



**A practitioner's guide to the ethical
conduct of research on child
marriage in humanitarian settings**

JANUARY 2021



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A Practitioner's Guide to the Ethical Conduct of Research on Child Marriage in Humanitarian Settings

1 INTRODUCTION

This guide is intended to offer practitioners a framework for decision-making considering whether and how to conduct research on child marriage in humanitarian settings. Our focus is on the ethical conduct of research among female and male adolescents and young people (10–24) who are at risk of or have experienced child marriage and are living in challenging, low-resource and often insecure environments. The reasons for this focus are several:

- While developing studies of child marriage in nine humanitarian settings over several years, we heard frequent and varied questions from study partners, not only about how to address the different ethical issues these studies presented—including their local contextual nuances—but also why informed consent matters, or what an Institutional Review Board (IRB) is and how to work with them. Based on our work on these studies, and our experience working with IRBs and dealing with research ethics in humanitarian settings over time, we hope to provide some guidance on these issues.
- In our literature review on child marriage research, and drawing upon our more general knowledge of research in humanitarian settings, we found a variety of other documents describing methods and designs for research in humanitarian settings, and resources for activities such as study design, sample size calculations, data analysis and the like. We provide links to many of these references and resources in the annexes, but do not otherwise describe them in detail.
- In developing this guide, we wanted to provide a reasonably short and accessible set of considerations for practitioners as they explore practical questions about research on child marriage in humanitarian settings. Rather than try to provide comprehensive answers to all these questions, we felt that the ethical conduct of human subject research was foundational to the other questions and a necessary starting point for planning and discussions.

This guide is designed to help practitioners make decisions about whether or not human subject research on child marriage is needed in humanitarian settings, and, if it is needed, to help them examine the key concepts, elements and options that should be considered in conducting ethical research. We do not, however, attempt to prescribe concrete answers but rather to set out a framework for informed decision-making within specific contexts. Furthermore, this guide is not intended as a training manual for practitioners on all aspects of study design, methodology, sampling strategies, instrument development or data analysis. There are a wide variety of well-regarded and detailed handbooks for this, and we provide references to many of them in the annexes.

While our studies were located in a range of geographical locations and humanitarian settings – including refugees, internally displaced people (IDPs) and affected host communities in Bangladesh, Djibouti, Egypt, Ethiopia, Lebanon, Myanmar, Nepal, northern Iraq and Yemen – we recognize that context is vital and do not suggest that these or any single set of guidelines would apply universally. It is our hope, however, that the approaches set out in the guide, and the examples from field experience, will provide a framework for examining local contexts and for making informed and ethical decisions about the research process.

A. KEY CONCEPTS AND DEFINITIONS

The following are some key definitions that guided our research and the development of this guide.

1. **Children** According to article 1 of the United Nations Convention on the Rights of the Child (CRC), children are defined as “every human being below the age of 18 years unless under the law applicable to the child, majority is attained earlier.” Article 3 states that “in all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration” (United Nations General Assembly [UNGA], 1989).
2. **Adolescents** Noting that there are no universally accepted definitions, United Nations organizations generally understand adolescents to include “persons aged 10–19 and youth as those between 15–24 for statistical purposes without prejudice to other definitions by Member States” (UNFPA, 2020). The World Health Organization (WHO) described adolescence as “the phase of life between childhood and adulthood... It is a unique stage of human development and an important time for laying the foundations of good health... Despite being thought of as a healthy stage of life, there is significant death, illness and injury in the adolescent years. Much of this is preventable or treatable. During this phase, adolescents establish patterns of behaviour – for instance, related to diet, physical activity, substance use and sexual activity – that can protect their health and the health of others around them, or put their health at risk now and in the future” (WHO, 2020a).
3. **Child marriage**, as defined by United Nations organizations, is “a legal or customary union between two people, of whom one or both spouses is below the age of 18” (Loaiza & Wong, 2016). An informal union is “one in which a couple live together for some time, intending to have a lasting relationship, but do not have a formal civil or religious ceremony” (UNICEF, 2020a).

Child marriage, according to UNICEF (2019), “is a form of violence against children”. According to the United Nations Office of the High Commissioner for Human Rights

(OHCHR; 2019), “child marriage is considered to be a form of forced marriage, given that one and/or both parties have not expressed full, free and informed consent.”¹

Child, early and forced marriage (CEFM) is often referred to as a single construct, as in Sustainable Development Goal (SDG) 5 to “achieve gender equality and empower all women and girls”, under Target 5.3: “Eliminate all harmful practices, such as child, early and forced marriage and female genital mutilation” (United Nations Development Programme [UNDP], 2019). In 2018, the United Nations General Assembly’s Third Committee agreed to a third resolution on CEFM, which noted that “the incidence and risk of child, early and forced marriage can increase during humanitarian emergencies, situations of forced displacement, armed conflict and natural disasters because of various factors, including insecurity, increased risks of sexual and gender-based violence, the misconception of providing protection through marriage, gender inequality, lack of access to continuous, quality education, the stigmatization of pregnancy outside marriage, the absence of family planning services, disruption in social networks and routines, [and] increased poverty and the absence of livelihood opportunities” (UNGA, 2018).

UNICEF (2020a) also states that “[m]arriage before the age of 18 is a fundamental violation of human rights. Many factors interact to place a child at risk of marriage, including poverty, the perception that marriage will provide ‘protection’, family honour, social norms, customary or religious laws that condone the practice, an inadequate legislative framework and the state of a country’s civil registration system. While the practice is more common among girls than boys, it is a violation of rights regardless of sex.”

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4. **Gender-based violence** UNFPA (2019) has defined gender-based violence (GBV) as “an umbrella term for any harmful act that is perpetrated against a person’s will and that is based on socially ascribed (i.e., gender) differences between males and females. It includes acts that inflict physical, sexual or mental harm or suffering, threats of such acts, coercion and other deprivations of liberty. These acts can occur in public or in private... The term ‘GBV’ also includes sexual violence committed with the explicit purpose of reinforcing gender inequitable norms of masculinity and femininity.”

UNFPA (2019) also noted that “during emergencies, the risk of violence, exploitation and abuse is heightened. At the same time, national systems, including health and legal systems, and community and social support networks weaken...When systems and services are disrupted or destroyed, women and girls face even higher risk of human rights violations such as sexual violence, intimate partner violence, exploitation and abuse, child marriage [emphasis added], denial of resources and harmful traditional practices.”

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5. **Humanitarian settings** Referring to humanitarian emergencies, WHO (2007) noted that the term is generally used “to refer to situations of armed conflict or natural disaster, often involving the displacement of populations, sometimes as refugees, other times as internally displaced people (IDPs).” Humanitarian crises can be defined as sudden-onset events such as earthquakes, tsunamis and tropical storms, or as slow-onset events such as droughts, food insecurity and prolonged armed conflict (United Nations Office for the Coordination of Humanitarian Affairs [OCHA], 2011). Infectious disease outbreaks, due to their varied origins and trajectories, may be characterized as sudden-onset or slow-

1 Article 12 of the CRC states that “States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child” (UNGA, 1989). However, the CRC also cites the Declaration of the Rights of the Child which states that “the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection” (UNGA, 1949), the implication being that a child lacks full autonomy of person (and thus may be compelled to attend primary school, get immunized against infectious diseases, etc. without consent) and lacks capacity to give full, free and informed consent.

onset or may have characteristics of both depending on how they spread. Humanitarian emergencies can also be characterized by levels of severity (acute or chronic) or by phases of intervention, from rapid response to rehabilitation to recovery. To further add to the complexity, humanitarian crises are often cyclical, and periods of recovery and stability can give way to new outbreaks of violence or recurring earthquakes or storms. Populations that have moved once may be displaced again, and recovery interventions must be reprogrammed into rapid-response efforts (WHO, 2007).

For the purpose of this guide, the term “humanitarian settings” includes any of the above scenarios and contexts, ranging from acute-phase response to an earthquake, to protracted displacement caused by persistent and unresolved conflict. Settings and contexts vary considerably, and it is important to contextualize decisions about study design and methods in order to maximize scientific value, and understand settings’ individual target population characteristics and circumstances. That said, all humanitarian settings have several things in common: “dependency, loss of autonomy, breakdown of community/social systems and ongoing security threats are the norm” (WHO, 2007).

B. BACKGROUND ON CHILD MARRIAGE IN HUMANITARIAN SETTINGS

Child marriage violates every child’s right to reach their full potential. Various United Nations Conventions deem child marriage a fundamental violation of human rights (UNGA, 1949; UNGA, 1989; UNGA, 2015) and a harmful practice because it denies girls and boys the right to the highest attainable standard of health, restricts life opportunities such as the right to an education, and restricts opportunities especially for girls – to participate fully in family, cultural and civic activities (Marphatia et al., 2017). Despite laws and international commitments to reduce the practice, child marriage remains globally widespread, with one in five girls married before their eighteenth birthday (UNFPA, 2020). This practice disproportionately affects those in the least developed countries, where approximately 40 per cent of girls are married before the age of 18 and 12 per cent are married before the age of 15 (UNFPA, 2020).

In both development contexts and humanitarian settings, child marriage is rooted in gender inequality and sustained by cultural and social norms, poverty, and a lack of opportunities. However, humanitarian crises, whether induced by conflict, natural hazards, (including climate change), or other factors, may amplify or alter pre-existing drivers, or introduce new drivers or moderators. Crises are often associated with increased sexual violence, a breakdown in the rule of law, disruption of social structures, as well as internal and international displacement, all of which have an impact on child marriage in various contexts.

Studies to date suggest that rates of child marriage tend to be particularly high in insecure environments (Tembon & Fort, 2008). Most of the countries with the highest rates of child marriage are also among the most vulnerable to impacts of natural hazards, and most frequently found on lists of failed states (Lemmon, 2014). According to a 2016 Women’s Refugee Commission (WRC) report, ‘A Girl No More’, nine of the top 10 countries with the highest rates of child marriage were considered fragile or conflict-affected States (Schlecht, 2016). According to the report by Organisation for Economic Co-operation and Development (OECD; 2018), ‘States of Fragility 2018’, as of 2018, all of the top 10 countries for high child marriage were fragile or conflict-affected. Most of the 25 countries with the highest rates of child marriage are also at high risk for disasters caused by natural hazards (Atkinson & Bruce, 2015).

Humanitarian crises do not give rise to child marriage from nowhere, but evidence from a

number of studies shows that they increase physical and economic insecurities, amplifying pre-existing drivers of child marriage (McAlpine et al., 2016; Schlecht et al., 2013; Zabel, 2016). High poverty rates and little access to education are frequently associated with child marriage, and both are often worsened as a result of conflict and disaster (Schlecht et al., 2013). Humanitarian crises may also create new drivers such as displacement, which can lead to break-up of family networks and weakening of social institutions, as well as exposure to restrictive host government laws and policies, and the threat of sexual and other forms of violence (Zabel, 2016).

Humanitarian crises impact women, girls, men and boys differently due to their differing status and roles in society, and can exacerbate pre-existing gender and power inequalities (IASC, 2018; van Dijkhorst and Vonhof, 2005). Humanitarian settings can also change gender dynamics and roles, which affects decision-making about marriage. Crises can provide opportunities to challenge discriminatory gender norms and unequal power relations, such as when women assume prominent roles in peacebuilding, or men take on greater care responsibilities (Green, 2013). Humanitarian interventions themselves can either address people's needs in ways that confirm traditional gender roles or promote gender equality (IASC, 2006).

C. OVERVIEW OF WRC/JOHNS HOPKINS UNIVERSITY (JHU) STUDIES

The WRC and Johns Hopkins University (JHU) Center for Humanitarian Health have partnered since 2011 to build the evidence base on child marriage in humanitarian crises. Between 2011 and 2015, the WRC, JHU and collaborating partners conducted research on three conflict-affected populations: Syrian refugees in Lebanon, Somali refugees in Ethiopia and IDPs in Kachin State, Myanmar. The studies concluded that in order to reduce or limit the effect of humanitarian crises on child marriage practices, programmes must ensure that the basic needs of families are met during the acute phase of an emergency, and ensure that programming is designed to promote the agency and value of adolescent girls.

Since 2016, we have collaborated on nine studies in countries across Africa, Asia and the Middle East (see Table 1). This research sought to understand how traditional practices around age of marriage may change during conflict, and which factors contributed to those decisions. At the time the research began, anecdotal information suggested an increase in this practice, but very little had been done to systematically explore the intersecting individual and societal factors contributing to changes in customs and norms around marriage, including child marriage. The WRC and JHU conducted mixed-methods research, which was commissioned by UNFPA Arab States regional office (ASRO) in 2018, on risk factors and outcomes related to child marriage among refugee and IDP populations in humanitarian contexts in the Kurdistan Region of Iraq (KRI), Djibouti, Yemen and Egypt. Fieldwork on those studies was completed in 2019 and reports and journal articles are forthcoming in 2020.

In 2018, the WRC and JHU were commissioned by the UNFPA Asia Pacific regional office and the UNICEF regional office for South Asia, under the Global Programme to End Child Marriage, to conduct research, with the following objectives:

- to measure the prevalence of child marriage in humanitarian settings in South Asia, specifically one population displaced by conflict (Bangladesh) and one population displaced by a natural disaster, in this case an earthquake (Nepal)

- to explore the drivers of child marriage within these same conflict-affected and climate-affected communities
- to develop recommendations for interventions and programmes.

TABLE 1 *Prior WRC/John Hopkins University (JHU) research on child marriage in humanitarian settings*

Country	Study population	Qualitative	Quantitative
Bangladesh	Rohingya refugees	✓	✓
Djibouti	Somali refugees Yemeni refugees	X	✓
Egypt	Syrian refugees	✓	X
Ethiopia	Somali refugees	✓	✓
Kurdistan Region of Iraq (KRI)	Iraqi IDPs Syrian refugees	✓	✓
Lebanon	Syrian refugees	✓	✓
Myanmar	Kachin IDPs	X	✓
Nepal	Earthquake-affected populations	✓	✓
Yemen	Yemeni IDPs	✓	✓

In virtually all of these studies, JHU served as the IRB of record, reviewing and approving each of the individual country research plans and study protocols. Each country study was also approved by a local IRB to ensure that the research plan was consistent with local norms and standards of ethical conduct of research. In addition, the study team in each country worked with local partners to adapt the study design to local contexts and to engage local communities in consultations about the aims, methods and field implementation procedures of each study.

D. SCOPE AND STRUCTURE OF THIS GUIDE

The guide is organized into 10 chapters including the introduction (chapter 1), followed by two annexes (references and resources for further reading and training). Chapters 3 to 10 set out elements that are central to the ethical conduct of human subject research, with a focus on child marriage in humanitarian settings:

- Chapter 2:**
Research in humanitarian settings
- Chapter 3:**
Vulnerability and vulnerable populations
- Chapter 4:**
Privacy and confidentiality
- Chapter 5:**
Informed consent
- Chapter 6:**
Institutional Review Boards (IRBs)
- Chapter 7:**
Study design and methodology
- Chapter 8:**
Study implementation
- Chapter 9:**
Community engagement and capacity-building
- Chapter 10:**
Public accountability for research

For each of these chapters, we lay out the topics we will address and the questions we hope to answer, including a checklist of questions for practitioners. The chapters include examples of how specific research ethics issues were discussed and addressed in different study contexts. The two annexes at the end of the guide provide a list of references cited in this report and also provide links to resources for further reading on research methods and ethical guidelines.

2 RESEARCH IN HUMANITARIAN SETTINGS

This chapter is divided into three sections. The first examines general issues around the ethical conduct of human subject research, including low-resource settings and emergencies. The second section looks more explicitly at the ethics of research in humanitarian settings. Finally, the third section presents some questions for practitioners to consider.

A. ETHICAL CONDUCT OF RESEARCH

When discussing the ethical conduct of research, it is important to answer two key questions:

- What is research and, in particular, what is human subject research?
- What principles guide the ethical conduct of human subject research?

Beyond these general questions are a range of more specific questions that arise when considering target populations and their vulnerability, the research methodologies available, and the local context within which the research would be conducted. These specific questions will be examined in more detail in the chapters that follow.

As will be seen, however, the general frameworks and principles of research ethics should be interpreted and operationalized in specific contexts. In describing these general principles, we draw upon international guidelines that are likely to have the broadest application across a variety of contexts and populations, but are still relevant for studying child marriage in humanitarian settings. One is the 2007 report, 'WHO Ethical and safety recommendations

for researching, documenting and monitoring sexual violence in emergencies'. The second is 'Gender-Based Violence Research, Monitoring, and Evaluation with Refugees and Conflict-Affected Populations' (Global Women's Institute, 2017), which incorporates the WHO general principles for safe and ethical research on sexual violence in emergencies. The third is 'International Ethical Guidelines for Health-related Research Involving Humans', which was prepared in 2016 by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. Additional guidelines and references will be discussed in subsequent chapters.

1. What is research and, in particular, what is human subject research?

While there is no universally accepted definition of research, the US Code of Federal Regulations defines "research" as "a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge" (US Department of Health and Human Services [HHS], 2020). When research is done with human beings (and animals), it must follow specific rules about the treatment of humans to ensure that they are treated with dignity and respect, and that the research causes minimal harm. The US National Institutes of Health (NIH; 2020) defines "human subject research" as "research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated." Meanwhile, the CIOMS (2016) defines "health-related research" as "activities designed to develop or contribute to generalizable health knowledge within the more classic realm of research with humans, such as observational research, clinical trials, biobanking and epidemiological studies. Generalizable health knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based related to health, which can be corroborated by accepted scientific methods of observation and inference."

To paraphrase, then, human subject research involves acquiring or using data and/or personally identifiable information about living individuals through the use of accepted scientific methods in order to contribute to generalizable knowledge. Examples of human subject research include collecting blood, conducting a survey, changing participants' environment, administering medicine, interviewing, administering a psychological test, collecting data, conducting a focus group and testing a new educational technique (NIH, 2020). Studies on child marriage in humanitarian settings might not include all these methods, but conducting surveys, interviewing, collecting data and conducting focus groups are common approaches and meet the criteria for human subject research.

There are a variety of ways in which some kinds of research might be exempt from human subject research regulations, and there are also a variety of information-gathering activities that would not be considered human subject research. In the context of humanitarian emergencies, rapid needs assessments, ongoing programme monitoring and evaluation, and public health surveillance are generally not considered human subject research. That said, it is not the purpose of this guide to tell practitioners, or their collaborating partners, whether their proposed study is or is not human subject research. That determination is best made either by consulting a local IRB or Institutional Ethical Committee (IEC; see chapter 6), or at least discussing the study with an experienced researcher (preferably someone with experience serving on an IRB) for preliminary guidance.

2. What principles guide the ethical conduct of human subject research?

The CIOMS (2016, p. 1) guidelines promote two core principles for human subject research to be ethically justified: "scientific and social value: the prospect of generating the knowledge

and the means necessary to protect and promote people's health." We might also add people's well-being to expand on the notion of social value. "Therefore, researchers, sponsors, Research Ethics Committees, and health [and other] authorities, must ensure that proposed studies are scientifically sound, build on an adequate prior knowledge base, and are likely to generate valuable information." But scientific and social value, while necessary, is not sufficient: "All research with humans must be carried out in ways that show respect and concern for the rights and welfare of individual participants and the communities in which research is carried out. This respect and concern is manifest in requirements for informed consent, ensuring that risks are minimized and are reasonable in light of the importance of the research, and other requirements [...] Research must also be sensitive to issues of justice and fairness" (CIOMS, 2016, p. 2).

The 'WHO Ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies'(2007, p. 7) define "ethics" as "a system or code of moral values that provides rules and standards of conduct." They also paraphrase a document known generally as 'The Belmont Report' (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979), which sets out ethical guidelines to protect human subjects. At the core of these were three ethical principles: respect for persons, beneficence and justice:

1. **Respect for persons**, which relates to respecting the autonomy and self-determination of participants, and protecting those who lack autonomy, including by providing security from harm or abuse.
2. **Beneficence**, a duty to safeguard the welfare of people/communities involved, which includes minimizing risks and assuring that benefits outweigh risks
3. **Justice**, a duty to distribute benefits and burdens fairly." (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979, as cited in WHO, 2007, p. 7)

Applications of these general principles to the conduct of research leads to consideration of issues such as informed consent, risk/benefit assessment, and selection of research participants. Informed consent and selection of study participants will be addressed in more detail in later chapters, but the concepts of study "risk" and "benefit" deserve discussion here. 'The Belmont Report' suggests that the justification of research on the basis of a favourable risk/benefit assessment – that is, when benefits to an individual (and sometimes also a group) outweigh the risks – is closely related to the principle of beneficence, or "do no harm".

In the context of human subject research, the term "risk" refers to a possibility that harm may occur" with terms like "minimal risk" or "more than minimal risk" referring to the probability of experiencing a harm and the severity or magnitude of the possible harm (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Risks of harm include "psychological harm, physical harm, legal harm, social harm and economic harm" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The term "benefit", on the other hand, "is used in the research context to refer to something of positive value related to health or welfare." In the case of "benefits", these are not expressed in terms of probabilities (that is, higher benefit or lower benefit) but rather in contrast to harms. Thus, a study intervention may confer psychological or physical benefits, or legal or social or economic benefits. A higher risk study, to be justified, must convey benefits that exceed the study risks. The same is true for a minimal risk study; benefits, however modest, must exceed the risks of participating in the study.

For research on child marriage in humanitarian settings, where interviews might be conducted with children who have experienced child marriage and GBV in the context of volatile and insecure environments, special attention needs to be given to ensuring that study benefits still outweigh study risks.

B. ETHICS OF RESEARCH IN HUMANITARIAN SETTINGS

Given these risks, research on child marriage in humanitarian settings must pay special attention to ethical considerations in order to:

- Promote scientific and social value through the selection of scientifically sound methods, and identification and training of a capable study team, to generate valuable information
- Respect the rights and welfare of the individuals and communities involved in the research
- Ensure that benefits exceed risks, not only in the implementation of the study but in the dissemination of results.

Given that so many humanitarian crises occur in low- and middle-income countries and in low-resource settings, the CIOMS (2016, p. 3) recommends that “as part of their obligation, sponsors, and researchers must also [...] make every effort, in cooperation with government and other relevant stakeholders, to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity.” In other words, equitable benefit in low-resource settings “demands that local social value be created.” This point will be addressed again in chapter 10 on Accountability. Ensuring that study benefits exceed risks in low-resource settings also means ensuring that implementation of research does not impose burdens on local organizations providing essential services.

For research in the context of disasters and disease outbreaks (although other types of humanitarian emergencies could also be included) the CIOMS guidelines (2016) note (emphasis added): “The **first and foremost obligation in acute disaster situations is to respond to the needs of those affected**. At the same time, **an obligation exists to conduct health-related research because disasters can be difficult to prevent, and the evidence base for effectively preventing or mitigating their public health impact is limited**. These two obligations can come into conflict. This is because humanitarian response and health-related research often rely on the same infrastructure and the same personnel, so priorities between the two may need to be set [...] Humanitarian workers, researchers and sponsors must be aware of these conflicts and ensure that their studies do not unduly compromise the disaster response. Researchers and sponsors should also aim to contribute to the infrastructure for the humanitarian response and integrate their research activities with this response [...] [A]ll studies must be responsive to the health needs or priorities of the affected populations” (p. 76). The focus need not be on health per se; the same point could be made about any other sectors engaged in humanitarian response.

In 2007, WHO outlined eight ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies:

1. **Analyse risks and benefits:** “The benefits to respondents or communities of documenting sexual violence must be greater than the risks to respondents and communities.”

2. **Methodology:** *“Information gathering and documentation must be done in a manner that presents the least risk to respondents, is methodologically sound, and builds on current experience and good practice.”*
3. **Referral services:** *“Basic care and support for survivors/victims must be available locally before commencing any activity that may involve individuals disclosing information about their experiences of sexual violence.”*
4. **Safety:** *“The safety and security of all those involved in information gathering about sexual violence is of paramount concern and in emergency settings in particular should be continuously monitored.”*
5. **Confidentiality:** *“The confidentiality of individuals who provide information about sexual violence must be protected at all times.”*
6. **Informed consent:** *“Anyone providing information about sexual violence must give informed consent before participating in the data gathering activity.”*
7. **Information-gathering team:** *“All members of the data collection team must be carefully selected and receive relevant and sufficient specialized training and ongoing support.”*
8. **Children:** *“Additional safeguards must be put into place if children (i.e. those under 18 years) are to be the subject of information gathering.” (WHO, 2007, p. 9)*

CASE STUDY 1 *Data collection in a war zone: Barriers in Yemen*

Yemen has been in civil war since 2015, leading to one of the worst humanitarian crises in the world. There were 3,974,100 IDPs in 2019, which is a 56 per cent increase from the year before (United Nations High Commissioner for Refugees [UNHCR], 2019b). When working in such settings, data collection can be a risk to both data collectors and participants. In order to mitigate both physical and political dangers, certain compromises had to be made to study protocols. The field coordinator of the child marriage studies in Yemen notified global partners that it would be impossible to enter some of the most dangerous areas, which meant that some of the most vulnerable populations were not sampled for the data. Additionally, the local authorities would not allow tablets to be used for electronic data collection, so enumerators used paper forms. The re-entry of paper forms into tablets increased the possibility of data errors. However, these decisions were necessary given the realities on the ground and the instability of the situation.

C. QUESTIONS FOR PRACTITIONERS

One of the key questions to ask about research in humanitarian settings is: is it necessary? Can it be done in non-emergency contexts and, if not, is it justified even in the context of an acute-phase response to a large-scale disaster, or should it be postponed until the situation has stabilized? The question of necessity is raised by WHO in its ethical and safety recommendations for research on sexual violence in emergencies: “in some situations, there is a risk that sexual violence is being ‘over-researched’. This risk arises when multiple sexual violence inquiries are conducted in the same place, by different organizations or individuals, with little or no information sharing or coordination” (WHO, 2007).

Below are a set of questions adapted from a checklist developed by the IRC (2017) for a ‘GBV Emergency Preparedness and Response: Participant Handbook’. Though their focus is more general in terms of information gathering on GBV among children for programmatic response, the points are still relevant to human subject research on child marriage. We have reframed the checklist in the form of questions. We will return to these questions throughout the chapters that follow.

TABLE 2 *Determining ethical conduct of research in humanitarian settings*

Have you determined that the benefits of gathering information outweigh the risks?

Have you put in place sufficient human and financial resources to conduct information gathering in an ethical manner?

Are skilled and capable interviewers available or can they be trained?

Do you know that the information needed cannot be gathered elsewhere or by other means?

Can you uphold specific procedures for ensuring children’s support and safety throughout the interview process?

Can you guarantee basic support and care services if a child is found to be in need?

Have you considered and sufficiently safeguarded against adverse consequences?

Have you consulted with community members and parents, guardians or caregivers to anticipate all possible consequences for children involved in the information-gathering process?

Have you actively sought community and stakeholder concerns, and have you consulted community leaders for permission to interview community members about children’s protection concerns?

Source: International Rescue Committee (2017).

3 VULNERABILITY AND VULNERABLE POPULATIONS

In order to understand vulnerability and vulnerable populations in the context of the ethical conduct of research on child marriage in humanitarian settings, it is important to ask:

- What does vulnerability mean, and who are identified as vulnerable individuals or groups, in the context of human subject research?
- What does vulnerability mean, and who are identified as vulnerable individuals or groups, in the context of humanitarian emergencies?

We will see that the definitions of vulnerability differ, but overlap, in research and humanitarian response contexts and we will see the same for types of vulnerable groups in these two contexts. Both the differences and commonalities come into particular focus when considering children.

A. VULNERABILITY IN HUMAN SUBJECT RESEARCH

The CIOMS 'International Ethical Guidelines for Health-related Research Involving Humans' (2016, p. 57) state that "persons are vulnerable because they are relatively (or absolutely) incapable of protecting their own interests." In some cases, vulnerability is present "when persons have relative or absolute impairments in decisional capacity, education, resources, strength, or other attributes needed to protect their own interests." Populations with this kind

of vulnerability could include children, persons with cognitive disabilities or persons who are illiterate.

In other cases, “persons can also be vulnerable because some feature of the circumstances (temporary or permanent) in which they live makes it less likely that others will be vigilant about, or sensitive to, their interests.” Persons with this kind of vulnerability could include prisoners and other institutionalized persons (residents of nursing homes or mental institutions, for example) or people who are “marginalized, stigmatized, or face social exclusion or prejudice that increases the likelihood that others place their interests at risk, whether intentionally or unintentionally.” This could include racial, ethnic, religious or sexual minorities, or persons living in an authoritarian environment.

While traditional approaches to vulnerability in research have tended to label entire groups or classes of individuals as vulnerable, the CIOMS guidelines emphasize looking at “the specific characteristics that may render individuals vulnerable.” The guidelines give the example of women, who should not be considered vulnerable in general, but may be vulnerable in research in specific circumstances. These include “studies with female or [transgender] sex workers; research on sexual and intimate partner violence; studies with trafficked women, refugees and asylum seekers; studies of abortion in jurisdictions where abortion is illegal; and research with women who live in a cultural context where they are not permitted to consent on their own behalf for participation in research, but require permission from a spouse or male relative” (CIOMS, 2016, p. 58).

Although there are many factors to consider when determining vulnerability in research, one of the most widely accepted and vital criteria is “limited capacity to consent or decline to consent to research participation” (CIOMS, 2016, p. 57). As will be discussed further in chapter 5 on informed consent, potential participants in human subject research must be able to give free and informed consent to participate. If that capacity is limited by one’s individual “relative or absolute impairments” or circumstances, then additional protections are required. In some cases, this could involve having consent provided by a parent, guardian or caretaker. In other cases, it may require the study team to build in procedures to prevent undue coercion and to monitor more than minimal risk.

We now come to the issue of children in human subject research. As a 2013 report, ‘Safeguarding Children’ (Presidential Commission for the Study of Bioethical Issues), concluded: “In the context of human subject research, children as a class are vulnerable in two ways. First, children are vulnerable to being exploited or unfairly taken advantage of in the research setting. Their vulnerability in this sense derives from the fact that children lack the developed cognitive capacities necessary to deliberate about and consent to participate in research, and are subject to legal and social expectations of deference to adult authority and imbalances of power between adults and children.” Children, in other words, have limited capacity to understand the potential risks and benefits of participating in a study, and they also have limited autonomy to act in their own self-interest. If they are also girls constrained by social and gender norms, and refugees or displaced persons, or marginalized by poverty and disadvantage, then it is of paramount ethical responsibility to protect them in the conduct of research.

B. VULNERABILITY IN HUMANITARIAN SETTINGS

In humanitarian settings, vulnerability has been defined as “the degree to which a population, individual or organization is unable to anticipate, cope with, resist and recover from the impacts of disasters. It is a function of susceptibility and resilience” (Blaikie et al. cited in

Wisner & Adams, 2002, p. 13). Humanitarian crises have differential impacts on individuals or groups who, because of their own characteristics and capacities and/or the circumstances of the hazard-causing events, are either more able to cope or more susceptible to harm.

As Wisner and Adams (2002, p. 13) note, “poverty (and its common consequences, malnutrition, homelessness or poor housing, and destitution) is a major contributor to vulnerability. In many situations, women and children are most vulnerable to disaster emergencies.” For WHO (2020), “children, pregnant women, elderly people, malnourished people, and people who are ill or immunocompromised, are particularly vulnerable when a disaster strikes.” The UNHCR identifies individuals who “are generally considered to be at heightened risk: girls and boys, including unaccompanied and separated children; persons with serious health conditions; persons with special legal or physical protection needs; single women; women-headed households; older persons; persons with disabilities; and persons of diverse sex, sexual orientation or gender identity (LGBTI individuals)” (UNHCR, 2010a).

Finally and most relevant to studies of child marriage in humanitarian settings, UNFPA Executive Director Dr. Babatunde Osotimehin (2015) said, “[d]uring crisis situations, women and girls are at much greater risk of reproductive health problems, sexual abuse and other forms of gender-based violence, forced marriage and even death.”

Bringing together the concepts and definitions of vulnerability in the context of human subject research and in humanitarian settings, we see that some types of vulnerable individuals and groups appear in both: refugees, asylum seekers and displaced people; ethnic, sexual, religious and other minorities; malnourished or poor people; people living with disabilities; women constrained by social and gender norms, and, of course, children. The factors that make them vulnerable in a humanitarian context overlap with those in a research context: the limits or constraints on their ability to act fully and freely in their own interest.

In both contexts, some of these limits or constraints (the level of risk or susceptibility to harm) may vary over time and will be influenced by positive and negative changes in their environment. Researchers in humanitarian settings need to be especially adept at assessing and managing risk, not only in the context of the ethical conduct of their research, but also as this research is embedded in a volatile and insecure environment, and they must accommodate the basic humanitarian needs of their study populations.

C. QUESTIONS FOR PRACTITIONERS

Table 3 contains a series of questions practitioners should consider when exploring and assessing vulnerability and vulnerable groups in the settings in which they anticipate conducting their research. We will explore these questions further in the chapters that follow.

TABLE 3 *Determining vulnerability and vulnerable individuals and groups*

What kinds of individuals or groups are you interested in studying? If children are included, what kinds of children might be involved in the research?

How might these individuals or groups be vulnerable from a humanitarian standpoint? For children, this could include unaccompanied/separated children, ethnic or religious minorities, children with disabilities, undocumented populations, etc.

How might these individuals or groups be vulnerable from a research standpoint? For children, how might research vulnerability differ from, or overlap with, humanitarian vulnerability?

What kinds of safeguards would need to be in place for humanitarian reasons? For children, be specific as to which safeguards would apply to which kinds of vulnerability.

What kinds of safeguards would need to be in place for research reasons? For children, be specific as to which safeguards would apply to which kinds of vulnerability.

Who would you need to consult—in terms of community members, service providers, local authorities, subject-matter experts and others—to assess research risks and protection for these vulnerable populations?

Who would you need to consult—in terms of community members, service providers, local authorities, subject-matter experts and others—to assess humanitarian needs and services for these vulnerable populations?

4 PRIVACY AND CONFIDENTIALITY

In this chapter, we will examine the concepts and definitions of privacy and confidentiality as they are applied in human subject research, for the purpose of answering the following questions:

- What is “privacy” and “confidentiality” in human subject research?
- What challenges do researchers on child marriage in humanitarian settings face in terms of protecting privacy and confidentiality?

A. CONCEPTS AND DEFINITIONS

The WHO 2007 ‘Ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies’ state that “preserving the confidentiality of personal information is one of the fundamental principles governing the collection of data about individuals. **Every person has a right to privacy, and this right imposes an obligation on those collecting personal data to keep this information confidential** [emphasis added]” (2007, p. 18). In discussing the issues of privacy and confidentiality in human subject research, it is often said that **privacy is about people** and **confidentiality is about data**. One university IRB elaborates:

“**Privacy** is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others [...] Privacy is about people, [their] sense of being in control of access that others have to [themselves], a right to be protected [from an invasion of privacy, and] it is in the eye of the participant, not the researcher or the IRB.

“Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure...Confidentiality is about identifiable data, is an extension of privacy, [and it] is an agreement about maintenance and who has access to identifiable data”, including the right to be protected from a breach of confidentiality (University of California, Irvine, Office of Research Integrity, n.d.).

WHO (2007, p. 18) notes that “in the context of sexual violence in emergencies, the stakes can be very high. In such circumstances, a breach of confidentiality does not only represent a breach of ethics, but can also lead to harm for the survivor and for the community.” The proper safeguarding of respondent information “governs not only how the data are collected (e.g. private space in which to conduct an interview), but also how the data are stored (e.g. without names and other identifiers) and how, if at all, the data are shared.”

As an example, consider a practitioner implementing a study of accessibility and acceptability of mental health services in a refugee camp or settlement. To approach someone in the waiting room of a health facility and ask them if they might want to participate in a study of mental health services could violate that person’s sense of privacy and perhaps cause them embarrassment that they are being approached so publicly about a sensitive matter. Similarly, knocking on a randomly selected door and asking the resident, within view and earshot of the neighbours, if they want to participate in a mental health study could also be an invasion of privacy. However, assuming that the researcher made discreet contact with a potential participant, who then gave their informed consent to participate in the study, and the respondent provided personal, identifiable information about their use of mental health services, the data recorded by the researcher—whether written on paper, or electronically recorded on a tablet, or in the form of an audio recording—must be kept confidential and a plan must be in place for dealing with adverse events or unanticipated problems, including breaches of confidentiality.

Hossain and McAlpine (2017, p. 32) recommend that, in the conduct of research on GBV in humanitarian settings, “despite the logistical restrictions in certain humanitarian settings (e.g. overcrowded refugee camp, poorly soundproofed shelters), the privacy of the individual participants must always be upheld to protect the participant from unwanted disclosure to his/her partner, family members or community.” They give the example of asking questions about political affiliation or viewpoints in the context of armed conflict. If such questions are critical to meet the aims of the research (this should be discussed at the outset in study design, selection of methodologies and in instrument development), then privacy concerns would require researchers to ensure that interviews are conducted privately (and this could preclude asking questions about political affiliations or viewpoints in focus group discussions – FGDs). Confidentiality concerns would require researchers to protect data so that in both the storage and sharing of these data, the risk of breach of confidentiality is minimized.

B. ISSUES AND CHALLENGES

The following are examples of several challenges that may arise and how to address them to protect study participants and their communities in the context of research on child marriage in humanitarian settings:

1. **Privacy:** Although child marriage may be normative behaviour in target populations, it is likely illegal (prior to study implementation, laws and regulations on child marriage should be investigated for all study populations, whether refugees, IDPs or host communities).

Thus, any recruitment procedures about a study on child marriage should take into account that the topic may be stigmatizing, embarrassing or distressing for a potential participant and/or their communities. We recommend that recruitment of qualitative interviews be done via word-of-mouth through community contacts and local service providers rather than posting public notices or flyers. In quantitative interviews that may require random selection of households, we recommend first, selecting interviewers who know the local communities and their customs and cultures and second, that any conversations involving recruitment, consent and the survey questionnaires themselves take place in a private location, so they cannot be seen or overheard by neighbours or even other family members.

Whether qualitative or quantitative in their methodological approach, interviews that gather personal information about child marriage experiences should be one-on-one. Where FGDs are used, the questions should focus on eliciting opinions from participants about community perspectives rather than individual experiences. For example, the interviewer should not ask, "Were any of you married as children? Tell me about your experiences." Rather the question could be posed as: "What is a typical age for girls to be married? For boys to be married? Who makes these decisions? What are some experiences of children married before 18?" In answering the latter kinds of question, it is possible for respondents to draw on their own experiences, but the questions are asked in such a way that they do not have to express any personal information in a group setting.

2. **Confidentiality:** While there are a number of confidentiality issues relating to data management, storage and use that will be addressed in later chapters, one issue of confidentiality that needs to be addressed in study design and planning is the possible need to breach confidentiality should an interviewer hear a respondent tell of an instance of child abuse that, under local laws and regulations, must be reported to the authorities.

There are certain contexts (the US is one example) where a researcher is obligated under law to report child abuse if it is observed or otherwise documented. The ethical approach in this context would be to say to the potential respondent during the process of informed consent something like: "we need to tell you that should we observe any child abuse or if you tell us about any child abuse in the household, we must report this to the authorities." This informs the potential participant that there may be a need to breach confidentiality should they participate in the study. They are then free to refuse to participate should this be a concern, or agree to participate knowing this possibility.

The 'WHO Ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies' (2007, p. 18) do not refer specifically to possible reporting requirements for observations or other evidence of child abuse, but they do recommend that "[i]n the case of children, **if immediate protection needs** [emphasis added] become apparent, it may not be possible to honour confidentiality and also serve the best interests of the child." WHO recommends that "further guidance and advice on this issue should be sought from child rights, ethics or protection experts when establishing SOPs [standard operating procedures] for confidentiality."

When child marriage studies are conducted in international contexts, the question of what might constitute "immediate protection needs" for children (specifically those that might be identified in the conduct of the research) should be explored early on in the study planning process, to explore local laws and regulations, elicit views from key stakeholders (community leaders, local authorities, subject-matter experts, etc.), and document this information so that it can be shared with IRBs and incorporated into the study protocols and interview training. In some instances, it may be appropriate to do this in the formative phase of research so that key local informants can be interviewed about their views as to whether child marriage constitutes a form of child abuse, and if so, whether and in what circumstances it may constitute a reportable activity.

CASE STUDY 2 *Finding private spaces in Bangladesh's crowded refugee camps*

In 2017, 700,000 Rohingya villagers spilled into Bangladesh, fleeing violence by Myanmar's army and Border Guard Police, and the burning of their homes. The refugees settled around two existing camps in Cox's Bazar District, forming the world's densest conglomeration of refugees, with 40,000 people per square kilometer (Hoque, 2020). In such settings, finding a private space to conduct an interview on a sensitive topic is difficult. In the Rohingya camps, this was particularly so for adolescent girls, who are often kept inside the family shelter following menarche. Adolescent boys were invited to accompany a male interviewer to an out-of-session school or other currently unoccupied community building. However, since adolescent girls were seldom allowed to do the same, interviewers would instead ask the other members of the household to exit the shelter for an hour, so that girls could be interviewed inside privately. It was important to ask the same of individuals offering to stay in the shelter's second "room", since the partition was generally a simple tarpaulin or sheet, and thus did not afford the necessary privacy. It should be noted that in all interviews in the Rohingya camps, the genders of the interviewer and the respondent were matched.

C. QUESTIONS FOR PRACTITIONERS

Table 4 contains a series of questions that we encourage practitioners to consider when making decisions about privacy and confidentiality in their research protocols.

TABLE 4 *Determining issues in privacy and confidentiality*

What are the cultural and social norms of the proposed study population in terms of their views on privacy as it relates to discussions of child marriage?

What laws and regulations govern reporting of child abuse or other "immediate protection needs" that might require reporting to local authorities or other interventions?

Are there particular risks in the local study context that might lead to a violation of the right to privacy or a breach of confidentiality?

How will recruitment procedures protect against invasion of privacy?

How will data collection, management and storage of study data protect against accidental or unintended breach of confidentiality?

What measures can be taken to maintain confidentiality of data after publishing the results?

5 INFORMED CONSENT

In this chapter, we will examine the concepts and definitions of informed consent as they are applied in human subject research, in order to answer the following questions:

- What is “informed consent” in human subject research?
- What challenges do researchers on child marriage in humanitarian settings face in terms of consenting study participants, including married and unmarried children?

A. CONCEPTS AND DEFINITIONS

Fundamental to the ethical conduct of human subject research on any topic and in any setting is the concept of **informed consent**. As the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979) notes in ‘The Belmont Report’, “respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.”

While there is not complete agreement about precisely what elements should be covered in the consent process and these may differ from one IRB to the next, “there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension, and voluntariness” (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

Information. Key items of information to provide to participants to ensure that they are adequately informed include study purposes, who is conducting the study, research procedures (survey questionnaire, interview, FGD, etc.), risks and anticipated benefits, and a statement offering them an opportunity to ask questions, and to withdraw from the study at any time (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Additional elements should include amount of time expected to participate, where the procedures will be carried out, payments (if any), information about who to contact in case of additional questions or concerns, and finally a statement about whether the process will involve signed or verbal consent (and a place to sign the form if consent is written).

Comprehension. For consent to be informed, “the manner and context in which information is conveyed is as important as the information itself” (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Information might be presented in a disorganized manner or too rapidly, or the process may provide too little time for consideration or for asking questions, adversely affecting a participant’s ability to make an informed choice. The ability to understand is a function of “intelligence, rationality, maturity and language.” In some special cases, tests of mental acuity and cognitive skills may be warranted, although ordinarily, consent processes are adapted to a participant’s maturity (usually measured by biological age) and language. Consent forms involving children (sometimes these are called “assent forms” which will be discussed later on) or involving populations where education levels may be lower, should include language that is simple, clear and concise. Consent forms that are to be presented in local languages (in addition to English, Arabic, French or whatever the principal language of the study team and study protocols and instruments may be) should be translated into those local languages by a professional and pre-tested for comprehension. Some IRBs also require a certificate of translation to ensure that the translation is accurate.

Voluntariness. “This element of informed consent requires conditions free of coercion and undue influence” in order to constitute a valid consent. “Coercion occurs when an overt threat of harm is intentionally presented [...] in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance” (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Coercion may be present (or perceived, which is effectively the same thing) if a potential respondent feels that refusal to participate could jeopardize access to services. This concern is especially critical in instances where a service-provider organization is helping to support a study and where those services may be vital to survival. Undue influence or inducement may occur if a payment to participate in a study may be of such value that an unemployed or poor person might risk participation in a study that she or he might otherwise refuse.

A ‘Human Subjects Research Ethics Field Guide’ developed by JHSPH emphasizes the point that “[i]nformed consent is an ongoing process that begins with the research team member explaining the study to the participant [...] [but it] does not end with the participant signing the consent form and agreeing to be in the study. The process of informed consent continues throughout the study... Sometimes it is important to check in with the participant from time to time to make sure that the participant continues to understand what the study is about, or what it involves” (JHSPH, 2010, p. 4). Asking clarification questions can help gauge what the participant has learned or is (or is not) understanding. Body language or verbal cues suggesting discomfort or confusion should also be monitored and addressed.

Consent involving children, including married children, deserves special focus. While we do not have global data, it may be fair to say that generally speaking, children under 18 are

considered to be vulnerable populations because they have a limited capacity to understand the potential risks and benefits of participating in a study, and also have limited autonomy to act in their own self-interest. That said, age limits for asking for children's consent vary across countries (Hein et al., 2015). In the US, for example, a parent or legal guardian would be asked to give permission for a child under 18 to participate in a study, while the child would be asked to provide their "assent" to participate.

However, exceptions to the requirement of parental permission can be made in the US and elsewhere if a child is married and thus considered an "emancipated minor" and able to consent as an adult; other exceptions for "emancipated" or "mature" minors would include pregnant minors (for consent for medical care), minors in the armed services, minors living apart from their parents and financially independent, and victims of sexual assault or abuse (for consent for medical care or counselling) (Hickey, 2007). The question of who counts as a child requiring parental permission to participate in research and who might give consent on their own is subject to a variety of laws and regulations, including national laws and governing IRB regulations. As will be seen later on, the challenges are further heightened in research on child marriage in humanitarian settings where participants may come from different countries and operate under different cultural and customary norms and practices.

B. ISSUES AND CHALLENGES

The following are examples of several challenges that may arise and how to address them to manage informed consent, especially for children, in the context of research on child marriage in humanitarian settings:

1. **Information:** We stated previously that in contexts where child marriage is likely illegal, the topic may be stigmatizing, embarrassing or distressing for a potential participant and/or their communities. In the context of consenting participants in a household, there may be the potential for harm if, for example, another member of the household learns that the study is specifically about child marriage and that a child in the household might provide answers to sensitive questions about their experiences.

In this instance, with IRB approval, we used language in the parental permission form (for unmarried 10–17 year olds) that stated simply, "we would like to talk to you about a research study on marriage and family life in this area" and that if the parent and child both agreed to participate, "We will ask [the child] questions about family life, education, work and marriage." [w]e further told the parent that "we will keep your child's information confidential. We will not share your child's answers with you or anyone outside the study team." For the children's consent forms (married children aged 10–17 did not need parental permission), we noted that "some of the questions we will ask may make you uncomfortable. We will ask about marriage and family life. You may skip any questions or take time to think about your answers. We will keep your answers private and will not share them with anyone else."

Practitioners considering studies of child marriage in humanitarian settings can consult the example consent forms, parental permission forms and child assent forms in the annexes. More importantly, they should discuss with their study IRBs (there may be more than one), stakeholders and subject-matter experts about what information is essential to convey so that the consent process is valid and thorough.

2. **Comprehension:** Issues of comprehension, as noted above, are more complicated in contexts of research on child marriage in humanitarian settings, when target populations include both children and adults, people with wide ranges of education, and people coming from different countries with different cultural and linguistic backgrounds. We recommend that as all relevant consent forms are developed and reviewed for

informational content, they are also reviewed for comprehension, including translation and back-translation by well-trained, local translators and that these forms are pilot-tested for clarity and comprehension. We also recommend that consent forms in local languages be certified as accurate by a translator who is not just fluent in the needed languages but also familiar with the study context.

3. **Voluntariness:** The emphasis on voluntary participation in a study begins with clarification of this point in preliminary discussions with local communities and stakeholders, and continues through the recruitment and consent process, into the data-collection procedures and beyond. It should be made clear to all participants that they may refuse to join the study, they may refuse to answer specific questions in a survey or interview, and they may withdraw from the study at any time (JHSPH, 2010). Regarding issues of coercion and/or undue influence, concerns can arise when an organization providing a service (non-governmental organization [NGO] or United Nations organization, for example) or in a position of authority (government, for example), is also supporting or implementing a study. It must be affirmed, not only in the consent forms but also throughout the planning and discussion processes where members of the target populations are involved, that participation or refusal in a study will not have any impact on continued access to services.

CASE STUDY 3 *Consent for married children in Nepal*

In April 2015, two major earthquakes rocked central Nepal, affecting 8 million individuals (United States Agency for International Development [USAID], 2015). The most heavily affected districts were Sindhupalchok and Dolakha, where in 2019, JHU and WRC conducted a study with earthquake-affected adolescents to assess the impact of the earthquake on child marriage. Although many countries consider adolescents under the age of 18 to be emancipated when they marry, and thus able to consent for themselves, this is not the case in Nepal. Thus, for adolescents to participate in the study, the consent of a parent or guardian was required. Because married girls most often go to live in the household of their husband's family, it was often not possible to get consent from their parents, who could be located some distance away. In lieu, the Nepal Health Research Council, the national IRB for health research, allowed for consent to be given by the girls' in-laws, who were considered their legal guardians while they resided in their home. Although some married girls asked for their husbands of legal age to consent for them, only parents, in-laws, or other legal guardians were permitted to consent for underage minors in the context of the study.

CASE STUDY 4 *Consenting emancipated minors in Yemen*

In Yemen, where interviews were conducted with IDPs and host community members, local customs and norms ordinarily grant women less decision-making power and autonomy than men. These social norms and structures can be disrupted in conflict, further heightening vulnerability, including that of married girls (UNFPA, 2015). While local laws stipulate that married girls are considered emancipated minors and thus can give their informed consent without the need for parental permission, local community members advising the study suggested that husbands should still be consulted for permission. In recognition of a married girl's legal right to be treated as an emancipated minor while also accommodating (at least in part) local community views, we instructed data collectors to seek informed consent from the married girls, but to ask the girls if there were any other members of their family that they wished to consult. This could include their husband, mother-in-law or another adult. In instances where the girl requested that an adult be consulted, and only with her approval, then an adult was asked for verbal permission.

C. QUESTIONS FOR PRACTITIONERS

Table 5 contains a series of questions that practitioners are encouraged to consider when making decisions about informed consent in their research protocols.

TABLE 5 *Identifying issues on informed consent*

What are the guidelines of the relevant IRBs relating to informed consent?

What are the guidelines of the relevant IRBs relating to consent of children, including emancipated minors?

What information about the study will be important to communicate to participants and stakeholders?

What issues of comprehension (age, level of education, languages written and spoken) will be important to address in developing consent forms and processes?

What issues of voluntariness (including coercion and undue influence) will be important to address in developing consent forms and processes?

6 INSTITUTIONAL REVIEW BOARDS (IRBS)

In this chapter, we will examine the roles and functions of IRBs in human subject research in order to answer the following questions:

- What are IRBs and what do they do?
- What issues do researchers face in terms of working with IRBs?

A. ROLES AND FUNCTIONS OF IRBS

IRBs may be called by many names, including Institutional Ethical Committees, Ethical Review Boards and Research Ethics Committees, and their specific functions vary from one institution to another. That said, their primary responsibilities include “providing an independent evaluation that proposed research is ethically acceptable, checking clinical [and non-clinical] investigators’ potential biases, and evaluating compliance with regulations and laws designed to protect human subjects” (Grady, 2015, p. 1,148). Table 6 is adapted from Grady (2015) and sets out some of the structures and functions of IRBs (note that these are based on US regulatory requirements and may vary in local contexts).

TABLE 6 *Structures and functions of Institutional Review Boards*

Membership	<p>At least five members of varying backgrounds, both sexes, and more than one profession/discipline represented.</p> <p>Members sufficiently qualified through diverse experience and expertise to safeguard subjects' rights and welfare and to evaluate research acceptability related to laws, regulations, institutional commitments and professional standards.</p> <p>At least one member knowledgeable about regularly researched vulnerable groups.</p>
Functions/ Operations	<p>Follow written procedures for initial and continuing review and for any changes and amendments.</p> <p>Written procedures for reporting unanticipated problems, risks and non-compliance.</p>
Review	<p>Authority to approve, require modifications of or disapprove research.</p> <p>Require informed consent and documentation (or approve a waiver).</p> <p>Continuing (commonly annual) review.</p>
Criteria for approval	<p>IRB should determine that risks are minimized; risks are reasonable in relation to anticipated benefits, and to the importance of the expected knowledge; participant selection is equitable and with attention to vulnerable populations; informed consent will be sought and documented; there are adequate provisions for monitoring; there are adequate provisions to protect confidentiality; there are additional safeguards for participants vulnerable to coercion or undue influence.</p>
Authority	<p>Institutional officials cannot approve research that is disapproved by the IRB.</p> <p>The IRB can suspend or terminate research for serious harm or non-compliance.</p>
Records	<p>Records of research proposals, meetings, actions, correspondence, members, etc.</p>

Source: Grady (2015, p. 1149).

We provide the above table in the hope that it will, on the one hand, help to “demystify” the roles and functions of IRBs while on the other hand, helping to clarify that IRBs do have regulatory requirements imposed by national regulations and/or institutional regulations that need to be understood by study teams. We will focus on two areas around which researchers and IRBs tend to interact the most: functions/operations, and criteria for approval.

Functions/operations. Typically, the first interaction that a research team will have with an IRB is when it submits an initial application for review and, it is hoped, approval. The elements of the application will vary but will likely include:

- **Research plan** (setting out study aims; background and rationale; study design; sample size; participants (including inclusion and exclusion criteria); recruitment process; consent process; study implementation; data custody, security and confidentiality protections; risks of the study; direct personal and social benefits; payment (if any); study management, and other IRBs/ethics review boards (if the IRB of record is in a country other than where the study is being conducted, local IRB approval is usually required))

- **Recruitment scripts**
- **Consent forms** (including child assent and parental permission forms if needed. Consent can be written/signed or it can be verbal/oral. In either case, a written form will be needed as part of the research protocol)
- Study instruments (also called research instruments, these are the measurement tools (survey questionnaires, semi-structured interview guides, etc.) designed to obtain data on a topic of interest)
- **Local IRB approval**
- **Letters of support** (these could include letters of permission from a government agency to conduct research in a particular location, or letters from a facility director for permission to conduct interviews on site or access programme records, etc.)
- **Certificates of translation** (these are needed for translations of recruitment scripts and consent forms into local languages).

Developing all these different documents can be time-consuming and may take from several weeks to several months, so research teams should allow for this in their project timetables. In addition, once an application is submitted, there is likely to be some back-and-forth between the study team (particularly the study's Principal Investigator [PI]) and the IRB before final approval is granted. Finally, should there be a need for approval by more than one IRB (a main IRB of record and a local IRB), this process may also take time. Overall, we recommend that a minimum of three months be set aside at the beginning of any project period to develop and finalize an IRB application and complete steps necessary for full and final approval.

In situations where research needs are urgent, there may be options for rapid, just-in-time reviews, but generally the research process requires an investment of time (even in humanitarian settings) in order both to promote scientific rigour and to establish procedures for the ethical conduct of the research.

Criteria for approval. The first and main criterion for IRB approval is whether study benefits outweigh risks. In some studies there might be direct benefits to participants (children measured as underweight would receive supplemental feeding, for example); in most cases, benefit is not direct (results from an interview would not directly help the respondent), though the benefits could be societal (results would help the broader population through improved understanding of a risk and recommendations for policy or programme action). Assuming that there is more benefit than risk, IRBs look to see if participant selection is equitable: are target populations selected so that they would share equitably in study risks and benefits? One way for participant selection to be equitable is for the study to employ probability sampling, whereby respondents are selected randomly (see chapter 8 on Study implementation). If non-probability sampling is used (for example, to select a purposive sample of adolescent girls and boys for in-depth interviews), the IRB will want to be sure that the method employed is consistent with sound scientific methods and that the expected knowledge to be gained is worth the burden of time involved, and the risk of breach of confidentiality.

Beyond these issues, IRB reviews look to see if adequate plans are in place during fieldwork (recruitment, consent, enrolment and interviews, or whatever the research intervention involves) to see if there is proper protection of privacy and confidentiality and that there is no coercion or undue inducement, particularly of vulnerable populations. In addition, study teams need to set out a well-defined plan for data storage and management, as well as an overall plan to monitor study implementation, to ensure that research protocols are being implemented properly.

This includes having a plan in place to deal with adverse events or unanticipated problems. Interpreting the sorts of events that meet these criteria, and determining what reporting (to IRBs and possibly to other entities) should follow, are complex processes and cannot be spelled out for all contexts. It is most important to clarify that the study team and partners know what to do if they encounter an unexpected event that is (or potentially is) related to the study and that places participants at greater risk of harm than was previously known or recognized. Unexpected and adverse reactions to an experimental drug, for example, would meet these criteria. An adverse event more germane to child marriage research would be learning that a child has been subjected to physical or psychological punishment by a family member for participating in the study; this would need to be reported to the IRB so that remedial action could be taken.

B. ISSUES WITH IRBS

The following are examples of several issues that may arise in working with IRBs in the context of research on child marriage in humanitarian settings.

1. **When is an IRB necessary?** One of the first questions that comes up among practitioners considering some form of systematic data collection that might be viewed as human subject research is: “[d]o we need to submit this to an IRB?” There are two parts to that question: a) Is this human subject research? and b) What are the international, national, institutional or other contexts that might inform this decision?
 - a. **Is this human subject research?** There is no single litmus test to determine clearly whether a proposed study constitutes research; this question must be asked and answered not only in the context of the study aims and design but also in terms of who is funding the study, who is implementing it, where it is being carried out, and what the expected outputs in terms of reports and publications are. As we noted previously, one definition of research is “a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge” (Office of Research Integrity (2020)). Using the Johns Hopkins IRB process as an example, the questions are as follows:
 1. *Does your study involve data or specimens from or about individual living people?*
 2. *If YES, are you or your team doing any of the following?*
 - Interacting with or obtaining consent from participants, or
 - Accessing or analysing identifiable data or specimens (identifiable data or specimens include any private information for which the identity of the subject may be ascertained by the investigator or is associated with the biospecimen. Even if data are coded, data may be considered identifiable if the study team has access to the codes), or
 - Receiving federal funding as the primary recipient?
 3. *If YES, then the study should be submitted to the IRB.*

The question about federal funding relates to specific US laws and codes governing federally funded research. This could apply in international contexts if the primary recipient of the study funds is receiving US federal grant money. More generally, IRB approval may be required if a research project is funded by a United Nations organization, a foundation or some other donor entity.

- b. Beyond the question of whether or not a study meets the criteria of human subject research, **national and institutional contexts must be considered**. The African Bioethics Consortium (2017) has published a ‘Research Ethics Committee Assessment Toolkit (RECAT)’ designed “to facilitate evaluation of the operational needs of Research Ethics Committees (RECs) globally to inform local quality assurance and quality improvement efforts” (p. 2). We include here some of the questions around national and institutional contexts that might help practitioners identify where IRBs (or RECs) might be available and required:

National contexts

1. *“Are there national policies in your country about health research and/or human subjects research?”*
 - If yes, do national policies require ethics review of all or some human subjects research protocols?
 - If yes, do national policies require that all or some human subjects research protocols be reviewed by a national ethics committee, regardless of prior approval from an institutional REC?
 - If yes, is there a national institution/agency that monitors human subjects research activities in your country to ensure compliance with national policies regarding ethics review?

2. *“Is there a national entity through which RECs are registered in your country?” (p. 14)*

Institutional contexts

3. *“Does the institution have a written policy that requires that human subjects research protocols be reviewed by an ethics committee?”*

4. *“Does the institution have a policy or other mechanisms that require RECs to register through some formal registration system, such as national, regional or international?” (p. 15)*

We have stated previously, but it bears repeating, that this guide is not meant to provide a clear answer on whether or not your intended study involves human subject research requiring IRB approval. That process is for the study team to carry out with its key stakeholders (donors, implementing partners, community leaders etc.).

2. **Knowledge of laws, regulations and vulnerable groups:** In the IRB membership section of Table 6, requirements generally call for inclusion of members who are able “to evaluate research acceptability related to laws [and] regulations” and who are “knowledgeable about regularly researched vulnerable groups.” IRBs, either local or the so-called IRB of record in another country, may have such knowledge, but it is possible that they do not, especially if the study population includes a diverse range of groups including refugees from one or two other countries, IDPs from different locations within the country, and host communities in rural and urban areas across a broad geographic region.

In these instances, we recommend that the study team seek to engage with community leaders from the target population (for example, Syrian refugees in the Kurdish Region of Iraq) to ask them about laws and regulations governing child marriage in their country and region of origin, so that they can share this knowledge not only with the study team, but also with IRBs if appropriate. The study team can also draw upon the specialized

knowledge of subject-matter experts (local academics who have done research among refugee and IDP populations, for example) or local service providers to understand more about the local context of vulnerability. These insights are of great value in informing a decision about lower age limits for interviews with children. Should the study only interview children aged 13 and over or is it appropriate, given local customs and norms and local patterns of child marriage, to also include children aged 10–12? IRB expertise alone may not be sufficient to answer this question, so additional subject-matter expertise and local knowledge should be solicited.

CASE STUDY 5 *Consulting the Rohingya community*

The ethical review for the Bangladesh child marriage study was formally provided by the Johns Hopkins Bloomberg School of Public Health IRB in the United States and the Brac University James P. Grant School of Public Health in Bangladesh. While these institutions were well equipped to assess the study plan for protecting research subjects, the study team questioned their ability to adequately represent the interests and needs of the Rohingya population, which had arrived relatively recently in Bangladesh. To address this gap, the study team held a series of community consultations, meeting (separately) with groups of male and female community leaders, adolescents, and parents of adolescents. During these meetings, the study intention was explained, the community's questions were answered and their input and feedback were integrated into the framing for the study. These meetings were held prior to finalization of the research plan, to allow for incorporation of community feedback and ensure their concerns could be addressed. The resulting community approval and buy-in contributed to high participation rates and supported the project's successful implementation in the community.

CASE STUDY 6 *Case Study 6. Compensation of research participants in Egypt*

In humanitarian settings, research participants are likely to have heightened needs for material assistance. The research team in Egypt was committed to compensating study participants for their time while adhering to generally accepted principles of research ethics. While cash payments are widely accepted in international guidelines, such payments raise several ethical issues, which are perhaps more pronounced in humanitarian contexts. Due to the heightened vulnerability of participants, cash incentives can serve as undue inducement, precluding truly voluntary participation. Additionally, there is limited guidance on the appropriate levels of payment that should be disbursed to participants in humanitarian settings. These two issues spurred extensive discussions with local partners working with Syrian refugees, who were more familiar with the local context. The discussions culminated in a decision to harmonize payments with those offered by the safe spaces and family centres to beneficiaries who use their services. It was agreed that the payment would be nominal, covering transportation, and that whenever possible, meals or refreshments would be offered to research participants.

3. **Payment to participants:** Payment to participants is another issue where IRB expertise alone may not suffice. The IRB focus tends to be on ensuring that no participants are offered undue inducements that may lead them to agree to take a risk and participate in a study that they would otherwise have refused. Concerns have also been raised about non-payment of study participants, particularly in studies involving refugees and displaced persons in low- and middle-income countries, who are subsisting on relief aid

and may have no real opportunities to generate income. What is the right amount? If some organizations in a relief operation pay study participants and others do not, could that be seen as inequitable and affect local community relations? These are issues where study teams need to engage with local communities and other stakeholders, as well as with the relevant IRBs. Some of these decisions may continue to be context specific but they may also lead to new insights for IRBs reviewing studies that take place in humanitarian settings.

CASE STUDY 7 *Local Institutional Review Board (IRB) and other approvals in the Kurdistan Region of Iraq*

While obtaining local IRB approval can be a fairly straightforward process in some cases, approvals in the Kurdistan Region of Iraq were much more complex during the study period. Along with ethical approval from the University of Sulaimani, additional approvals were required from multiple ministries before data collectors were able to conduct a sample survey among IDPs and Syrian refugees across three governorates. These local authorities included the Ministry of Interior, the High Council of Women’s Affairs and the Judicial Council. The documents required included an overall review of study procedures, as well as individual certificates of human subject research training for each data collector. The approval process took over two months to complete, which altered the timeline of the study and fieldwork. This process highlights the importance of creating partnerships in which international organizations are able to work together with local partners who are more adept at understanding and navigating the legal and institutional requirements for ethical review processes.

C. QUESTIONS FOR PRACTITIONERS

Table 7 contains a series of questions we encourage practitioners to consider when developing their IRB applications and interacting with IRBs about study reviews and decisions.

TABLE 7 *Identifying issues for Institutional Review Board (IRB) applications*

Which IRB will serve as the IRB of record (central IRB if more than one) for the study? What are their structures, functions and processes for submitting and reviewing applications?

Which local IRBs exist in the country where the study is taking place? What are their structures, functions and processes for submitting and reviewing applications?

What information about laws and regulations governing child marriage among target populations (both in current and previous locations) would be important for the study team to know and to share with the IRB? Who is knowledgeable about such laws and regulations and how can they be involved in study design?

What information about vulnerable populations in the context of child marriage among target populations (both in current and previous locations) would be important for the study team to know and to share with the IRB? Who has special knowledge about these populations and how can they be involved in study design?

7 STUDY DESIGN AND METHODOLOGY

Designing a research study involves answering a series of questions:

- What are the aims and objectives of the study?
- What is the context and setting of the study?
- Who are the target populations?
- Which research methods are best suited for the study?
- Which sampling designs are most appropriate for the study?
- What kinds of questions should be included, and how should they be organized?

A. STUDY AIMS

For an operational aid organization, key questions might include: What are the population's needs? What programmes and services are necessary, which of them take priority, and for whom are they necessary? What factors contribute to population risk and resilience over time? Are some kinds of intervention more effective than others? To answer these questions, certain types of information will be needed. The kinds of information that needs to be gathered, and the precision with which the findings should be framed, will help to determine if research is needed or if the questions can be answered using other forms of information gathering (needs assessments, review of programme and organizational records, public health surveillance, etc.).

For the studies we conducted on child marriage in humanitarian emergencies, our aims were to calculate prevalence rates of, and assess drivers and risk factors associated with, child marriage among crisis-affected populations in nine different countries. Some of these populations were refugees from other countries, some were IDPs and some were affected host populations. Some were in established rural or urban camps and settlements, and some were living in urban or rural areas outside of camps and settlements. Some were recently displaced (within the last year or two) and some had been displaced for five to 10 years or more. One study (Yemen) was undertaken in the context of active conflict, seven (Bangladesh, Djibouti, Egypt, Ethiopia, the Kurdish Region of Iraq, Lebanon and Myanmar) were in the context of protracted displacement following conflict (as well as drought and food insecurity in Ethiopia), and one (Nepal) was undertaken in the context of a natural disaster, in this case an earthquake (albeit several years after the event).

The questions we were seeking to answer relating to the prevalence of child marriage and its drivers in humanitarian settings, and the precision and rigour required, indicated that the study would involve human subject research and that we should adopt a mixed methods approach (this will be discussed further in the chapter on methods). The different contexts called for different sampling strategies and each study presented a unique set of logistical and ethical challenges.

B. CONTEXT

In designing a study, key contextual factors to consider include the following:

1. **Type of disaster/emergency:** The speed of onset of a disaster, as well as its cause and likely duration, could have a major effect on how research is designed and conducted. For sudden-onset disasters, for example, some research may need to be implemented in a matter of days or weeks; in slow-onset or protracted crises, the time horizon may be months or even years. The cause of the disaster may also dictate the geographic scope of a study (see 3) Setting), as well the allowances that must be made for the presence of infectious disease, hazardous environments and/or insecurity.
2. **Phase of emergency:** While it is possible that some research will take place in the rapid-response phase of an acute emergency, research will more likely take place in later phases, as the response moves to rehabilitation and recovery. However, as noted previously, humanitarian crises are often cyclical and periods of recovery and stability can give way to worsening conditions.
3. **Setting:** Research can take place in a variety of settings, according to the type of disaster that has occurred, where it has occurred, and its primary and secondary effects. For the purposes of study design, considerations of setting should take into account the following factors:
 - » **Population distribution:** Is the population concentrated in specific areas or dispersed across wide areas? Are populations unmixed (living in refugee camps or IDP settlements) or mixed (living among host communities in urban or rural areas)? Are populations accessible or inaccessible? In the case of disasters, such as earthquakes or industrial accidents, inaccessibility may be due to a continuing hazard. In complex emergencies, inaccessibility is more likely to result from conflict and insecurity or a government decision to restrict certain kinds of access (in Yemen, for example, practitioners were restricted from carrying out the study in districts experiencing high levels of violence). Some populations may also seek to remain hidden or hard to find due to their undocumented status or some other potentially sensitive characteristic (ethnic or religious minority, survivor of rape or human rights abuses, etc.).

- » **Stakeholders:** A variety of different organizations, institutions and interested parties may have a stake in disaster assessments. It is important to recognize, first, that these various stakeholders exist and, second, that their interests do not always coincide and may even conflict. Key stakeholders include governments (donors and hosts), international organizations, NGOs and community organizations (from both displaced and host communities).
- » **Constraints:** Research studies face any number of constraints that may impede successful implementation. These include time allotted to conduct the study and generate results; human, material and financial resources; insecurity and volatility, and geography.

C. TARGET POPULATIONS

When designing a study of child marriage in humanitarian settings, target populations should be determined as soon as possible, as these will dictate not only study design and methods, but also the requisite ethical protocols and protections. Population characteristics to consider include:

- » **Age:** Since the study is on child marriage, it would be reasonable to assume that children would be interviewed, though some measures of child marriage could be made by interviewing adults (either household members and/or community members). Assuming that children are interviewed, appropriate age ranges should be considered. In our studies, we interviewed married and unmarried children aged 10–17 years, though only with parental permission (unless the child was married and thus considered an “emancipated minor”, but even in these instances, we asked the child if she/he/they wished to talk to an adult or guardian about the study).

The IRC ‘GBV Emergency Preparedness & Response Participant Handbook’ argues that children aged 12 years and under should not be involved in studies on sexual violence during an emergency, recommending that the focus should be on older adolescents aged 15 years and above (IRC, 2017). We have conducted studies of very young adolescents (aged 10–14 years) in emergency settings and recommend 10 years as the lower bound for the age range of children, though if involving children aged 10–14 years in the research, this must be preceded by extensive consultations with community leaders and stakeholders to determine if this meets local standards and norms for research (in Yemen, for example, local authorities deemed that we could not interview children under 15 for the qualitative study). Second, any ethical review committees (duly constituted IRBs as well as any community advisory committees) must approve and would likely call for additional protections of these particularly vulnerable populations.

- » **Gender:** While the greatest burden of child marriage globally falls upon girls, there may be good reason to also include boys in both quantitative and qualitative interviews—both because boys may be married as children and because their perspectives about child marriage may be valuable in understanding how social and gender norms operate. Little research has been done on child marriage in humanitarian contexts among lesbian, gay, bisexual, transgender, queer and intersex (LGBTQI+) populations, and this would warrant consideration in some settings.
- » **Population type:** It is fairly common to consider refugees and IDPs in humanitarian contexts, but there may be other populations to consider, including migrant populations, survivors of human trafficking and stateless people. When studying any type of displaced or mobile population, it is important to assess what kinds of patterns of movement may be salient in terms of understanding how and when people moved, and how many places they may have settled in in the process. Host community experiences of child marriage may be helpful for comparison purposes and to see whether any intermarriage is occurring.

- » **Location:** This has been discussed in the context section of this chapter, but it is important to consider the different types of locations where target populations are living – camps and settlements vs. intermixed with host communities, and rural vs. urban areas, for example – as well as how many different locations might need to be included in the sample to capture the geographical variability among target populations.

CASE STUDY 8 *Earthquake-driven migration and displacement in Nepal*

Humanitarian settings often involve an element of displacement. Migration patterns and timing affect what we learn about child marriage in humanitarian settings. Following the 2015 earthquakes in Nepal, 800,000 houses were damaged or destroyed and 2.8 million people were displaced for lengths of time varying from a few weeks to months or even years (United States Agency for International Development, 2015). Even after most had returned to their homes or villages, migration continued. Due to the economic disruption, outmigration for work increased, largely to the Arab States, India and Kathmandu (United Nations Entity for Gender Equality and the Empowerment of Women, 2015). Consequently, the timing of the study interviews affected which community members were more likely to be captured by the survey. Immediately after the earthquake, a survey might find only the least affected community members remaining in a village, with others displaced more widely. Years after the earthquake, a survey may find a dearth of married adolescent boys in districts of origin, as was the case in the Nepal study, as most of those newly married had to travel elsewhere to find sufficient income to support their family.

D. METHODS

As noted previously, the focus of this guide is the ethical conduct of research on child marriage in humanitarian emergencies; it is not intended as a training manual for practitioners on all aspects of study design, methodology, sampling strategies, instrument development or data analysis. There are a wide variety of well-regarded and detailed handbooks for that, and we provide references to many of them in the annexes. For methods, we recommend (and use in our teaching and training) John Creswell's textbook, *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* (2013). Unless otherwise specified, quotes in this section are from the Creswell textbook.

1. **Quantitative methods:** Creswell defines quantitative research as “an approach for testing objective theories by examining the relationship among variables. These variables, in turn, can be measured, typically on instruments, so that numbered data can be analyzed using statistical procedures. The final written report has a set structure consisting of introduction, literature and theory, methods, results, and discussion. Like qualitative researchers, those who engage in this form of inquiry have assumptions about testing theories deductively, building in protections against bias, controlling for alternative explanations, and being able to generalize and replicate the findings.”

Creswell identifies two basic types of quantitative designs (though there are more). Survey design “provides a quantitative or numeric description of trends, attitudes, or opinions of a population by studying a sample of that population. From sample results, the researcher generalizes or draws inferences to the population.” In experimental design, “investigators may also identify a sample and generalize to a population; however, the basic intent of an experimental design is to test the impact of a treatment (or an intervention) on an outcome, controlling for all other factors that might influence that outcome.”

Partly for reasons of space, we will focus on survey designs rather than experimental designs, which, to our knowledge, have not yet been applied in studies of child marriage in humanitarian settings. That may be because the research questions in humanitarian contexts are better suited to exploratory, cross-sectional surveys. That said, if there is a need to rigorously evaluate the impacts of a particular programme intervention (for example, school-based programmes providing life-skills training to educate girls and boys about the risks of child marriage), then quasi-experimental and experimental designs would be warranted, using, for example, case-control designs or even randomized control trials.

Creswell offers a useful checklist of questions for designing a survey. These are modified and somewhat simplified in Table 8 to create an 11-point checklist:

TABLE 8 *Checklist of questions for designing a survey*

What is the purpose and rationale of the survey design?
Who should be involved in the survey design and when should they be brought in?
What is the structure of the survey (cross-sectional vs. longitudinal)?
What is the target population and size?
What is the sampling strategy (systematic random, cluster, stratified)?
How many people will be in the sample? On what basis was this size chosen?
What will the sampling procedure be (probability vs. non-probability)?
What instrument will be used in the survey? Who developed the instrument?
What is the survey implementation timeline (including piloting and field testing)?
What specific steps will be taken in data analysis?
How will the results be interpreted and shared (including local dissemination)?

Source: Creswell (2013).

2. **Qualitative methods:** Creswell defines qualitative research as “an approach for exploring and understanding the meaning individuals or groups ascribe to a social or human problem.” The process of qualitative research involves examining emerging questions and procedures, and data analysis that inductively builds from particulars to general themes, and involves the researcher interpreting the meaning of the data.

Creswell identifies five types of qualitative designs (there are more, but he selected these for being “popular across the social and health sciences today”). In humanitarian research, the most common qualitative designs involve single or combined forms of two designs: phenomenological research and grounded theory.

- » **Phenomenological research:** “A design of inquiry coming from philosophy and psychology in which the researcher describes the lived experiences of individuals about a phenomenon as described by participants. This description culminates in the essence of the experiences for several individuals who have all experienced the phenomenon. This design [...] typically involves conducting interviews.”
- » **Grounded theory:** “A design [...] in which the researcher derives a general, abstract theory of a process, action, or interaction grounded in the views of participants. This process involves using multiple stages of data collection and the refinement and interrelationship of categories of information.”

The CORE Group SBC Working Group developed a training manual in qualitative research methods for development and relief aid partners. The following are the three main interview modes and formats, as described in the training manual (CORE Group, 2005), with their source documentation in parentheses:

- » **FGD:** “A loosely structured discussion among six to ten individuals that is used to gather information on a particular research or program topic. A moderator, who guides the discussion, encourages participants to talk freely and reveal their thoughts and feelings about the research topic. FGDs are repeated with several groups of similar makeup until the discussions no longer reveal anything new and relevant to the research.” (Debus, 1997)
 - » **In-depth interview:** “A qualitative research method in which a researcher/ interviewer gathers data about an individual’s perspectives on a specific topic(s) through a semi-structured exchange with the individual. The researcher/interviewer engages with the individual by posing questions in a neutral manner, listening attentively to responses, and asking follow-up questions and probes based on those responses.” (Mack et al., 2005)
 - » **Key informant:** “An individual who has special knowledge on a topic and can speak about general community beliefs and practices. S/he may be interviewed in great depth and is often interviewed many times. The topics covered during these interviews can have a wide range. Key informants may be people from the community who, because of official position or informal leadership, have access to information about the community. Key informants can be government officials, local health service personnel, traditional healers, community leaders (elected or self-appointed), local shop owners, and members of nongovernmental organizations.” (Weiss & Bolton, 2000; Scrimshaw & Gleason, 1992)
3. **Mixed methods:** Creswell defines mixed-methods research as “an approach to inquiry involving collecting both quantitative and qualitative data, integrating the two forms of data, and using distinct designs that may involve philosophical assumptions and theoretical frameworks.” The basic assumption of mixed-methods approaches is that “the combination of qualitative and quantitative approaches provides a more complete understanding of a research problem than either approach alone.”

Creswell identifies six types of mixed-methods approaches or strategies, all of which can be reviewed in his textbook. For the purposes of this guide, we focus only on the three that we have found more commonly used in international health research, particularly in humanitarian settings:

- » **Sequential explanatory strategy:** This strategy “is characterized by the collection and analysis of quantitative data in a first phase of research followed by the collection and analysis of qualitative data in a second phase that builds on the results of the initial quantitative results.”
- » **Sequential exploratory strategy:** This strategy “involves a first phase of qualitative data collection and analysis, followed by a second phase of quantitative data collection and analysis that builds on the results of the first qualitative phase.”

- » **Concurrent triangulation strategy:** In “probably the most familiar of the six major mixed methods models [...] the researcher collects both quantitative and qualitative data concurrently and then compares the two databases to determine if there is convergence, differences, or some combination.”

For our nine studies of child marriage in humanitarian settings, we preferred a **mixed-methods approach**, utilizing the **concurrent triangulation strategy**, employing a **survey design** with a stratified population sample for the quantitative method, and varying combinations of **key informant interviews, in-depth interviews and FGDs** for the qualitative methods. However, in some countries (Djibouti and Myanmar), it was only possible to conduct quantitative research and in one country (Egypt), it was only possible to conduct qualitative research.

E. SAMPLING

Sampling is a key element of study design and is linked not only to the kind of precision and rigour required to investigate study aims, but also to the choice of research methods (quantitative, qualitative or mixed methods). Sampling methods are commonly broken down into two general types: probability and non-probability samples. Probability samples employ some form of random selection mechanism to control for subjective bias. Non-probability samples do not randomly select participants and subjectivity is either tolerated or, in some cases, intended in the method. Probability samples enable researchers to measure the uncertainty (sometimes referred to as confidence limits) in applying estimates derived from sample data to the population of interest. With non-probability samples, the uncertainty of extrapolations cannot be measured.

Non-probability samples have their uses, particularly in qualitative research, while probability samples are typically employed in quantitative research. The advantage of adopting a mixed-methods approach (as discussed above) is that the researcher has access to the insights gained from both approaches. This section presents only a few of many sampling techniques. For probability samples, we include cluster and stratified sampling. For non-probability samples, we include purposive and network sampling. Note that there are a number of comprehensive training manuals on sampling, both quantitative and qualitative; this guide does not attempt to provide training on sampling but rather to discuss several of the methods that practitioners should be aware of when considering child marriage study designs.

1. Cluster sampling

Cluster sampling is “probability sampling in which sampling units at some point in the selection process are collections, or clusters, of population elements” (Kalton, 1983). Cluster sampling is most useful when a population is geographically dispersed or when a sampling frame is not available. As such, it has become widely used in disaster settings. Although cluster sampling may involve several variations, its most common form is multi-stage with probability proportional to size.

In humanitarian settings, cluster sampling is generally chosen over other methods for practical reasons: 1) complete population lists are hard to come by in many developing countries and are rarer still when crises occur and populations are displaced, and 2) valuable time can be saved by selecting basic sampling units in closer proximity to one another. Practicality, however, is not without risks. The lack of complete lists compels a survey team to rely on estimates that may be inaccurate or biased. Selecting clusters with probability proportional to size may be better than the alternative methods, but it is only as good as the estimates of population size on which it is based.

2. Stratified sampling

Stratified sampling involves grouping the study population into strata (layers or sections) and selecting a random sample within each stratum (Fathalla & Fathalla, 2004). Stratified sampling has the advantage of focusing analysis on a particular population characteristic of interest (and of reducing standard errors, though the reasons for this are beyond the scope of this guide). Stratified sampling, however, may require post-sample weighting and other statistical adjustments during analysis. Examples of stratification in humanitarian settings (and ones that we used in our studies of child marriage in these settings) include stratifying by camp and non-camp settings; population types (refugees, IDPs, host communities, and geographic location (province, rural/urban, etc.).

3. Purposive sampling

Purposive sampling is the selection of a sample with an “intention (purpose) of representing certain characteristics” (Kielmann et al., 2012). Variations of purposive sampling include:

- Typical case sampling, in which researchers select cases that are considered average or typical of the population or phenomenon of interest
- Extreme or deviant case sampling, in which researchers select unusual or extreme examples of a phenomenon (for example, extreme wealth or poverty, extreme isolation or social connectedness, etc.)
- Maximum variation sampling, in which researchers select cases from a wide range of characteristics (varying levels of socio-economic status, health, religious practice or other measures)
- Homogenous samples, in which researchers select cases that are considered typical and largely similar. Selecting samples for FGDs is often based on organizing fairly homogenous groups that might talk more freely and easily with others like themselves (adolescent boys, adolescent girls, mothers, fathers, etc.) (Kielmann et al., 2012).

Purposive samples have the advantage of being relatively quick, simple and inexpensive to implement (though like most qualitative methods, transcription, coding and analysis of results can be time-consuming). They are useful for identifying problems and obtaining perspectives of key stakeholders in the local community, as well as members of vulnerable groups. Purposive samples carry a risk of bias, but some of that is intentional. Examples of purposive samples include interviews with refugee community leaders, clinic workers or female heads of household. In each case, individuals are selected for inclusion in the sample based on particular characteristics or knowledge that are of interest to the researcher.

4. Network sampling

Network sampling (also known as snowball sampling, or in reference to a particular kind of network sampling design, respondent-driven sampling) relies on known members of a particular group helping the research team identify new and unknown members of the same population. In network sampling, researchers start by identifying a population of interest and locate a “first case” from that population. The characteristic of interest might be GBV survivors, or undocumented migrants who may be hiding from authorities and/or settled among the local population. The first case is asked if they can help identify someone else with the same characteristic who, in turn, is asked to identify a third, and so on until no more new members can be found or the sampling is otherwise stopped.

Network sampling is especially useful for assessing sensitive issues and/or locating people who are hiding or simply hard to find. It is also helpful in identifying how such populations are networked. The method is biased by the characteristics of the “first case” and thus may systematically overrepresent (or miss) some population members, even if those populations are small. Network sampling may also expose vulnerable and stigmatized populations to unwanted attention, so it must be done with care and discretion.

F. RESEARCH DEVELOPMENT

There are a variety of resources available on how to develop instruments for quantitative and qualitative research. Generally, quantitative methods incorporate some kind of survey questionnaire, while qualitative methods may use semi-structured interview guides for key informant interviews, in-depth interviews and FGDs (Global Women's Institute, 2017; Kielmann et al., 2017; Fathalla & Fathalla, 2004). The focus of this guide is identifying some approaches to instrument development that address content and format issues relevant to rigorous (and thus more ethical as contributing to scientific benefit) research on child marriage in humanitarian settings.

1. Quantitative instruments

For quantitative surveys, one of the most efficient ways to design questionnaires is to base them on previously developed surveys that are publicly available. Suggested resources for designing quantitative survey questionnaires include (Global Women's Institute, 2017):

- Multiple Indicator Cluster Surveys (MICS)
- Demographic and Health Surveys (DHS)
- WHO Multi-Country Survey on VAWG [violence against women and girls] in Conflict Situations
- International Men and Gender Equality Survey (IMAGES)
- Gender Equitable Men (GEM) Scale

To assess prevalence and factors associated with child marriage, UNICEF (2020a) and partners agreed to focus on five indicators related to child marriage:

1. Percentage of women aged 20 to 24 years who were first married or in a union by age 15 and by age 18, by age group
2. Percentage of girls aged 15 to 19 currently married or in a union
3. Spousal age difference
4. Percentage of women currently in a polygynous union, by age group
5. Percentage of ever married women who were directly involved in the choice of their first husband or partner.

Accurate and robust measurement of age and other characteristics is central to estimating prevalence and conducting statistical analysis of associations between background variables (such as socio-economic status of the head of household, education level of children, etc.) and the outcome variable of interest (married or not married as a child). MICS and DHS provide

standardized and validated questions for many of these measures. As ages can often be difficult to recall, WHO recommends:

- Asking if birth/marriage occurred around well-known events
- Using seasonality to determine month of birth (i.e. rainy seasons, floods, dry seasons etc.)
- Providing data collectors with year-age charts to reference if a year is given

Child marriage research involves interviewing vulnerable populations and asking sensitive questions, and this should be taken into account when designing surveys. Particularly sensitive sections, including questions about mental health, sexual activity or violence, should be prefaced with an introductory statement that explains the purpose of the questions and reminds participants that they do not have to respond if they are uncomfortable doing so. These questions should also be placed later in the survey so that participants are able to build a level of comfort with the interviewer before these kinds of questions are asked.

2. Qualitative instruments

As with quantitative surveys, one of the most efficient ways to design qualitative interview guides is to base them on previously developed and publicly available materials. Resources for qualitative questionnaires include:

- 'Gender-Based Violence Research, Monitoring, and Evaluation with Refugee and Conflict-Affected Populations' (Global Women's Institute, 2017)
- 'Question guide: researching norms about early marriage and girls' education' (Jones et al., 2015)
- 'Measuring Violence Against Children in Humanitarian settings: A scoping exercise of methods and tools' (Landis et al., 2013)

For qualitative interviews, questionnaires should be designed to encourage detailed responses and, in the case of focus groups, elicit discussion among participants. One way to start this process is to outline a conceptual framework or theory of change upon which to base tool development. A conceptual framework acts as a hypothesis that can serve as an outline for different sections or methods of questioning.

CASE STUDY 9 *Participatory research with Syrian refugee children in Egypt*

Conducting qualitative research with children – married or unmarried – is a complex process, and thus there is substantial value in using participatory and participant-centred research methods. In Egypt, where we conducted qualitative research among Syrian refugee populations, the research team used photo elicitation, which is a visual method that uses photos to help researchers understand the lived experience of research participants. The team compiled locally relevant pictures of girls and asked participants to describe what they saw in the photos. Despite planning to use photo elicitation exercises at the beginning of FGDs with girls, we were unable to obtain the printed pictures in time for the pilot. As a result, in the first pilot FGD with unmarried refugee girls, silence was pervasive and the moderator – who has ample experience collecting data – struggled to kickstart the conversation. In contrast, subsequent discussions were more dynamic and engaging. Not only did photo elicitation exercises break the ice and empower participants to speak up, but they also generated valuable insights into how girls think and how they interpret reality as they see it.

G. QUESTIONS FOR PRACTITIONERS

Table 9 contains a series of questions that practitioners are encouraged to consider when making decisions about study design and methodology in their setting.

TABLE 9 *Determining study design and methodology*

What are the aims and objectives of the study?

What is the context and setting of the study?

Who are the target populations?

Which research methods are best suited for the study (quantitative, qualitative or mixed)?

If quantitative, what are the best designs for your objectives and context?

If qualitative, what are the best designs and data-collection procedures?

If mixed methods, what is the best strategy for your objectives and context?

Which sampling designs are best for your study?

What kinds of questionnaires and interview guides will you use? What resources are available to guide development of these instruments?

8 STUDY IMPLEMENTATION

In this section we describe study implementation issues, looking particularly at the ethical and safety issues framed in the WHO 2007 report, 'Ethical and Safety Recommendations for Researching, Documenting and Monitoring Sexual Violence in Emergencies', whose eight recommendations are also supported by the Global Women's Institute manual, 'Gender-Based Violence Research, Monitoring, and Evaluation with Refugee and Conflict-Affected Populations' (2017). Many of these have been addressed in the previous chapters on study design and methodology, privacy and confidentiality, and informed consent. This chapter focuses on interview team selection, training and support; safety (for participants and the study team), with a particular focus on safeguards for children, and referral and support services for study participants. As noted previously, this guide does not attempt to prescribe particular answers for all these issues but rather to set out a framework for informed decision-making within specific contexts.

A. INTERVIEWER SELECTION, TRAINING AND SUPPORT

One of the eight ethical and safety recommendations made by WHO (2007) was that “[a]ll members of a data gathering team must be carefully selected, and receive relevant and sufficient specialized training and ongoing support.”

1. Interviewer selection

When working with vulnerable populations and asking about sensitive topics, participants should feel as comfortable as possible with the person doing the interview. The best way to ensure this is by recruiting data collectors who share similar demographics with the study population. These characteristics may include language, age, gender, place of origin or ethnicity. For research on child marriage, the interviewer’s gender, and in some cases age, are particularly important for building trust and establishing a rapport with respondents. It is strongly recommended that, when interviewing boys and girls, the interviewer is the same gender as the respondent.

In some settings where levels of education among women and girls may be low, it may be difficult to find interviewers with sufficient levels of literacy and numeracy to carry out some more complicated surveys. Women with a high-school education (often set as the recommended minimum) or higher, particularly those with some interviewing experience, may be in high demand in humanitarian settings. It is important to check with organizations working in the study area. Recruits may also be found at local universities or other educational institutions. If the availability of capable interviewers is limited by low levels of literacy or other factors, computer-assisted interviewing methods might be used to support data collection, though this requires other kinds of resources (financial, technological and human) to be used effectively.

In some cases, it may be necessary to recruit interviewers with less experience or more limited interviewing skills. In these cases, additional training might be necessary. Generally, we recommend that priority be given to limiting the number of data collectors in order to maximize high-quality and rigour in data collection, whether through quantitative or qualitative approaches.

CASE STUDY 10 *Interviewer selection in Bangladesh*

Interviewer selection can significantly impact a study’s success. In the Rohingya camps, most prior research was conducted by Bangladeshis from Chittagong, a region of Bangladesh that shares a border with Myanmar, the language of which significantly overlaps with the Rohingya language. This was done largely because it was easier to find well-trained Bangladeshis and the Chittagonian language can be represented with the standard Bengali script, whereas Rohingya currently has no written form. However, formative research found that language divergence often occurred in sensitive and intimate topics, such as those discussed in the context of child marriage. In addition, Rohingya refugees often perceived an attitude of superiority from Bangladeshis towards Rohingya, hindering trust and creating a tension that was heightened by ongoing discussions about repatriation and the impact of the camps on the local economy. Consequently, the study team decided to engage Rohingya refugees themselves as interviewers. The study team felt that the consequential rapport and language fidelity outweighed the somewhat more complex recruitment and training process.

2. Interviewer training

Training content, format and length will vary based on the study design and scope, research methodologies, local context, and the capacity of data collectors (education level, previous training, etc.). These considerations should be discussed well in advance of study implementation (usually, an IRB will want to know what kind of training is provided to the interviewers, not just to ensure that there is proper training in human subject research but also to promote a rigorous study, which is related to the scientific benefits of the study). The training team should include people who are familiar with the study methodology as well as people knowledgeable about the local context, including the populations of interest, local programmes and services, and field security.

Generally, we recommend a minimum of five working days for training, though 10 days may need to be allotted, both to provide more time for possible supplemental training and to allow for contingencies. Table 10 provides a sample training agenda for a six-day mixed-methods training.

TABLE 10 *Sample training agenda for a mixed-methods study of child marriage*

* Pilot testing should not be performed on potential study subjects but rather on those similar to the target population who can answer the questions knowledgeably. Pilot testing should include all consent procedures before starting interviews, but no data should be published from pilot testing.

3. Interviewer support

Ongoing support for interviewers in the field will be critical, especially in areas where there is conflict and insecurity. Some of the support will be technical, including the routine monitoring of data as it comes in from the field (whether uploaded from electronic devices or reviewed from hard copies of surveys and interview notes), as well as routine discussions with interviewers about any concerns or suggestions they might have. Problems should be identified and addressed as soon as possible, in some cases through retraining on problematic aspects of the data-collection process.

As data is monitored and interviewers are supervised, it is also important to assess whether there have been any ethical concerns or questions raised by study participants, or problem events to be reported by the field team. This is particularly important in the early days of the study when respondents or other community members might raise concerns about the study, or when interviewers note a concern about recruitment methodologies or privacy of interview sites. Protocols for identifying unanticipated problems and adverse events should be part of the training, but proper supervision and follow-up is critical to ensure that any of these kinds of events are being reported and addressed.

Finally, support for interviewers must include ongoing monitoring of the security situation and maintenance of proper safety and security protocols. To help ensure safety (and maintain data quality), the following materials should be provided to data collectors to have with them throughout data collection:

- Notebooks
- Tablets or other devices if collecting electronic data (including charging equipment, batteries, etc.)
- Daily field plan (sampling design for local sites, target number of interviews, etc.)

- Contact information for supervisors
- Contact information for referral services
- Printed copies of study instruments (study information briefs, recruitment scripts, consent forms, questionnaires, interview guides, etc.). – these should be available as a back-up even if electronic devices are used to collect data
- Maps of the area
- Identification (ID card or introduction letter) from sponsoring organization(s)

B. SAFETY AND SECURITY

Another of the eight WHO ethical and safety recommendations (2007) was that “[t]he safety and security of all those involved in information gathering about violence is of paramount concern and in emergency settings in particular should be continuously monitored.” This should include the safety and security of both study participants and interviewers (including their personal safety and the security of the data collected).

1. Study participants

Safety is a primary concern during data collection, especially in humanitarian settings. In terms of assessing and maintaining the personal safety of study participants, the study team should conduct ongoing security monitoring using their own resources or through consultation with appropriate government authorities, international organizations, international or local NGOs, and/or consultations with community members. Safety is not only about security, however, and study teams should also engage in discussions with community leaders and other local stakeholders where data will be collected to ensure acceptability and awareness of the study objectives, timeline and field activities.

As discussed in chapter 4, privacy and confidentiality are important aspects of child marriage research. Ideally, surveys should be conducted in a private location so that participants feel comfortable sharing personal information without fear of repercussions. This is especially true when interviewing women or children, who, in many cultures, face strict supervision (and possible sanction) by spouses, parents or other family or community members. As the Global Women’s Institute (2017) noted, “[r]espondents from conflict-affected settings may be put at heightened risk from others in their community—or even the government, in some circumstances—for speaking to outsiders. These concerns increase when the subject matter includes sensitive issues such as experiences of violence. In addition, participants can be placed at increased risk within their own homes; for example, facing consequences from an abusive partner because they spoke about the violence to a data collector.”

Speaking about violence can raise concerns about privacy in child marriage, but discussions about other aspects of child marriage and behaviour of household members can also be quite sensitive. For example, a child may not feel comfortable talking about her husband when another family member (for example a mother-in-law) is present. The study should establish protocols about which questions can or cannot be asked when another family member is present. In all cases, the respondent should be asked if they wish to continue the interview, but the interview should be truncated or terminated if the interviewer has any concern that the presence of another family member presents a risk to the respondent or the quality of the data being collected.

Maintaining data confidentiality requires not only proper management of the data once it has been collected (including safe transfer to secure physical or electronic storage, de-identifying data, etc.) but also ensuring that confidentiality is maintained locally. This may mean encouraging respondents who have just finished an interview not to share their answers with others in their family or community, unless they feel that they need to for support and/or are very certain that this information will be respected and protected. In the context of FGDs, the risk of loss of confidentiality through other FGD members sharing information outside the group should be clarified in the consent form and should also be raised again during and at the end of the FGD session, so that all participants commit to maintaining confidentiality on behalf of one another.

2. Interviewers and study team members in the field

To promote the personal safety of study participants, the study team should conduct ongoing security monitoring with appropriate government authorities, international organizations, international or local NGOs, and/or consultations with community members. The safety of interviewers and study team members can also be promoted by discussions with community members and local stakeholders about study objectives and activities. Whether in conflict settings or in environments disrupted by natural disasters, interviewers may be perceived as strangers and viewed either with suspicion or with expectations that their presence will be accompanied by immediate or direct aid. Engagement with the community to introduce team members and to clarify expectations can increase their safety and ability to move more freely in the community.

In terms of securing data once they have been collected, it is important that interviewers are trained to keep any personally identifiable information, including names, phone numbers and addresses of respondents, separate from the questionnaires. Personally identifiable information is often needed for recruitment and consent purposes, but that information should be kept safely and only be accessible to the study team. This can be kept electronically on password-protected or encrypted devices. When using paper or audio recordings, there must be a plan for the safe transport of these data from the field to a study office, where they can be kept in locked rooms or cabinets until the data are electronically entered and, where possible, de-identified.

CASE STUDY 11 *Study team safety and community engagement in Ethiopia*

The Dolo Addo region of Ethiopia is home to five refugee camps, primarily hosting Somalis experiencing protracted displacement. Data collection took place in Kobe camp, which was the second largest in the area with 47,465 residents in 2018 (UNHCR, 2018). In an effort to make the adolescent girls feel comfortable sharing personal information, data collectors were chosen based on age, gender and literacy. However, they were recruited from camps throughout the Dolo Addo region, and only two were from Kobe camp. On the first day of data collection, representatives of a local community group who disapproved of investigators from outside Kobe camp threatened physical harm to data collectors if they proceeded. The interviewers were immediately brought back from the field and data collection was halted until community leaders were consulted and it was assured that the study could continue safely.

CASE STUDY 12 *Ensuring the safety of female study team members in Bangladesh*

At the time the study was getting under way in the Rohingya camps in Bangladesh, an extremist movement was gaining traction in the camps, using violence to discourage women from working outside the home. The inclusion of female interviewers was critical to ensure the participation and trust of adolescent female respondents. To ensure the safety of the female study team members, surveyors were put into pairs of one man and one woman who would travel together for the duration of the study period. Although they would not both be present in each interview, to maintain same gender interactions, the other team member would conduct an interview in a nearby house, ensuring that there was always a partner nearby. A detailed safety and security plan was also drawn up, with focal points in each camp and an action plan to follow in the event of any incidents.

C. REFERRAL AND SUPPORT SERVICES

Another of the eight WHO ethical and safety recommendations (2007) was that “[b]asic care and support to survivors must be available locally before commencing any activity that may involve individuals disclosing information about their experiences of violence.” We strongly recommend that the availability of referral and support services be assessed in the early stages of study design and planning. In some settings, such as a well-established refugee camp or a setting with higher levels of resources (urban areas, for example), these services might include medical, psychosocial, protection/security or legal support. In the context of newly emergent crises or in settings where resources are low in general, “consider setting up temporary services—particularly for psychosocial support—to provide assistance to anyone who experiences distress when talking about their own experiences” (Global Women’s Institute, 2017). In some humanitarian contexts, funding for such services needs to be included in the research budget (Dahab, 2017).

Given the likely involvement of children as study participants, child marriage studies should include the availability of child protection services in their initial assessments, including counselling and referral for more specialized forms of care.

CASE STUDY 13 *Strengthening links between research and programmes for Syrian refugees in Egypt*

As of January 2020, Egypt hosted around 129,642 officially registered Syrian refugees, half of whom were female and close to 20 per cent of them were girls aged under 18 years. Data collection in Egypt took place in three urban sites with high concentrations of Syrian refugees. The FGDs and in-depth interviews were conducted in Women and Girls Safe Spaces (WGSS) supported by UNFPA. These are spaces designed to support physical safety and emotional wellbeing, provide social support, support the acquisition of relevant skills (such as livelihood and vocational training), and enhance access to safe and confidential GBV-response services. To ensure that the research was not merely extractive and that it informed immediate action and programming, the research team set up a referral system whereby research participants who shared stories of abuse, trauma or violence could immediately be referred to the resident psychologist and social workers in the WGSS. In addition, participants who were recruited to take part in the study were invited to enrol in WGSS activities and to return for services around the time study interviews were conducted.

D. QUESTIONS FOR PRACTITIONERS

Table 11 contains a series of questions that practitioners should consider when preparing to implement the study.

TABLE 11 *Identifying issues in study implementation*

What are the capacities of local interviewers? What are the training capacities of the study team?
What mechanisms need to be put in place for interviewer selection, training and support?

What is the level of security in the study area? What risks does this pose to potential study participants and to the study team?

What is the sensitivity and acceptability of the topic in the study area?

Which partners and stakeholders need to be involved in assessing risk?

What referral and support services exist in the study area? If they do not exist, what resources must be mobilized to provide these? What referral and support services should be available for children in particular?

9 COMMUNITY ENGAGEMENT AND CAPACITY-BUILDING

In this chapter, we will examine the issue of community engagement and capacity-building in human subject research, looking at some challenges and opportunities researchers may face in humanitarian settings in particular.

A. CHALLENGES AND OPPORTUNITIES

In a systematic review of literature on community-based research in the United States, Drahota et al. (2016) concluded that “research carried out in community settings has traditionally progressed in one direction, in which academic researchers conceptualize research projects with minimal (or perhaps without any) input from community stakeholders; implement interventions or programs, often without a plan for sustainment in the communities; obtain data and information from community members; and disseminate the newly gained knowledge and information to peers and colleagues rather than to members of the community.” As a result, research findings often “fail to be translated [...] to ‘real-world’ settings and program implementation, with community stakeholders reporting a lack of investment in the research, and needs different from those being addressed by the researchers” (Drahota et al., 2016).

The contexts may be different and the research may not always, or only, involve academics, but anyone involved in research in humanitarian settings – whether international organizations, international NGOs, government agencies or indeed, academics – can understand the sentiments expressed by community stakeholders that research does not always invite their participation, reflect their needs or have impacts on their “real-world” concerns and priorities. We offer some examples from our studies of child marriage in humanitarian settings of some of the challenges that may present themselves, and the opportunities to promote community engagement and capacity-building.

The definition we use of community capacity is “the cultivation and use of transferable knowledge, skills, systems, and resources that affect community- and individual-level changes consistent with public health-related goals and objectives” (Rogers et al., 1995, cited in Hacker et al., 2012). The focus here is on engaging and building community capacity in the ethical conduct of research, so that community organizations can play more of a lead role in this research, both for and by themselves and in partnership with others.

Hacker et al. (2012) identified several domains relevant to capacity-building: partnerships, transfer of knowledge and skills, and infrastructure and resources.

- » **Partnerships:** In a narrower sense, research partnerships can refer simply to organizations and entities collaborating to conduct research, usually with roles (funded or unfunded) spelled out in the research plan, defining responsibilities as co-investigators or collaborators in study design and planning, training, data collection, data analysis, and uptake and dissemination of study findings. Hacker et al. (2012) suggest that partnerships “represent a form of ‘social capital’ that can facilitate resource acquisition (e.g., dollars, political power), uncover multidisciplinary approaches to solving complex problems, and enhance capacity to improve health.” In addition to health, we can add general living conditions, protection, equitable treatment, etc.
- » **Transfer of knowledge and skills:** As part of study design and planning (as well as in data collection, analysis and dissemination of findings) transfer of knowledge and skills between communities and researchers is vital to the proper conduct of the study. Hacker et al. (2012) reference the importance of this transfer being bidirectional and intergenerational.
- » **Infrastructure and resources:** In the context of community capacity-building, Hacker et al. (2012) gave an example of infrastructure as the “mutual creation of guidelines and frameworks for collaboration”, which seems like a useful point of discussion on building capacity for the ethical conduct of research.

CASE STUDY 14 *Building research capacity in the Rohingya community*

The entire Bangladesh study team felt it important that the project not only had community buy-in and support, but that it also increased local research capacity. In addition to the Rohingya surveyors and the Rohingya team members who led the community consultations, the study team also included two Rohingya research assistants. One helped to oversee study implementation and was an integral member of the formative research process, community consultations and finalization of the study protocol. The other stayed in touch with all the surveyor teams and tracked their progress. Several of the surveyors who had worked with one of the co-investigators previously and gained further experience through the child marriage research have now worked on several additional studies and become known among a local pool of skilled researchers.

CASE STUDY 15 *Sharing study results with the community of internally displaced persons (IDPs) in Myanmar*

Long-running conflict between Myanmar's military-dominated regime and the Kachin Independence Army has led to the internal displacement of more than 100,000 people from ethnic minority groups in Kachin State (Ho, 2018). Internal security regulations and checkpoints prevented international members of the study team from carrying out direct visits to the IDP camps and communities along the China-Myanmar border. Instead, our local partner, the Kachin Development Group (KDG), organized several community meetings involving parents of IDP adolescents, along with community leaders, IDP camp management and local community members. KDG shared results and key findings from the quantitative survey of IDP households and individuals. Comments and feedback from more than 125 people who attended the meetings indicated that they agreed with the main findings and were committed to engaging the community as a whole, as well as particular agencies working on promoting child rights and protection, in improving child-friendly services.

B. QUESTIONS FOR PRACTITIONERS

Table 12 contains a series of questions that practitioners are encouraged to consider when exploring local challenges and opportunities for community engagement and capacity-building.

TABLE 12 *Identifying challenges and opportunities for community engagement and capacity-building*

Which local NGOs and community-based organizations are in the study site areas and could participate in the research?

What needs for capacity-building exist for these organizations and how might the study help meet those needs? What resources do those organizations have that could strengthen the study?

What challenges and opportunities exist to build community partnerships during the study and to sustain them beyond the study?

What challenges and opportunities exist to promote a mutual transfer of knowledge and skills?

What challenges and opportunities exist to build infrastructure (guidelines and frameworks for collaboration) and identify resources to sustain that?

10 PUBLIC ACCOUNTABILITY FOR RESEARCH

To achieve the full social and scientific value of research, the CIOMS 2016 ‘International Ethical Guidelines for Health-Related Research Involving Humans’ state that “public accountability is necessary [...] therefore researchers, sponsors, research ethics committees, funders, editors and publishers have an obligation to comply with recognized publication ethics for research and its results.” The obligation to share results in an ethical manner and to be accountable to the public for their completeness and accuracy is based on several objectives (and expectations) of shared scientific research (CIOMS, 2016):

- To maximize benefits from the research
- To reduce risk to future study volunteers from undisclosed harm identified in previous studies
- To reduce biases in evidence-based decision-making
- To improve efficiency of resource allocation for interventions and future research
- To promote societal trust in health-related research

The results of research on child marriage in humanitarian settings should be published and disseminated, and responsible data sharing should be promoted, though safeguards must be in place to protect the privacy and confidentiality of study participants.

A. PUBLICATION AND DISSEMINATION OF RESULTS

Research on child marriage in humanitarian settings is likely to have a range of sponsors, stakeholders and target audiences, and publication and dissemination strategies should embrace that same diversity. We strongly recommend publishing study results in peer-reviewed journals, as well as in the form of technical papers, policy briefs or fact sheets. CIOMS (2016) states that “[r]esearchers must also communicate the results of their work to the lay public. Ideally, researchers should take steps to promote and enhance public discussion. **Knowledge resulting from the research should be made accessible to the communities in which the research was conducted** either through publication in scientific journals or through other channels.”

In humanitarian settings, the ethical imperative to make knowledge accessible to the communities involved in the research aligns with a humanitarian imperative to make the findings (including recommendations for policy and programme interventions) available as soon as possible (Sphere Association, 2018). Practitioners undertaking research may find it challenging to balance the fact that good research – including data analysis, write-up and dissemination of results – takes time, while humanitarian programmes and beneficiaries demand – and deserve – prompt action. In some cases, project partners may face trade-offs between publishing in peer-reviewed journals, which may be a lengthy process, and disseminating results quickly through meetings and conferences, policy briefs and social media releases. Those trade-offs and strategic decisions must be discussed and dealt with by project partners and their constituents. For any and all types of public dissemination of findings, however, it is critical to engage with community advisory boards and community representatives and to discuss study results, and the risks and benefits of sharing these results publicly.

There are several potential benefits of publicly sharing results for the communities in which the research was conducted. The study results could raise awareness of population vulnerability and the need for more effective interventions. They could also include recommendations for programme and policymakers to increase resources for interventions. Finally, the results might be useful to community organizations themselves, particularly for those who might have collaborated in the research, to raise awareness of their own work and to provide an evidence base for advocacy, coalition-building and fundraising.

Publicly sharing study results can also bring risk, particularly to marginalized groups such as refugees, IDPs, undocumented migrants, and racial, ethnic or religious minorities. As CIOMS (2016) notes, “results could indicate – rightly or wrongly – that a group has a higher than average prevalence of alcoholism, mental illness or sexually transmitted disease [...]. Research results could therefore stigmatize a group or expose its members to discrimination.” In conducting a study, researchers typically pay more attention to protecting the right to privacy and confidentiality of individual participants. In publishing and disseminating study findings, however, researchers and partners must not only continue to prevent risk to individuals (by not providing names or specific, personal details about respondents); they must also prevent risk of harm to the communities from which study volunteers have been selected.

In the context of research on child marriage in humanitarian settings, child marriage may be more prevalent among refugees and displaced persons from other countries or other regions than among the local population. In and of itself, this finding may be important for providing evidence of child marriage prevalence and promoting support for interventions to reduce prevalence and mitigate risk. Seen another way, a study could single out a particular refugee or displaced community as practising a behaviour that may be illegal in local contexts and/or may be stigmatizing as an example of “harmful cultural practices”, as child marriage is sometimes categorized by United Nations organizations (UNICEF, 2020b). In other words, the concerns and priorities of local communities are not necessarily the same as those of the researchers and sponsors, and these issues must be discussed with community advisory boards and community representatives throughout the study, including when the time comes to share the results.

CASE STUDY 16 *Audio dissemination of findings to illiterate community members*

The Rohingya language currently has no written form and there is no standard form of transliteration into any other script. Although most Rohingya community members speak some level of Burmese, not all can read the Burmese script, and though there is some overlap between Rohingya and Bengali, most Rohingya cannot read the Bengali script. Disseminating study findings to the Rohingya community therefore presents a challenge. To ensure accessibility, the study team planned to prepare a written summary of findings translated into both Burmese and Bengali, as well as an audio recording of the same information in the Rohingya language. Many of the refugees have smart phones and regularly share files, providing an existing means for distributing an audio file, or playing it for those who do not own phones. In this way, findings can be shared with any member of the Rohingya refugee community.

B. DATA SHARING

The ethical conduct of research requires not only the building of collaborative relationships between and among various stakeholder groups –including practitioners, researchers, sponsoring organizations, collaborating partners, communities in which the research is conducted and, of course, the wider public – but also “careful balancing of competing considerations” (CIOMS, 2016). One area where both collaboration and competing interests and agendas may come into play is that of data sharing. Here, we mean not only the sharing of study results in the form of journal articles, policy briefs, fact sheets, meeting and conference presentations, etc. but also the responsible sharing of the “raw” data, including datasets, codebooks, interview transcripts and other materials gathered in the conduct of the research. CIOMS cites a number of reasons to share data: responsible sharing of data strengthens the science of safe and effective interventions; it also “fosters sound regulatory decisions, generates new research hypotheses, and increases the scientific knowledge gained from the contributions of [...] participants [...] researchers, and [...] funders.”

It is becoming increasingly common for donors to request that grant recipients have a plan to share data (the Elhra programme, Research for Health in Humanitarian Crises, does this, for example) and for academic journals to request authors to make their data available for others to analyse. For research in humanitarian settings, just to give one example, the Humanitarian Data Exchange houses 17,765 datasets from 253 locations and from 1,371 sources (as of September 2020). Whatever the mechanisms, data from studies of child marriage in humanitarian settings should be shared for maximum scientific and societal benefit. That said, CIOMS (2016) notes that there are risks, burdens, challenges and benefits for the various

stakeholders: “[w]hen sharing data, researchers must respect the privacy and consent of study participants. Researchers want a fair opportunity to publish their analyses and receive credit for carrying out studies [...]. Other researchers want to analyze data that would otherwise not be published in a timely manner and to replicate the findings of a published paper. Sponsors want to protect their intellectual property[...]. All stakeholders want to reduce the risk of invalid analyses of shared data.”

Despite the challenges, we recommend that data from studies of child marriage in humanitarian settings be shared responsibly, employing data use agreements and observing all necessary privacy protections. This should help to create and foster a culture of responsible data sharing. To develop mutually reinforcing incentives for this, donors should require that data be shared and provide adequate support for this; researchers should not only share data but also design studies in which they should expect to be required to do so; research institutions should encourage researchers to share data; journals should request that authors share their analytical data sets, and regulatory agencies around the world should harmonize requirements and practices for data sharing (CIOMS, 2016).

C. QUESTIONS FOR PRACTITIONERS

Table 13 contains a series of questions that practitioners should consider when preparing for and carrying out publication and dissemination of study results, and responsibly sharing data.

TABLE 13 *Identifying issues in public accountability*

What are the risks and benefits of public dissemination of results?

What steps should be taken to engage with local communities to solicit their views? What are the risks and benefits to individuals and groups?

Which strategies for publication and dissemination will present maximum benefit and minimum risk to stakeholders?

Which strategies for publication and dissemination will present maximum benefit and minimum risk to stakeholders?

What plans need to be put in place for responsible data sharing?

Who needs to be involved in the discussions and planning for data sharing? What competing interests, if any, need to be addressed?

CHILD MARRIAGE RESEARCH DURING THE COVID-19 PANDEMIC

This section addresses at least some of the questions that might arise as practitioners ask how, or even if, they should conduct research on child marriage in humanitarian settings during the COVID-19 pandemic. We preface our comments by saying that while science and public health are learning as rapidly as possible about how the virus behaves and what can be done to prevent or mitigate its spread, there are still far too many unknowns to predict what conditions will look like at the end of 2020, or in 2021 and beyond. Even at time of publication, local contexts varied widely, with many high-income countries heavily affected and struggling to contain the spread, and many middle- and low-income countries coping with more limited impacts. Those trends could continue or could change significantly. However, we can say with some confidence that without safe, effective and universally available vaccines and/or treatments, the most effective forms of prevention will involve mask wearing and social distancing, including limits on gatherings of people.

All the fieldwork for the research we conducted on child marriage in humanitarian emergencies was completed before the end of 2019, so we did not need to adjust or amend any study protocols and do not have insights on COVID-19 research that draw directly on that work. We base our comments here on experience from other ongoing studies, from conducting ethical reviews of other studies and from reviewing literature published since the beginning of 2020 on COVID-19 research protocols. There are multiple questions about when, how and whether to conduct child marriage research during COVID-19, including research that incorporates a focus on COVID-19, but they come down to three central questions that readers of this guide will understand: what are the (minimal to significant) risks of conducting research during the pandemic, what are the (individual and/or societal) benefits, and do the benefits of the research outweigh the risks?

A. IMPACTS OF COVID-19 ON CHILDREN

To assess the risks and benefits of child marriage research on or during COVID-19, it may help to begin by examining the impacts of COVID-19 on children. These have been well summarized by Gabrielle Berman (2020) in the report, 'Ethical Considerations for Evidence Generation Involving Children on the COVID-19 Pandemic'.

- The spread of COVID-19 has been protracted and containment has been difficult, leading to extended isolation of families. Given this potential for extended isolation in homes or institutional settings, children “may be subjected to direct, indirect, and possibly prolonged exposure to violence, including physical, sexual and verbal abuse and ongoing and repeated exposure to risky behaviours” (Berman, 2020).
- Children may experience higher levels of stress due to isolation and limited social interactions and may have had to deal with the grief and anxiety associated with illness or death of family members.
- Children’s privacy in lockdowns and isolation with families may be severely limited.
- Loss of employment by parents or caregivers can not only add to stress but also threaten access to food, shelter and emergency care.
- Children may have even less access than before to psychosocial support during the pandemic. In particular, “child safeguarding and other relevant child services and supports may not be possible to deliver remotely, may be overburdened resulting in significant delays, or may not be considered ‘critical’ and therefore may not be available” (Berman, 2020).

B. WEIGHING UP RISKS AND BENEFITS OF RESEARCH

In weighing up the risks and benefits of conducting child marriage research during COVID-19, the principle of “do no harm” should serve as the guiding moral imperative. Given the restrictions on movement, the traumas that children may be experiencing, and the additional risks posed to everyone by face-to-face contact, Berman (2020) recommends that “to ensure the safety of children, their communities and data collectors, **serious consideration should be given and action taken to cease all face-to-face primary data collection** even in contexts where cases are currently low and no social distancing measures are in place.” Berman further recommends that “**online/mobile evidence generation for the sake of data collection should be avoided [...].Where it is undertaken, the purpose, nature and value of any direct data collection to participants should be clear and appropriate, and adequate support services should be provided.**”

We should note that these are general recommendations and local contexts may differ, as might particular guidelines for research issued either by health authorities or by IRBs. Before continuing any research during the pandemic or initiating new research, practitioners should carry out a full risk analysis, engaging with all relevant stakeholders, including community representatives, local health officials, subject-matter experts and IRBs. There may be situations where face-to-face data collection can continue when proper personal protective equipment is worn and proper hygiene and social distancing practices are maintained. There may also be situations where remote data collection methods might be appropriate, though these options must be examined in light of the potential risks and benefits to study participants. Berman

(2020) provides a helpful table on ethical considerations for COVID-19 research involving children in the emergency and recovery phase of a humanitarian crisis. JHU (2020) also provides the framework 'Human Subjects Research: International Supplemental Guidance', on research during the pandemic. Links to these and other resources are provided in Annex B: Resources.

As for the potential benefits of research on child marriage during COVID-19, that depends largely on which questions the research seeks to answer and whom it would benefit. , 2020b) In the 2020 WHO report, 'Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D' (WHO, 2020b), WHO noted that "[t] here is an ethical imperative to conduct research during public health emergencies, as some research questions can be adequately investigated only in emergency contexts." The report cites guidance developed from previous outbreaks (severe acute respiratory syndrome [SARS] in 2003, influenza A [H1N1] in 2009–2010 and Ebola in 2014–2016) and summarizes "key universal ethical standards" as including "scientific validity, social value, collaborative partnership, fair and voluntary participation, reasonable risk-benefit ratio, independent review, and equal moral respect for participants and affected communities."

Generally speaking, the types of research given priority in public health emergencies, particularly infectious disease outbreaks, include public health surveillance and testing of emergency interventions that might have immediate and direct benefit to study populations. Even then, WHO (2020b) cautions that "research should be conducted only if it does not impede emergency response efforts." Research on child marriage is not likely to be of immediate, direct benefit to study participants, unless it were seen to be linked to a specific pandemic-related intervention. In this case, it might be given priority, though this is an issue requiring full discussion and collaborative decision-making with relevant stakeholders at the study site.

C. QUESTIONS FOR PRACTITIONERS

Table 14 contains a series of questions that practitioners should consider when preparing for (or if already involved in) child marriage research during the COVID-19 pandemic.

TABLE 14 *Child marriage research during the pandemic*

Which questions is the research seeking to answer?

What are the risks of starting, or continuing, the research during the pandemic?

Are there any emergency response efforts that are being, or would be, impeded by the research?

What potential benefits exist for the research? Are there any immediate and direct benefits to the study participants?

Who needs to be involved in the discussions about study risks and benefits? If this is a current study, who needs to be involved in decisions about suspending the study or revising any study protocols?

ANNEX A: REFERENCES

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ANNEX B:

RESOURCES

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