Lessons learned

- 2.1 When determining a survey project schedule, leave ample time to procure human subjects approval from the necessary institution(s). Depending on the agencies involved, obtaining approval can take many months and delay start dates. This can interfere with the comparative nature of a 3MC survey, if, for example, one country has the necessary ethics approval to begin fieldwork but another country cannot begin until several months later.
- 2.2 Risk-benefit analyses will differ depending on the research topic. Trauma-focused research, such as that in disaster or conflict regions, is particularly challenging and provides a useful example of special considerations necessary for conducting research on certain topics and/or in certain locations. In trauma-focused research, it is crucial that respondents and interviewers be adequately protected from both psychological and physical harm, and the definition of 'vulnerable population' may need to be expanded in trauma-focused research. "In the context of a disaster, the benefits from participation, along with auspices and affiliations, must be made clear to potential respondents. That is, any link (or lack thereof) between participating in research and receipt of aid or other benefits should be explicit, and all study materials should clearly state the purpose of the research and list all affiliations. Recognition of opportunity for increased respondent and interviewer burden is important as well.
- 2.2.1 Researchers must consider whether respondents are capable of providing voluntary consent in the aftermath of a disaster, necessitating carefully designed consent procedures, based on the context and location of the disaster.
- 2.2.2 High profile events can lead to increased respondent burden, with multiple survey requests to individuals from numerous organizations.
- 2.2.3 After the tsunami in the Indian Ocean in 2004, researchers warned that victims in Sri Lanka may feel pressured to comply with survey requests because of a presumed link of survey participation with humanitarian aid, and appealed to the international community to adequately address the issue of respondent protection in extenuating circumstances. Similarly, interviewers should not deceive respondents about benefits to participation. In a study in India, dishonest interviewers were believed when they told respondents that survey participation would result in new schools, roads, and an electricity supply.
- 2.2.4 Refusal rates were high in a Haitian study after the 2010 earthquake because respondents had already been interviewed several times and never received the aid or assistance they had expected.
- 2.2.5 Interviewer safety and security is crucial in a disaster or conflict zone, and an adequate understanding of current conditions is necessary before fieldwork begins. Additionally, if recruited locally, interviewers themselves may be struggling with the aftermath of the disaster or conflict, as was the case in research on populations after Hurricanes Katrina and Rita in the United States in 2005. In such cases, interviewers should offer the same mental health referral services that they offer to respondents in need.
- 2.2.6 See Chapters 3, 4, and other chapters in this book for further details to consider when conducting research in these populations.
- 2.3 It is a well-known concern that sharing certain information with the respondent, such as specific research questions or the study aims to address, can produce undesirable bias. In such cases, it may be desirable to omit certain specific information, while at the same time, sharing information that is only truthful, and without any deception.
- 2.3.1 In some contexts, such as surveying in areas of armed conflict, "researchers need to give careful thought to how the study is introduced in any scripted material and how it is presented by interviewers... From a measurement perspective, affiliating the study with a political party or even an aid agency may influence respondents' answers affecting the validity of the data"; see also Chapter 5.
- 2.3.2 Project Camelot was a U.S. Department of Defense research study designed to evaluate the Chilean military's potential for revolutionary political action, and to determine the most effective means of counteracting that action. Participating Chilean social scientists were not told that the U.S. Department of Defense was funding the project and would ultimately receive the data. When Chilean researchers learned the facts, the study was cancelled. The image of the U.S. funders and U.S. research suffered greatly.

- 2.3.3 In a 3MC study in the Middle East conducted by researchers in the U.S. in collaboration with national in study site countries, researchers were concerned that respondents would be reluctant to participate if they knew that the study was affiliated with a U.S. institution. Therefore, researchers obtained permission from the university's IRB to omit reference to the IRB in the consent documents, and interviewers introduced the respondents as being conducted by the study country partner. However, all participating project member, study country research organizations and academic institutions had full knowledge of the U.S. collaboration.
- 2.3.4 Beginning in 1961, psychologist Stanley Milgram conducted a study at Yale University. Test subjects told that they were part of an experiment on punishment and memory, and that they would act as teacher. 'teacher' subjects were instructed by the experimenter to administer an electric shock to a 'learner' if the learner failed to perform as required. Unbeknownst to the subject, the 'learner' was one of the research team and deliberately gave many incorrect answers. The subject was ordered by the experimenter to give higher and higher intensity shocks to correct this poor performance. Although in fact no shocks were administered, the majority of subjects believed that they were actually administering electric shocks to the 'learner.' As a result, subjects experienced distress and tension during the experiment; several even had seizures. The unethical Milgram study was highly criticized after the event, and became a landmark in the effort to develop ethical guidelines for social science research. However, while attacked from an ethics perspective, the Milgram study made a major contribution to research on obedience in social psychology. This study illustrates how it can be a challenge to balance the goals of science and ethical considerations.
- 2.4 3MC studies may involve the use of field research methods beyond the survey interview. Participant observation is a field research technique that involves the researcher becoming a trusted, yet temporary, participant in the community under study. This temporary membership may lead to feelings of abandonment on the part of the participants. Possible solutions include maintaining honesty with the participants and community as well as providing the researched community with a final copy of the research results in the community's native language.
- 2.5 Regarding respondent burden and privacy, the duration and location of interviews varies among established surveys.
- 2.5.1 The average duration is approximately one hour and is usually administered in the respondent's home, although other locations are sometimes used. Similarly, the interview is completed in the respondent's home or workplace.
- 2.5.2 The basic face-to-face portion of the European Social Survey (ESS) takes approximately 60 minutes and is conducted in the respondent's home (see [here](#)).
- 2.5.3 The [International Social Survey Programme](#) (ISSP) questionnaire consists of 60 questions, not including demographic questions, and takes approximately 15 minutes to complete.
- 2.5.4 The length of the survey varies across participating countries, depending upon the number of modules administered.
- 2.5.5 The [Survey of Health, Aging and Retirement in Europe](#) (SHARE) is completed in the respondent's home and takes approximately 80 minutes to administer to a single-family household, and 120 minutes to administer to a multi-family household.
- 2.5.6 The average length of the interview for the World Mental Health Survey varies across participating countries, ranging from 49 minutes as a computer-assisted interview in Italy to 210 minutes as a paper-and-pencil interview in South Africa; most interviews are administered in the respondent's home, but in some countries, they are also conducted in the respondent's place of employment, group quarters, cafes, libraries, or the office of the research organization.

3. Obtain informed consent from every research participant. *Rationale* Informed consent is an important component of the ethical principle 'respect for persons' and is mechanized through the idea that all people deserve the right to exercise autonomy and agency to make a choice to participate. Informed consent must provide the respondent with enough information about the project and its risks and benefits to make an informed choice. ***Procedural steps***

3.1 Develop the necessary documentation to obtain either oral or written voluntary informed consent. In implementing the consent process, provide the following information and adhere to the following principles.

3.1.1 Information to provide (in oral or written form, as appropriate):

- A clear identification of the research firm.
- A brief description of the survey or examples of questions or topic areas that can be easily understood by research participants.
- A description of the role of the respondent in the study, including the expected duration of the respondent's participation (i.e., what the respondent is being asked to do).
- A clear indication that participation is voluntary and that the information provided will be held in a confidential manner, unless there are special circumstances in which respondents have waived confidentiality. For example, disclosure of harm to self or others may trigger a breach of confidentiality, and such an exception should be noted in the informed consent document.
- A clear indication of the use of any electronic equipment (e.g., taping, recording, photographing) and/or one-way viewing rooms.
- A clear description of any benefits and risks associated with participation.
- A clear indication that a respondent's contact information will be held for possible future contact if there is an anticipation of a second wave of data collection in the future.
- Contact information for a study investigator or other research team member whom respondents can contact (provided or available on request).
- Contact information for a review board member whom respondents can contact if the study has been reviewed by an ethics review board). If consent is obtained orally, the interviewer can provide a paper document with relevant contact details to the respondent.
- See [Appendix A](#) for examples of both oral and written requests for informed consent.

3.1.2 Principles to follow when developing materials to obtain voluntary informed consent:

- Do not use coercion through force or threats.
- Do not use excessive or disproportionate influence to recruit research participants. Whether a practice is as coercive or not may vary by culture, population, and study.
 - For example, large monetary payments that are given to participants may be considered to be too good to refuse, particularly in resource-poor populations. Always take into account the local context, particularly when surveying vulnerable populations, and discuss any planned incentives with study country collaborators. See [Data Collection: General Considerations, Guideline 3](#) for further discussion on appropriate use of incentives.
- Consider what medium "best protect[s] the human subject".
- Respect the rights of individuals to refuse to be interviewed, to refuse part of the interview, and to terminate an interview in progress. Whether or not follow-up with individuals who initially refuse the survey request is appropriate may vary by culture, population, and study. The right of individuals to refuse participation in research and all part of the interviewer is an important part of the concept of 'respect for persons.'
- Respect the right of individuals to refuse to answer any question in the interview.
- Consent information should be conveyed in a format that is easy for respondents to understand, with language suitable for the general public. Consider the literacy level of the intended population. Written formats that will be appropriate include a document with narrative text, a list of Frequently Asked Questions (FAQs), and a brochure format. Samples of these formats can be found in [Appendix A](#) and from the .

- Protect rights to privacy of study participants. This should include a careful review of government privacy laws and regulations, which could vary on the type of data and persons that are covered and the definition of “identifiable” case .

3.2 Obtain and document consent. Whether consent is obtained in oral or written form depends on a number of factors including government laws and regulations, risk of harm for respondents revealing sensitive information, the type of data collection, the type of information requested, and cultural norms. For example, in mail surveys, consent is implied (that is, not explicitly obtained in oral or written form) if the respondent chooses to fill out the questionnaire and mail it back.

3.2.1 Obtain oral or written informed consent from all adult research participants.

3.2.2 Obtain oral or written informed consent from a parent or responsible adult before interviewing children or young people. Minors cannot consent to participate in research but can give their oral or written assent after obtaining parental permission.

3.2.3 Avoid making inaccurate or overly restrictive statements (e.g., the data will only be shared with the research team) if the data will be archived and shared with the research community .

3.2.4 It is difficult to foresee all possible future uses of survey data.

3.2.5 Develop protocol for use in the field to monitor that informed consent is received for each completed interview. For example, interviewers can be provided with a checklist of items to complete at each interview with the list including obtaining informed consent.

Lessons learned

3.1 Obtaining informed consent and assent may be simple and straightforward in one location but require multiple steps in another. In Western cultures, simple parental consent may suffice when studying minors. In Mali, on the other hand, a medical research team that wanted to study children under 9 years of age who had been exposed to malaria first discussed the study with a group of village elders. Next, they convened focus group discussions with the heads of extended families. Then, they held similar discussions with mothers whose children might become part of the study. Finally, they obtained the consent of the individual families involved .

3.2 When obtaining informed consent for a study that has been reviewed by an ethics review board, contact information for a review board member whom respondents can contact may not be useful. For example, contact information for a U.S. university review board may be irrelevant for the rural population in a country or context where actually contacting the U.S. IRB is not realistic due to language, access, or other issues. In such cases, it is more relevant to provide contact information for a local, within-country entity whom the respondent could more realistically contact with any questions or concerns.

3.3 The American Association for Public Opinion Research (AAPOR) also has a number of [examples of consent forms](#) for review.

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4. Develop protocol for interviewers and other project members to use to protect respondent identifying details in survey data. *Rationale* Protection of respondent identity and data is a crucial element of the concept 'beneficence'; protecting respondents from harm, and, specifically, harm stemming from disclosure of survey responses. Protection of respondent confidentiality is achieved through appropriate interviewer training as well as data processing, storage, and dissemination procedures. ***Procedural steps***

- 4.1 Provide appropriate training to interviewing staff about ethical standards and study specific procedures to protect human subjects. Interviewers are often the first (and only) member of the research team with whom the respondent has contact. It is crucial for interviewers to understand the responsibility they have in protecting the identity and confidentiality of the respondent, as well as adequately conveying the respondent's rights with regard to the research process.
 - 4.1.1 To the extent allowed by law or regulations, train staff to keep confidential both identifying material (e.g., respondent names, addresses, and telephone numbers) and all information given by respondents.
 - 4.1.2 Conduct staff training on the concepts of respect for persons, beneficence, and justice and the steps all team members must take to ensure compliance with ethical standards. Consider requiring staff to complete an online ethics course, such as the ethical training course offered by the Collaborative Institutional Training Initiative ([CITI](#)).
 - 4.1.3 Discuss with staff the protocols that will be used to detect data falsification and of the negative contribution to the integrity of the research process.
 - 4.1.4 Require staff to sign a pledge of confidentiality or to provide assurance in some form that they will maintain confidentiality (see [Appendix B](#) for an example of a pledge of confidentiality). It is important to note that maintaining confidentiality takes on even greater significance if local interviewers are working in areas where they may be acquainted with sample members prior to the interview request.
 - 4.1.5 Include discussion of ethical standards in any interviewer training refresher courses conducted during the data collection period.
- 4.2 Separate personally identifiable information (PII) from the respondent data. PII minimally includes name, a telephone number, and identification number(s) (including an identification number assigned by a government agency such as a social security number in the United States or a national registration identity card number in the United Kingdom), but may include other information including biometric data.
- 4.3 Keep secure and confidential any data source which links survey responses to identifiable respondents.
- 4.4 Use information gained through the research activity for study-related purposes only.
- 4.5 Adhere to government laws and regulations on storage, retention, and dissemination of survey data.
- 4.6 Limit access to confidential data to project staff members who have pledged to maintain confidentiality and been trained on appropriate use of study data.
- 4.7 If disclosing survey data to outside parties, require all subcontractors, consultants, and third parties to enter into an agreement to maintain respondent confidentiality. This agreement should include an explicit statement that the third party cannot use contact information or any other information to recontact the respondent for any reason not directly related to the study (e.g., data cannot be used to approach respondents for a different study or for marketing purposes).
- 4.8 Report any breach of confidentiality in accordance with ethics review board policies and government regulations.
 - 4.8.1 Establish specific protocols for interviewers to report breaches of confidentiality and provide protocol for interviewer training. Interviewer training should include examples of anticipated breaches of confidentiality (such as reporting of abuse witnessed within the household), as well as discussion about the use of common sense based on what interviewers know about the survey, to determine whether a breach has occurred or a breach may be necessary.
 - 4.8.2 Establish specific protocols which dictate how the principal investigator and study personnel must report a breach of confidentiality to the IRB overseeing the project.

- 4.8.3 If the data collection mode involves any form of technology, take the appropriate steps to secure electronic data and train interviewers accordingly (see [Data Collection: Face-to-Face Surveys, Guideline 3](#)). Loss of equipment containing confidential survey data is a breach of confidentiality and should be reported to the IRB overseeing the project.

Lessons learned

- 4.1 Circumstances leading to a necessary and intentional breach of confidentiality can, in some cases, be anticipated and in other cases be unexpected.
- 4.1.1 In the United States, interviewers may be mandated to report suspicions of child abuse or neglect that they witnessed during the research process, depending on individual state laws. If state and/or local laws apply, researchers should clearly explain interviewers' responsibilities during the training process and document such breaches of confidentiality accordingly.
- 4.1.2 In the course of the data collection period, unexpected events can arise that also necessitate a confidentiality breach. During the production period of a survey in a South Asian country, political activists burglarized a local data collection firm and stole several laptops which contained survey data files. Fortunately, the data were securely encrypted and did not contain any identifying information. Nevertheless, the incidence was reported to the IRB overseeing the project.

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5. Develop procedures and obtain voluntary informed consent for any additional data collection activities.

Rationale It is becoming increasingly common for survey research to include additional measurement modes beyond the survey questionnaire, including collection of biometrics in addition to linkages to other data sources, such as government registries (e.g., U.S. Social Security Administration data) or social media data (e.g., Twitter activity). After the survey questionnaire is complete, a second consent procedure—that is, a reconsent—is administered for the secondary data collection. **Procedural steps**

- 5.1 Consider whether a secondary data collection will be administered. For further discussion on secondary data collection, see chapter on [Paradata and Other Auxiliary Data](#).
- 5.2 Develop oral or written reconsent documentation, which should address the same principles as the primary procedures outlined in [Guideline 3](#).
- 5.3 Provide reconsent-specific training to interviewers.
- 5.4 Obtain reconsent from research participants prior to collecting secondary data or performing any linkage to a respondent's secondary data source.
- 5.5 Protect data obtained from secondary data collection equally to that obtained from the survey questionnaire.

Lessons learned

- 5.1 In a secondary data collection, the World Mental Health Survey in Saudi Arabia successfully collected saliva from respondents, from which DNA was extracted for analyses. Because there would be a cost born by the study for processing, the reconsent form explicitly stated that the respondents would bear no extra cost as a result of participation in this study. Respondents were given the option to receive a general summary of the study results or to receive the results of the study that pertain specifically to the respondent. Additionally, respondents were asked a series of questions regarding consent to the potential use of any leftover saliva samples in the future.

- 5.2 stress that consent should always be required for collecting auxiliary data used to make inferences about or complement other information collected from the respondent. Researchers have to assess the objective of the use of auxiliary data against possible disadvantages for respondents (e.g. the inherent lack of consent when using data to analyze nonrespondents). The authors explain and compare the challenges of current consent-seeking procedures in the European Union connected to the General Data Protection regulation (GDPR) and in the United States (based on the Common Rule on Federal Policy for the Protection of Human Subjects).

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6. Maintain sensitivity to cultural and social differences. *Rationale* Designing study protocols that are sensitive to cultural traditions and norms is vital to building trust and gaining cooperation. Being respectful of cultural norms and customs also leaves individual participants with a positive impression of the research community. Beyond the individual level, it may forestall negative political and social consequences. Finally, participation in social science and health research may promote awareness of research issues in the community. *Procedural steps*

- 6.1 Consider a medium of data collection that is “appropriate for participants,” rather than only a form convenient for researchers.
- 6.2 Do not exclude minority groups, native populations, or aboriginal peoples in the sample, unless it is appropriate to do so. Document any necessary exclusions.
- 6.3 Identify ethnic or religious power structures in the areas in which data collection will occur and approach study participants in accordance with the cultural traditions and norms of the ethnic or religious groups (e.g., through the head of the family or a local leader).
- 6.4 Involve other individuals or groups in the consent decision-making process as appropriate (e.g., older family members or local leaders).
- 6.5 Observe local customs in planning for and conducting the interview (e.g., giving advance notice before arriving, dressing in a culturally appropriate manner, removing one’s shoes inside the house, partaking of refreshment, a thank-you note).
- 6.6 Be flexible when implementing consent procedures (e.g., obtaining permission to accept oral consent in place of written form, if literacy is an issue).
- 6.7 Present study materials in a form that can be understood by the respondent (e.g., in the respondent’s native language or orally rather than written if literacy is an issue). Avoid the use of technical language or jargon.
- 6.8 Observe cultural norms when assigning interviewers to sample elements (e.g., matching female interviewer with female respondents, if matching is culturally appropriate).
- 6.9 Attempt to conduct interviews in settings that afford as much privacy as possible while still respecting cultural norms (see [Data Collection: Face-to-Face Surveys, Guideline 4](#)).
- 6.10 Identify the level or degree of sensitivity for different question topics during preliminary fieldwork, observation, and pretesting, since sensitive topics often vary among cultures and societies.
- 6.11 Consider cultural traditions and norms when deciding whether to offer respondent incentives and determine the type of incentives would be most appropriate. See [Data Collection: General Considerations, Guideline 3](#) for more on incentives.
- 6.12 Determine whether it is appropriate to follow up with persons who initially refuse the survey request and develop follow-up protocols in accordance with cultural traditions and norms.

- 6.12.1 Interviewer training should specify the definition of a 'hard refusal' from a respondent, how many call-back attempts are permissible, and appropriate methods to address respondent concerns.
- 6.12.2 In the case of panel surveys, develop protocol to specify whether to contact in latter wave(s) those respondents who refused to participate in former wave(s).
- 6.13 Do not over generalize. caution against generalizing in a way that implies “universality and sameness” (p. 1). These authors also recommend care in how language is interpreted or what the semantics of language is assumed to mean.

Lessons learned

- 6.1 As with other aspects of research, we cannot assume that 'one size fits all' when implementing a study protocol with regard to ethics.
 - 6.1.1 There may be different levels of requirements for privacy in different cultures. In a study involving 11 boys in India, in-home interviews tended to include relatives and neighbors. At times the interviewers had to exercise considerable tact to discourage members of the audience from interjecting their own answers to the questions being asked.
 - 6.1.2 In some cultures, it may be necessary to gain approval from authority figures within a community (gatekeepers). In a fertility study in Guatemala, interviewers were effectively barred from a rural municipality by the single act of a local priest. The priest warned his parishioners against the “red urbanites who would tempt women from having children,” as he described the researchers.
 - 6.1.3 Respondents in some cultures may be reluctant to provide written documentation of consent. Research in Mali found that documenting the consent process with a signed paper was a challenge. At first, villagers opposed to signing any document, because they strongly believed that their word should be sufficient. In addition, participants found the legal language difficult to understand. It took very careful explanation and patience to overcome this resistance. Oral consent may also be necessary because of literacy limitations in which sensitivity should be applied.
 - 6.1.4 Sensitivity of topic can vary widely across countries and discussions with study country collaborators to identify sensitive topics are imperative. In some religiously conservative countries, such as Egypt, it is considered inappropriate to ask general questions about religion, such as whether the respondent believes in God. In a 3MC survey in the Middle East, researchers prefaced the item about belief in God with the statement “Please keep in mind that we ask the next set of questions because we will compare the results from [COUNTRY] with many other countries.” This phrase diffused some of the sensitivity surrounding the topic.
- 6.2 Transformative researchers who empower community members to work with researchers for social change respect as involving critical study of “cultural norms of interaction in diverse communities across cultural groups. Quality, or the degree to which findings reflect participants’ perspectives, relates to the “degree of collaboration between researchers and the researched. Collaboration allows “the meanings and diffusion of knowledge” to the hands of local participant groups. “It is vital that Indigenous peoples have direct input into developing and defining research practices and projects related to them”.
- 6.3 In 3MC surveys, researchers may confront situations that require careful consideration and possible design trade-offs in order to comply with ethical principles and minimize sources of survey error while maintaining comparability across countries or cultures. emphasizes that no one ethical principle overrides all others, and that researchers consider such trade-offs accordingly, to ensure that the involved researchers meet widely accepted standards for ethical, professional, and scientific conduct for all stages of the study (such as design, implementation, dissemination and reporting). As an example, notes that maintaining sensitivity to cultural differences by having other family members present during an interview may conflict with ethical obligations to protect confidentiality and to maintain objectivity.

error in respondent reporting. Recognizing this type of conflict at the design stage allows for a creative solution as the use of a self-administered questionnaire for sensitive items, which offers both privacy for the responder responding to sensitive items and cultural sensitivity by allowing the presence of a third party. Ideally, this approach would be taken in all study countries to minimize comparison error in the context of a 3MC survey.

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7. Report research findings and methods and provide appropriate access to study data. *Rationale* Professional science organizations generally agree that their members should report findings to benefit the widest possible community. From this, it follows that data collection agencies should provide full information to allow readers and data users to evaluate both methodology and results. Dissemination of results and research reports also increases public confidence and allows potential users to assess limits of accuracy and reliability, avoiding misinterpretation of findings. In addition, sharing documentation on study methods can assist other researchers in making informed choices about research design and implementation in future studies. While providing access to study data and methods is advantageous for the reasons here, researchers must also assess the risk of a breach of confidentiality and address this concern when preparing data dissemination. *Procedural steps*

- 7.1 Report findings as completely, widely, and objectively as possible, while also protecting participants' confidentiality. While the full reporting of results is an important ethical obligation, it is also important to consider the negative impact that reporting unfavorable findings about a specific ethnic, religious, or other social group may have on members of that group.
- 7.2 Make available as much of the study's methods, results, and raw data as possible, within the bounds of protecting participants' confidentiality, in order to permit others to evaluate the study and to replicate the findings.
- 7.3 Evaluate the risk of a breach of confidentiality and implement appropriate techniques to protect the confidentiality of the data, including de-identification of publicly available datasets to the greatest extent possible (see [Data Dissemination](#) for a detailed discussion).
- 7.4 Provide a summary report of the study methodology and findings. See [Appendix C](#) for a checklist of items to include in the summary report.
- 7.5 Provide a copy of the findings to all researchers and organizations that were involved in the study.
- 7.6 Provide a copy of the de-identified dataset(s) and documentation to a trusted national data repository. See [Data Dissemination](#) for further details about dissemination and documentation.
- 7.7 Provide safe, sustainable storage of the datasets and documentation.
- 7.8 Adhere to government laws and agreements that address disclosure of survey data both within and across borders.
- 7.9 If an error is discovered after publication of the results, make an effort to correct the error using an erratum document that describes the error and its likely effect on study results, and provide an additional variable or variables along with appropriate documentation for analysts to identify the corrected value(s).
- 7.10 Make an effort to respond to specific written requests for additional items pertaining to the publicly released findings.

Lessons learned

- 7.1 There are useful examples of efforts to fully document study methods and provide survey data from 3MC surveys to a wide community of users. In part or whole, their approach and templates can serve as models for other studies.

- 7.1.1 The European Social Survey website provides comprehensive information on study methodology and data for any registered user. Registration is free and easy to complete.
- 7.1.2 The World Mental Health Survey Initiative used a standardized web-based survey instrument to collect information on study methodology from participating countries.
- 7.1.3 It is important to be aware that some national standards require that raw and de-identified datasets be stored for a minimum time period (e.g., 10 years is the German National Science Foundation standard for empirical research).

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8. Institute and follow appropriate quality control procedures. *Rationale* Development and implementation of quality control procedures is necessary to ensure that the procedures that have been developed to meet standards for ethical research are being carried out appropriately. If a failure to meet these standards is detected, protocols should be in place to rectify the failure. In addition, monitoring of procedures related to the ethical conduct of the study should inform efforts to improve quality and cost-effectiveness at all stages of the life cycle process. For a more in-depth discussion of the survey quality framework, see [Survey Quality](#). *Procedural steps*

- 8.1 Pretest consent protocol and forms to ensure comprehension.
- 8.2 Translate and adapt consent protocols and forms according to best practices (see [Translation](#) and [Adaptation](#)).
- 8.3 Consider reviewing recorded interviews and monitoring live interviews when possible to assure adherence to informed consent procedures.
- 8.4 Monitor implementation of confidentiality protocols and procedures, including, but not limited to performing spot checks to determine adherence to these protocols and procedures.
- 8.5 Securely store signed pledges of confidentiality and consent forms.
- 8.6 Recontact a sample of cases for each interviewer to verify that screening and interview procedures were appropriately followed. See [Data Collection: General Considerations, Guideline 5](#) for additional information.
- 8.7 Use analyses of paradata (e.g., identification of question-level timings that are unusually short or long and identification of unusual variable distributions for one or more interviewers compared to the overall distribution) and a detailed description of the use of paradata to assess survey quality, see [Paradata and Other Auxiliary Data](#).
- 8.8 Conduct disclosure analysis. (See [Data Dissemination](#) for more details.)
- 8.9 Investigate any deviation from ethical protocols and take appropriate action to address the situation.

Lessons learned

- 8.1 Sometimes a small group of interviewers can have a large impact on the quality of survey estimates. In a mental health survey of six European countries, the prevalence rates of mental health disorders were unusually low among German respondents. Experienced German interviewers were suspected of skipping screening questions that led to a more extensive set of follow-up items in order to complete interviews more quickly. Even though only a small number of interviewers had prior interviewing experience, they conducted a sizeable percent of the total number of interviews and the responses that they solicited were very different. In general, positive responses screened respondents into more extensive sections on mental health disorders. Only 14.5% of screening questions administered by the interviewers with prior interviewing experience were positive, while 44.7% of screening questions administered by interviewers without prior experience were positive.

9. Consider whether there are any other ethical issues resulting from design decisions, particularly when technology is used. *Rationale* With the continual expansion of technology into survey research, a number of other ethical issues have arisen, such as the accuracy of data obtained through web surveys, whether consent for the capture of certain types of paradata should be obtained, and how social media might be used in the survey process. We highlight several more ethical concerns here, but advise researchers to review their study design to identify any such issues, especially with technology. Ethical questions such as these will continue to arise and evolve, as there is further innovation in technology.

Procedural steps

- 9.1 If the survey design includes the use of a web survey administered without any interaction with an interviewer, consider the following:
 - 9.1.1 Data collected through a web survey should be encrypted adequately for protection against a security breach.
 - 9.1.2 If minor children are not included in the study design (and there is no assent process in place for their inclusion), then there should be a procedure to verify that all respondents to the survey are indeed consenting adults.
 - 9.1.3 See [Data Collection: Self-Administered Surveys](#) for further considerations when using a web survey.
- 9.2 If the survey design includes automated or interviewer-recorded capture of paradata or other auxiliary data, whether reconsent should be obtained from the respondent and/or whether the respondent should be informed of paradata capture (see [Paradata and Other Auxiliary Data](#)).
- 9.3 Be aware of the potential uses of social media. The inclusion of social media in the survey process has increased in recent years. If the study design includes the use of social media, researchers should consider whether usage complies with the principles of beneficence, justice, and respect for persons. Possible uses of social media (e.g., Facebook, Twitter, Instagram, etc.) include:
 - 9.3.1 Use of social media profiles to screen respondents from a sample frame to identify those having particular attributes of interest.
 - 9.3.2 Use of social media profiles to track respondents in a panel survey.
 - 9.3.3 Use of survey respondents' publicly available social media data, both profile information and Facebook updates, Twitter tweets, etc., to augment data from survey questionnaires.
 - 9.3.4 Use of social media to identify questions, domains, and concepts in populations of interest during study development.

Lessons learned

- 9.1 The American Association for Public Opinion Research (AAPOR) has published the *Social Media Task Force Report*, outlining the most recent considerations on emerging technologies in public opinion research .

10. Document materials and procedures related to the ethical conduct of the study and ethics committee review

Rationale In research that involves human subjects, it is critical to maintain documentation of materials that were used to inform potential participants about study participation and subsequently record consent, in case there is ever a question about ethics violations or a request for additional information from an ethics review board. In addition, documentation of a

survey procedures including those related to the ethical conduct of the study is a key element of high quality scientific research. ***Procedural steps***

10.1 Consider what ethical concerns may pertain to the issue of selecting research findings to publish .

10.2 Maintain a copy of the following documents:

10.2.1 Scripts, letters, fact sheets, and any other materials provided to respondents to give them information to make an informed decision about participation.

10.2.2 Consent form templates and protocols.

10.2.3 Translated or adapted consent form templates and protocols.

10.2.4 Individual consent information for each respondent, stored in a safe environment separate from survey

10.2.5 Confidentiality procedures and protocols.

10.2.6 Pledge(s) of confidentiality completed by staff.

10.2.7 Records of completion of any specialized staff training on ethics.

10.2.8 The original submission to the Ethics review board, requests for modification to study protocol, and renewal material (see [Appendix D](#) for a checklist of materials to include in an ethics review board submission).

10.2.9 Ethics review board correspondence (e.g., letters of approval).

10.2.10 Documentation of any other ethical review required by study sponsors, individual study countries, etc

10.2.11 Any correspondence between study staff or ethics review board members/staff and respondents regarding ethical issue or concern.

10.2.12 Reports of quality control activities (e.g., documentation of verification activities).

10.3 Provide a copy of the following documents to any central coordinating organization:

10.3.1 Translated or adapted consent form templates and protocols.

10.3.2 Ethics review board original submission and requests for modification to study protocol.

10.3.3 Ethics review board correspondence (e.g., letters of approval).

10.3.4 Reports of quality control activities (e.g., documentation of verification activities).

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