ETHICAL CONSIDERATIONS IN RESEARCH ON FEMALE GENITAL MUTILATION

human reproduction programme hrp
research for impact
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Ethical considerations in research on female genital mutilation

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ACRONYMS AND ABBREVIATIONS

ARP	alternative rites of passage
CBO	community-based organization
CBPR	community-based participatory research
CIOMS	Council for International Organizations of Medical Sciences
DHS	Demographic and Health Surveys
FGM	female genital mutilation
FGM/C	female genital mutilation/cutting
MICS	Multiple Indicator Cluster Surveys
NGO	nongovernmental organization
SDG	Sustainable Development Goal
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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PREFACE

Female genital mutilation (FGM) is a harmful traditional practice that involves the partial or total removal of external female genitalia or other injury to female genital organs for non-medical reasons (WHO, 2020). Over 200 million girls and women alive today have undergone FGM, with approximately 3 million girls at risk each year (UNICEF, 2016). FGM is widely condemned from a human rights and public health perspective. The abandonment of FGM is a target in the Sustainable Development Goals (SDG target 5.3) (UN, 2015).

High-quality, ethical research on FGM is an essential component of international, national and local efforts to end the practice to enable investors, policy-makers and programmers to make evidence-based choices to maximize the impact of interventions, while ensuring that the rights of research participants are respected. Research on FGM has been conducted for many decades with no specific ethical guidance available as a resource for researchers, despite it involving a complex range of potential risks and harms that require careful consideration to maximize the value and impact of the research while minimizing the risks.

Research on FGM uses a range of study designs and methodologies. This guidance document has been developed to strengthen the ethical conduct of all research on FGM by highlighting the key ethical considerations faced by researchers developing protocols and conducting research and by research ethics committees reviewing protocols. The document is grounded in concepts from existing ethical guidance for research involving human subjects (CIOMS, 2016) as applied to research on FGM.

Due to the sensitive nature of FGM and the potential risks individuals may face when conducting or participating in research on FGM, specific guidance is needed on how to ensure that safety measures and ethical principles are addressed in all stages of research on FGM, from study design and implementation to the interpretation and dissemination of the results.

In communities where FGM is practised, questions of identity and power are closely linked to the FGM status of a girl or woman. The very nature of information that might be shared during research on FGM, and on other sensitive topics, is often personal and linked to individual and cultural identity. It is also linked with the overlapping layers of risk and vulnerability due to age, class, race, ethnicity, educational level and other individual, family or community characteristics.

When women and girls participate in research on FGM, they are potentially at risk of unintended harms, which may have implications for them and their family. When women and girls are asked about their experiences of undergoing FGM, they may be at risk of secondary trauma from the retelling of traumatic events, and fear of disclosure, or actual disclosure of their FGM status. These fears may affect their responses to questions in a context in which deviation from social norms may result in sanctions to them or their family, including social isolation and exclusion of their family from social and economic opportunities.

Individuals and groups considered vulnerable should not be excluded due to their vulnerabilities, but rather their experiences and needs should be reflected in the research. However, special additional measures may need to be put in place to ensure their inclusion and protection throughout the research process, such as ensuring that appropriate referrals and support services are offered to all research participants.

While the same principles of ethical research are applicable for all research studies, the sensitive nature of FGM means that their application requires specific consideration about how research on FGM is conceptualized and undertaken, and how the results are interpreted and disseminated. Hence, this document is structured around these three stages of research – the design stage, the implementation stage, and the analysis and dissemination stage – with key issues presented for each of these stages, as well as hypothetical scenarios and checklists to ensure that ethical considerations are appropriately addressed. It is hoped that this document can serve as a resource for researchers, research ethics committees, and anyone reviewing research protocols or interpreting research findings.

PART I: BACKGROUND

CHAPTER 1: INTRODUCTION

1.1: Research on FGM
1.2: Methodology
1.3: Types of research most frequently carried out on FGM

CHAPTER 2: OVERVIEW OF ETHICAL PRINCIPLES IN RESEARCH

2.1: Key principles
2.2: CIOMS guidelines
2.3: Existing guidance for researching violence against women, and other sensitive topics
2.4: Application of ethical principles and frameworks to research on FGM

1 INTRODUCTION

Female genital mutilation (FGM) is a harmful practice that involves the partial or total removal of external female genitalia or other injury to female genital organs for non-medical reasons (WHO, 2008). Over 200 million girls and women alive today have undergone FGM, with approximately 3 million at risk of undergoing FGM each year (UNICEF, 2016).

The World Health Organization (WHO) opposes FGM since the practice is a violation of the human rights of girls and women, including the rights of the child; the right to health, security and physical integrity; the right to be free from torture and cruel, inhuman or degrading treatment; and (when the procedure results in death) the right to life (WHO, 2008). It is also an extreme form of gender discrimination. There is widespread condemnation of FGM from a human rights perspective and the international community is actively intervening to bring about the abandonment of all forms of FGM, as evidenced by the inclusion of FGM as a target within the Sustainable Development Goals (SDG target 5.3) (UN, 2015).

1.1 RESEARCH ON FGM

High-quality, ethical research on FGM is an essential component of international, national and local efforts to end the practice, enabling investors, policy-makers and programmers to make evidence-based choices to maximize the impact of interventions, while ensuring that the rights of research participants are respected.

Research on FGM has been conducted for many decades with no specific ethical guidance available as a resource for researchers, in spite of the complex range of potential risks and harms that require careful consideration, to maximize the value and impact of the research while minimizing the risks.

Research on FGM involves inquiry on a highly sensitive and frequently traumatic practice experienced by girls and women. In some practising communities, talking about the practice is taboo. Whether or how a girl or woman has undergone FGM can have a significant impact on her status, security and life opportunities. Inherent in the communities where FGM is practised are many contradictory forces, resulting in conflicting messages in support of, and in opposition to, the practice. In some settings, FGM may be illegal technically while simultaneously being considered by some leaders within the community to be obligatory. It is considered to be a social norm (Neville, 2014; UNICEF, 2010), often deeply embedded in traditional beliefs. Some types of FGM are, in some contexts, supported by some religious leaders, although it is not a religious practice. In settings where FGM occurs, it is strongly defended and justified by powerful voices within practising communities.

This guidance document has been developed to strengthen the ethical conduct of research on FGM by informing the practice of researchers involved in research on FGM and providing guidance to research ethics committees tasked with reviewing research protocols on FGM. It applies concepts from existing ethical guidance for research involving human subjects (CIOMS, 2016) to the specific ethical considerations relating to research on FGM, recognizing the sensitive nature of the topic.

1.2 METHODOLOGY

This guidance document was informed by existing ethical guidance and developed through a consultative process with a geographically representative and multidisciplinary group of experts. The process included the following steps:

1. review of existing ethical guidance for research involving human subjects;
2. review of existing ethical guidance for research on sensitive topics – in particular, violence against women and girls and adolescent sexual and reproductive health;
3. extraction of relevant ethical principles from the *International ethical guidelines for health-related research involving humans* (CIOMS, 2016);
4. individual and group consultations with advisory group members,[1] who provided written and/or oral feedback to the draft document; and
5. peer review of the draft document.

1 The advisory group consisted of 11 experts, including research ethicists and researchers specializing in FGM or other sensitive topics, and representatives from community-based organizations and health professionals working with survivors of FGM. The advisory group was geographically representative, with members from five of the six WHO regions (these were the African Region, Region of the Americas, Eastern Mediterranean Region, European Region and South-East Asia Region) and from countries with high and low prevalence of FGM. The consultations included both individual and group discussions. They took place over a period of a week using remote technology due to restrictions necessitated by the coronavirus disease 2019 pandemic. Advisory group members were also given an opportunity to review and comment on the draft of the document.

1.3 TYPES OF RESEARCH MOST FREQUENTLY CARRIED OUT ON FGM

Research on FGM takes place in a variety of settings, particularly in health facilities and community settings, and includes a range of study designs and methodologies, depending on the research question of interest. In 2016, over half (52%) of all published research articles on FGM were on the medical and psychological consequences of FGM, with 34% focused on the prevalence and ethics of the practice and 14% on the socioeconomic consequences (Mpinga et al., 2016). This distribution is likely to shift as more emphasis is placed on generating evidence on what works to bring an end to the practice and to accelerate programmatic efforts.

Different study designs bring up different ethical challenges and this section of the document briefly describes how different study designs have been applied to research on FGM to ensure ethical principles are applied regardless of study design.

RESEARCH ON FGM FALLS BROADLY INTO FOUR CATEGORIES:

- **descriptive studies**
- **observational studies of associations/correlations**
- **experimental and quasi-experimental intervention research**
- **implementation research**

1.3.1 DESCRIPTIVE STUDIES

Descriptive studies are intended to contribute to the overall body of knowledge, including the prevalence, the drivers and the meaning of the practice in a particular setting. They can inform the development of appropriate and culturally relevant approaches to prevent FGM or mitigate its consequences by providing relevant background information or ethnographic information about affected groups. The following data sources can be used with the goal of describing or summarizing the practice and its impact on individuals or a community:

- ***Population-based household surveys*** **–** such as the Demographic and Health Surveys (DHS) or the Multiple Indicator Cluster Surveys (MICS) – include a standardized module on individual experience of FGM, attitudes about FGM and circumstances surrounding FGM. These data can be used to calculate prevalence and monitor trends over time and to make comparisons across countries.

- ***Other surveys*** **–** whether carried out in community samples, health facilities, schools or other settings – can also generate information on FGM status and experiences, and provide descriptive data about the practice.

2 Programme evaluations are not generally considered to be research and are not specifically addressed in this document; however, elements of this document are relevant to governmental and nongovernmental organizations, international nongovernmental organizations or community-based organizations carrying out programme evaluations.

(continued)

- ***Ethnographic or anthropological investigations*** involve immersion in a community for periods of time and enable the researcher to gain insights on FGM by observing and interacting with the community members to understand the cultural relevance of FGM, related power structures, social dynamics, decision-making processes, roles, norms and relations of community members.
- ***Rapid assessment processes*** use a mix of quantitative and qualitative methods to gain an overview of FGM in a specific setting, which may include identifying attitudes, beliefs and behaviours of different stakeholder groups in relation to FGM, assessing the available support services and the needs of individuals and the community.
- ***Case studies*** may use a range of methods and result in a descriptive analysis of a particular research setting, whether a country, a community or a community group.

Research participants involved in each of these methods can include participants selected because they are representative of their community, including men and boys, or because they have a specialized role, such as elders, teachers, health workers, community and religious leaders, government officials, policy-makers and other relevant stakeholders.

These methods help to increase understanding of the characteristics, beliefs, power structures and practices of communities, which can contribute to the understanding of social norms associated with FGM and enable programme managers, policy-makers and practitioners to tailor interventions to be relevant and feasible to a particular context when developing programmes to respond to FGM and eliminate the practice. Population-based data are also critical for tracking the progress of indicators for global monitoring efforts – for example, the Sustainable Development Goals (SDGs).

1.3.2 OBSERVATIONAL STUDIES OF ASSOCIATIONS/CORRELATIONS

While various study designs can be used to gather data to analyse associations between variables, the defining feature of observational studies of association is that the researcher is not testing an intervention or altering any variable, but rather observing differences between groups to explore a particular hypothesis about whether or not different variables are associated. In these studies, data may be collected cross-sectionally or longitudinally, and may relate to retrospective or prospective experiences. Individuals who have a specific condition or who have undergone an experience, such as FGM, might be compared with those who have not; or individuals with a specific risk factor or variable might be compared to determine whether they are more or less likely to have undergone FGM. For example, a study might investigate the correlation between the types of FGM undergone by women and the health complications experienced, or the awareness of young men about FGM and their support for the practice. It is important to note that causality cannot be inferred when associations are observed in observational studies, but observed associations can indicate increased risk of an outcome, requiring additional investigation.

As with descriptive studies, FGM-related data can be collected in a range of settings, including households, health facilities, schools or other community settings using a survey, questionnaire or other data-collection tools. Existing medical records or population-based surveys can also be sources of data for these types of analysis.

1.3.3 EXPERIMENTAL AND QUASI-EXPERIMENTAL INTERVENTION RESEARCH

Research on interventions can include those on:

- primary prevention interventions to prevent FGM from occurring in high-risk communities;
- secondary prevention interventions to prevent it from reoccurring in the case of infibulated women who are de-infibulated;
- tertiary prevention interventions, which involve treatment and care interventions to mitigate the health and psychosocial consequences of FGM and to actively encourage health-seeking behaviour and engagement with health systems regarding FGM-related morbidity.

Generally speaking, experimental and quasi-experimental designs are preceded by preliminary steps, which help the researcher to develop an appropriate intervention for the target population of interest and to answer the research question of interest. These preliminary steps can include any or all of the following: a literature review of the existing evidence gaps; formative research using mixed methods with relevant stakeholders to assess the feasibility, relevance and acceptability of a proposed intervention; and/or a pilot test phase to pretest the intervention on a small scale.

- An ***experimental study*** is one in which one group is exposed to an intervention (intervention group) and one group is not (control group) through random assignment to groups. Experimental studies can also be called randomized controlled trials; when pharmaceuticals or other clinical interventions are being tested, they may be called clinical trials. Random allocation can be done at an individual level or at a cluster level (e.g. health facility or community). Experimental designs provide the highest level of scientific evidence when designed well with sufficient sample size, since the study design controls naturally for the potential confounding of other variables by balancing them out through the randomization process. A study that randomizes at the individual level provides a higher level of scientific evidence than a cluster trial. Baseline and endpoint data-collection periods are a defining feature of experimental designs, with mid-term and other data-collection points also possible. The impact of the intervention is assessed through comparison of outcomes at the study endpoint between the intervention and control groups.

- ***Quasi-experimental studies*** also include baseline and endpoint, or pre- and post-intervention, data collection, but do not include randomization to different intervention conditions. Participants might self-select into groups or be assigned in a non-random manner by paired comparisons done purposively. The decision to not randomize might be made for practical or ethical reasons. The greater the degree of similarity between the study groups at baseline on potentially confounding characteristics, the lower the risk of design bias. Lack of randomization limits the scientific level of evidence and should be recognized as a methodological limitation.

1.3.4 IMPLEMENTATION RESEARCH

Implementation research in public health is a scientific approach to understanding why and how the implementation of particular programmes, policies and interventions result in desired outcomes in real-world health settings (Peters et al., 2013).

Study designs used in implementation research vary depending on the research questions to be explored. The defining characteristics are that they involve the scaling up of interventions previously shown to be effective in specific contexts, or they seek to understand barriers and conditions under which specific strategies achieve results, thereby increasing the effectiveness and impact of subsequent intervention. Examples of implementation research might include studies investigating:

- scaling up the training of midwives to counsel mothers on the impact of FGM at a health facility, having previously had positive outcomes in a pilot study;
- extending a successful school peer mentor programme on FGM prevention, from a girls' secondary school to a range of co-educational secondary schools in rural and urban settings.

Some of the reasons that public health interventions do not achieve expected results can include:

- a lack of community involvement in the design and implementation of an intervention;
- health systems processes and structures that have not been adequately mapped or understood;
- unrecognized power relations related to gender, race, ethnicity, socioeconomic status, or other power dynamics.

Specific ethical considerations in implementation research include potential effects of alterations in health systems on clients or patients who have not consented to it, or who are not aware that these approaches were being tested in the place they are seeking services. Likewise, health-care providers and other members of the health systems workforce may be participating but might not have been fully informed of this. Similarly, implementation research in a community setting may involve community members who might be unknowing research participants or recipients of an intervention. Who gives consent and who is affected by the research are important questions relating to implementation research.

When the studies are conducted appropriately and ethically, the findings of implementation research can ultimately improve how effective interventions are delivered and/or scaled up, and can ensure that particular groups are given equitable access.

2 OVERVIEW OF ETHICAL PRINCIPLES IN RESEARCH

2.1 KEY PRINCIPLES

All evidence-based policies and programmes are, by definition, based on the results of research, much of which involves human participants. How that research is conducted has implications not only for the rights and welfare of the participants, but also for the quality and validity of the results and how the findings subsequently inform programmes and policies.

Respect for persons, beneficence and justice have become widely accepted as core principles for the ethical conduct of research involving human subjects, placing ethical obligations on researchers and research ethics committees (WHO, 2019, pp. 4–5).

- ***Respect for persons*** highlights the importance of three components of informed consent (information, comprehension and voluntariness). It distinguishes between people with and without autonomy to protect their own interests, and places a strong focus on how those with diminished autonomy should be treated (e.g. children, and people without the mental capacity to protect their own interests).

- ***Beneficence*** includes two complementary intentions: do no harm; and maximize possible benefits while minimizing possible harms. Beneficence particularly manifests itself in the delicate process of the assessment of risks and benefits, which need to be considered explicitly in relation to the context of each research initiative involving human subjects.

- ***Justice*** involves issues of fairness in the selection of participants and in how the research findings are applied, ensuring that research subjects are not selected solely because of ease of accessing them or because of their vulnerability. Likewise, learning from the research should not benefit some groups more than other groups because of their status.

For research to be carried out ethically, these principles need to be applied during all stages, including research conceptualization, design, data collection, analysis and dissemination, regardless of whether the research is a population-based household survey or a health facility-based study. Given the sensitive nature of FGM and the potential for harm to participants of discussing the topic, serious consideration is required of how the risks and potential harm to research subjects could be minimized and whether they outweigh the potential benefits of the research.

2.2 CIOMS GUIDELINES

The concepts outlined in the *International ethical guidelines for health-related research involving humans* published in 2016 by the Council for International Organizations of Medical Sciences (CIOMS) are the foundation of this document and are applied to the topic of FGM. CIOMS, founded in 1949 under the auspices of WHO and the United Nations Educational, Scientific and Cultural

Organization (UNESCO), first developed research ethics guidelines in 1982, drawing on historical declarations, including the 1947 Nuremberg Code, the 1948 Universal Declaration of Human Rights of the United Nations and the Belmont Report of 1979. Subsequent revisions in 1993, 2002, 2009 and 2016 have drawn on additional authoritative documents, including the World Medical Association's Declaration of Helsinki in 2013, together with learning from the HIV/AIDS global epidemic and advances in medicine, biotechnology, human rights and research involving vulnerable populations in high- and low-resource contexts. The 2016 CIOMS guidelines reflect recent thinking in relation to the importance of translational research (i.e. research leading to improved health outcomes), fair research in low-resource settings, community engagement in research, the need to avoid the exclusion of potentially vulnerable groups and the increase in big data research.

The *International ethical guidelines for health-related research involving humans* (CIOMS, 2016) provide an authoritative ethical framework to inform decision-making for the protection and safeguarding of the rights and welfare of research participants in health-related research.

CIOMS GUIDELINES

1. Scientific and social value and respect for rights
2. Research conducted in low-resource settings
3. Equitable distribution of benefits and burdens in the selection of individuals and groups of participants in research
4. Potential individual benefits and risks of research
5. Choice of control in clinical trials
6. Caring for participants' health needs
7. Community engagement
8. Collaborative partnership and capacity-building for research and research review
9. Individuals capable of giving informed consent
10. Modifications and waivers of informed consent
11. Collection, storage and use of biological materials and related data
12. Collection, storage and use of data in health-related research
13. Reimbursement and compensation for research participants
14. Treatment and compensation for research-related harms
15. Research involving vulnerable persons and groups
16. Research involving adults incapable of giving informed consent
17. Research involving children and adolescents
18. Women as research participants
19. Pregnant and breastfeeding women as research participants
20. Research in disasters and disease outbreaks
21. Cluster randomized trials
22. Use of data from the online environment and digital tools in health-related research
23. Requirements for establishing research ethics committees and for their review of protocols
24. Public accountability for health-related research
25. Conflicts of interest

CHAPTERS 3, 4 AND 5 *of this guidance document apply the 2016 version of the CIOMS guidelines, highlighting areas where special consideration is required for research on FGM.*

2.3 EXISTING GUIDANCE FOR RESEARCHING VIOLENCE AGAINST WOMEN, AND OTHER SENSITIVE TOPICS

Since 2001, WHO has published several documents that have set ethical standards for research on violence against women, the landmark one being *Putting women first: ethical and safety recommendations for research on domestic violence* (WHO, 2001). *Putting women first* was subsequently adapted for specific populations, including trafficked women (WHO, 2003), women in emergencies (WHO, 2007), and for supporting research and testing interventions to address violence against women (WHO, 2016). While each set of recommendations was written to address the specific needs of undertaking research in a specific context, all raise ethical issues relevant to research on FGM. Annex 1 summarizes the recommendations and guiding principles from these documents in the three stages of research around which this current document is structured: (i) conceptualization and study design, (ii) implementation and (iii) data analysis and dissemination.

Contreras-Urbina and others (2019) applied the *WHO ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies* and explored ethical and methodological considerations under four headings: (1) risk-benefit assessment, (2) methodological and conceptual approaches, (3) safety considerations, and (4) analysis and research uptake. The authors highlight the importance of applying an iterative process of reflection–critique–adaptation and strong collaboration with local community leaders, to develop context-specific solutions for relevant ethical issues, including assent and consent processes for married children.

The WHO guidance for research on sexual and reproductive health topics among adolescent populations (WHO, 2018a) explores four themes that are relevant to research on FGM, namely: (1) defining adolescents as a study population, (2) determining an adolescent's capacity and maturity in the research context, (3) conflict between ethical and legal obligations in relation to adolescent research participants, and (4) information sharing. Each of these is directly relevant to research on FGM, as young people are key stakeholders and often research participants informing estimates around prevalence and attitudinal and behavioural changes.

The document outlines key considerations in consent processes, including: (1) the maturity of the young person – that is, whether or not they have the maturity to understand and participate in the research without harm or distress; (2) the legal age of consent in the specific country, considering that the United Nations Convention on the Rights of the Child defines a child as someone below 18 years of age but that age of consent varies by country and context; and (3) the need to identify an appropriate and safe adult to give consent on behalf of a young person under the age of consent, whether a parent, guardian or family member, or in the case of a young married woman, her husband, noting that there may be instances where it is not appropriate to gain consent from a guardian or family member – for example, where this might pose a risk of harm to the young person.

2.4 APPLICATION OF ETHICAL PRINCIPLES AND FRAMEWORKS TO RESEARCH ON FGM

While the principles of ethical research outlined in **SECTION 2.1** are applicable for all research studies, the sensitive nature of FGM means that their application requires specific consideration into how research on FGM is conceptualized and undertaken, and how the results are interpreted and disseminated.

Research ethics committees and research teams need to understand the intensely private nature of individual experiences of FGM and the risks women and girls may be exposed to as a result of participating in research on FGM. The concepts of privacy, vulnerability and confidentiality need to underpin all stages of the research process. The concept of voluntariness is also a core ethical principle of research in making informed choices about whether or not to participate. Voluntary participation is contingent on the protection of privacy and confidentiality of participants, while ensuring that their rights are protected, especially for vulnerable groups, and that principles of non-coercion are addressed throughout the research process.

PRIVACY

The right of research participants to privacy is a fundamental element of ethical research. Researchers must ensure that participants are in control of the type and level of information they choose to divulge about themselves throughout the research process, and that personal information is collected and stored in a way to ensure privacy.

Santi (2016) draws a distinction between private information provided during biomedical research and the sharing that occurs in qualitative research, of intimate and sometimes traumatic experiences. In communities where FGM is practised, questions of identity, power and voice are intimately linked to the FGM status of a girl or woman. Therefore, the very nature of the information that might be shared during research on FGM or other sensitive topics is often highly personal and linked to personhood. Consequently, consideration needs to be made to ensure that, throughout the data-collection process, research participants have trust in the people interviewing them and that they do not feel coerced to disclose a greater depth of information than they are comfortable with.

VULNERABILITY

The appropriate protection of vulnerable persons is central to undertaking ethical research, recognizing that contextual factors play a significant role in determining the different forms of vulnerability of individuals and groups (CIOMS, 2016; Bracken-Roche et al., 2017).

When women and girls participate in research on FGM they are potentially vulnerable to a range of psychosocial and physical harms, which may have immediate and long-term implications for them and their family.

When women and girls are asked about their experiences of undergoing FGM, they may be at risk of unintended harms or secondary trauma from the retelling of traumatic events. In addition, in communities where the prevalence of FGM is high, there are often sanctions imposed on people who do not conform to the social norms associated with the practice (UNICEF Innocenti Research Centre, 2010). These sanctions may extend to the family, which may become vulnerable to social isolation and practical sanctions – for example, a family being excluded from community decision-making as well as social and economic opportunities.

Luna (2009) discusses "layers" of vulnerability, with each additional layer adding to the degree of an individual's overall vulnerability, and that these vulnerabilities should be acknowledged and addressed throughout the study. Measures taken should not influence decisions about participation or the validity of responses. If they are not addressed, these vulnerabilities can bias recruitment, the validity of responses and the overall validity of findings, as well as put participants at risk of unintended harms. A male community elder in an FGM-practising community, for example, might be vulnerable to disapproval and social isolation if it becomes known that he opposes the social norms on FGM. A young girl in the same community may have additional layers of vulnerability because of her age and sex as well as her FGM status, making her vulnerable to secondary trauma from the retelling of her experiences. A midwife might experience pressure to perform FGM, which would have implications for her status or livelihood; or a mother may be vulnerable to social isolation if she chooses not to have her daughter undergo FGM, thereby not conforming to social norms. In this way, Luna argues that women and girls may have more layers of vulnerability to harm than others in their community, which need to be addressed throughout the research process.

These vulnerabilities can be mitigated to some extent with procedures in place to protect privacy and to maintain confidentiality; however, it is difficult to eliminate them completely. Appropriate support services and referrals should be put in place during – and preferably continue after – the research. These should be accessible to all research participants, including individuals or communities in control groups.

It is important that vulnerable groups and individuals are not excluded from research on FGM since their perspectives can better inform findings, but measures need to be in place to ensure that they have access to participation and have adequate protection from harms (CIOMS, 2016).

CONFIDENTIALITY

The purpose of managing confidentiality throughout the research process is to reduce the risk of harm through the disclosure of sensitive data that could be attributed to specific research participants.

When researching FGM, sensitive data include:

- ***personal information*** (e.g. sociodemographic and biometric data, clinical records, FGM status);
- ***experiences*** (e.g. an account of a girl or woman undergoing FGM, health complications arising from FGM, sanctions experienced by someone opposing the social norms on FGM);
- ***beliefs*** (e.g. cultural or religious beliefs in relation to FGM, opinions for or against abandoning FGM);
- ***behaviours*** (e.g. whether a mother intends for her daughter to undergo FGM, accounts of speaking out on FGM).

Members of the research team are responsible for establishing the overall framework within which confidentiality is managed by ensuring:

- appropriate procedures and protocols are in place to ensure data are anonymized and stored securely to avoid individual identification;
- research team members are trained and provided with the resources required to adhere to the protocols on confidentiality;
- community leaders, community mobilizers and other key members of host communities are aware of the protocols on privacy and confidentiality;
- research participants, particularly in focus group discussions, are made aware of their responsibility to maintain confidentiality of information shared by other research participants; and
- confidentiality is maintained in the dissemination phase, including not disclosing any identifying information that can link to individuals in the presentation of results.

PART II: ETHICAL PRINCIPLES AT ALL STAGES OF RESEARCH

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3 STUDY DESIGN

3.1 JUSTIFICATION OF RESEARCH

The ethical justification for undertaking research on FGM requires the potential scientific and social value of the study to outweigh any potential harm to research participants. CIOMS states that, "Scientific and social value cannot legitimate subjecting study participants or host communities to mistreatment, or injustice" (CIOMS, 2016, guideline 1).

There are three linked questions when justifying a specific research study.

? i. *What is the scientific and social value of the study and how might the research bring about positive change?*

Existing research on FGM has generated quantitative and qualitative data from different settings on a wide range of topics, including to determine prevalence rates and trends; drivers of the practice; and to some extent what works to address the practice. Future research should focus on addressing knowledge gaps to inform new policies and programmes.

Current thinking in research emphasizes the need for research to be applied or translational – that is, research that is explicitly focused on acquiring new knowledge likely to result in improved health and social outcomes (CIOMS, 2016). It follows, therefore, that research proposals should include a clear statement of the knowledge gaps on FGM to be addressed and a clear description of the intended application of results for advocacy, policy-making and/or programming.

? ii. *Would the overall benefits of undertaking the research outweigh the risks/costs to individuals and communities?*

CIOMS recommends a two-step approach (CIOMS, 2016, guideline 4): first, assess the potential benefits and risks to the individual research participant when engaging in any specific research activity; second, assess the aggregated benefits and risks of the entire study. The benefits will include the scientific and social value of the research in contributing to the improved health and well-being for survivors of FGM, the development of more effective interventions to reduce the incidence of FGM and/or the impact of FGM on the lives of girls and women who have already undergone the practice. With research on FGM, the benefits are often indirect rather than direct; and medium to long term, rather than immediate or short term.

When inviting women and girls to participate in research, whether it be a facility- or community-based study, the assessment of the benefits and risks needs to take into account whether:

- participants are reporting on their past experiences and what impact that might have on them; and
- participants will be randomized to different conditions or groups, and what the potential risks are of being assigned to those groups.

Processes must be in place to:

(a) explain the potential benefits of the research to participants and how the findings will be disseminated; and

(b) minimize the potential risks of harm, including respecting privacy and maintaining confidentiality.

The risks of research on FGM include:

- the potential physical, psychological and psychosocial harm to individuals of reliving traumatic experiences, and potential repercussions by community members for their participation;
- the commitment required by communities to support the research processes, and the risk of increased tension through exposing differences in beliefs and attitudes; and
- the potential harm of unmet expectations of interventions to improve quality of life.

Community-based participatory research (CBPR; **see box**) can potentially increase the beneficence of the research for participating communities since communities are involved from the conceptualization of the research throughout the process, and researchers are usually already recognized and respected members of the study communities. In CBPR, communities should be actively involved in providing accurate information, correcting misperceptions, and identifying and limiting unintended risks of the research. This can be done through discussing potential research with community leaders and at community forums, training community members as research team members, and disseminating research findings in the local language(s) through workshops or using appropriate channels such as radio.

COMMUNITY-BASED PARTICIPATORY RESEARCH

Community-based participatory research (CBPR) is a specific form of community-based research that involves community members in research design, implementation and dissemination. By definition, CBPR nurtures a close partnership between researchers and community stakeholders, and joint ownership of the research process and findings (Johnson et al., 2009). This process can lead to an enhanced understanding of the power structures affecting the community and the perspectives and needs of community members; it can encourage the development of interventions acceptable and appropriate to the community. By taking into account the social and cultural dynamics of communities, CBPR pre-emptively identifies bottlenecks and obstacles to implementation and may overlap with implementation research models and methodologies.

Regardless of the study design, the principles of CBPR can be applied to a broad range of community-based research on FGM.

iii. *What would be the appropriate study design?*

Decisions about research design and methodology are based on the research questions of interest, while being aware of the private and sensitive nature of women's and girls' experiences in relation to FGM.

Where studies include quantitative data collection, issues of sample size and sample selection require careful consideration to ensure the results are representative of the population of interest and that the study has an adequate sample size and statistical power to answer the research question.

Where data collection is qualitative, including in-depth interviews, focus group discussions and other qualitative methods, the study design should provide safe spaces within which research participants can control the extent to which they talk about their experiences.

The use of hypothetical vignettes – where research participants are invited to explain how they or others in their community would respond to specific scenarios – can be useful in exploring social norms relating to FGM without participants having to disclose illegal or stigmatized behaviours.

Most data on prevalence and type of FGM come from population-based studies, such as the DHS or MICS, which include a module on FGM and rely on self-reporting of one's own or one's daughter's FGM status. Correlation between self-reporting and clinical examination has been shown to be generally high, although girls and women may not recall or be aware of the type of FGM they have experienced (Elmusharaf et al., 2006). Some studies capture FGM status during health-care visits, which would be appropriate only if a genital examination was warranted during the medical visit, either as part of routine gynaecological care or for management of a specific complication. Informed consent explaining how the information will be used for the purpose of research would be required.

Where the research assesses the impact of specific interventions, experimental or quasi-experimental methodologies are preferable when appropriate and feasible. Experimental study designs have the advantage of enabling scientific comparisons to be made between those individuals or communities exposed to the interventions and those who have not been exposed (control communities). The benefits and risks need to be weighed for control individuals and communities. Adopting a stepwise study design – where control individuals or communities receive the intervention in subsequent phases of the study – can ensure that all engaged in the research are exposed to the intervention if it proves to be effective.

Quasi-experimental studies that use pre- and post-measurement to assess the potential impact of an intervention without control groups can be valuable in identifying and understanding changes over time. However, changes due to other factors not controlled for cannot be ruled out – for example, changes in policy on FGM or community characteristics. While quasi-experimental designs can be a practical solution in cases where scientific designs might not be feasible or ethical, it is important for researchers not to infer causality and not to attribute observed changes to the intervention since the study design would not support these conclusions (see **HYPOTHETICAL SCENARIO F** on page 41).

With implementation research – that is, where evidence has shown that the intervention is efficacious and the research is either focused on the scale up of the intervention or determining effectiveness in a real-world setting, in new contexts or with specific groups – community engagement is essential to assess the population health needs and priorities and to understand implementation challenges (Gopichandran et al., 2016, p. 3).

3.2 LEGAL STATUS OF FGM

The legal status of FGM in the country where research is taking place impacts how the research is conceptualized, justified and undertaken. However, the legal status of FGM is both complex and in some cases contentious.

It is widely accepted that FGM violates well-established human rights principles. These include the principles of equality and non-discrimination on the basis of sex; the right to life when the procedure results in death; and the right to freedom from torture or cruel, inhuman or degrading treatment or punishment; as well as the rights of the child. FGM was named in the 1979 Convention on the Elimination of all forms of Discrimination against Women (general recommendation number 14). SDG 5, which aims to achieve gender equality and empower all women and girls, includes target 5.3 – to eliminate all harmful practices, such as child, early and forced marriage and FGM by 2030.

Most countries contend that their national law is underpinned by the principles of human rights. However, not all countries have legislation on FGM. The World Bank *Compendium of international and national legal frameworks on female genital mutilation* summarizes the domestic legislative position in 84 countries where there are specific or general laws prohibiting FGM (World Bank, 2020). Where legislation on FGM exists, it varies in whether FGM is named specifically or considered to fall under a broader definition of violence, bodily harm or discrimination. Public understanding of the law on FGM tends to be limited. There are wide variations in what is considered to be illegal (e.g. performing FGM on any girl or woman, or performing FGM only on girls under the age of consent); who is subject to prosecution; whether it falls under criminal or constitutional law; the penalties and how the law is applied. The number of prosecutions is low. In most countries where there is legislation on FGM, the penalties include custodial sentences and/or fines. In some places, the law on FGM is used as the justification for the separation of a daughter from her mother, putting girls at risk of other forms of abuse.

In countries where FGM is illegal, researchers may be asking research participants to disclose illegal activities. This has implications in terms of:

- the willingness of potential participants to consent to participate and to provide accurate information on their personal experience or behaviour;
- research team members being clear about their role and what action to take when collecting data, if illegal actions or intentions are disclosed; and
- ensuring confidentiality when participants are asked to disclose illegal actions, and considering indirect ways of exploring these issues – for example, through vignettes or hypothetical scenarios.

HYPOTHETICAL SCENARIO A

Research relevance

BACKGROUND:

A research team that has extensive experience conducting research on child health is encouraged by colleagues to conduct research on the drivers of FGM, since the institution will be eligible for funds specifically related to research on this topic. The research team is based in a country that has high levels of FGM and many members of the team have an interest in this topic; they therefore decide to take up this recommendation so they can learn more about this important public health issue. The team writes a proposal for a descriptive study using mixed methods, including interviewing a range of stakeholders.

ETHICAL CHALLENGE:

Since the research team is not well acquainted with the topic of FGM, they are not aware that there are several existing studies, some from the country where they are based, exploring the drivers of FGM. The research they are seeking to carry out will not fill relevant research gaps and will likely duplicate existing studies.

PROPOSED SOLUTION:

Before developing the proposal, the research team should carry out a literature review to determine the relevance of their research questions and to ensure that their study fills a research gap and does not duplicate existing efforts. They should also meet community leaders, health providers and opinion formers, including those representing women and girls, to ensure that their research is relevant and feasible in the specific context, with a preference for research that will inform the development of a programmatic initiative or test the effectiveness of an existing programmatic intervention.

3.3 THE AMBIGUITY OF LANGUAGE IN RELATION TO FGM

The WHO classification on FGM provides a definition of the types of FGM (WHO, 2018b, pp. 26–33; see TABLE 1). However, when talking to community members, the ambiguity of the language used in relation to FGM becomes apparent. For example, in many practising communities, the term "to purify" can be used to refer to different types of FGM. In communities where infibulation is commonly practised, the terms FGM and FGM/C (female genital mutilation or cutting) are often seen as referring primarily to WHO types 2 and 3, resulting in some people campaigning for zero tolerance on FGM, yet supporting types 1 or 4 locally (Newell-Jones, 2017, p. 14). In addition, the same term can be used to refer to different types of FGM, as in Somalia, where "sunnah" can refer to WHO types 1 or 4 and sometimes type 2, potentially resulting in underreporting of type 2 (Elmusharaf et al., 2006; Crawford and Ali, 2015). Communities may perceive themselves as abandoning FGM when stopping one type of FGM, while remaining strongly committed to another that is seen as less harmful (Crawford and Ali, 2015, p. 81; Newell-Jones, 2017). There might also be euphemisms or other coded ways of referring to FGM without actually specifying it. In the Mano River region of West Africa, for example, phrases like "joining the secret society or the bondo" are used to refer to FGM (Bjälkander et al., 2013).

TABLE 1. WHO classification of FGM

TYPE 1	Partial or total removal of the clitoral glans and/or the prepuce.
TYPE 2	Partial or total removal of the clitoral glans and the labia minora with or without removal of the labia majora.
TYPE 3	Also known as infibulation, this is the narrowing of the vaginal opening through the creation of a covering seal. The seal is formed by cutting and repositioning the labia minora, or labia majora, sometimes through stitching, with or without removal of the clitoral glans or prepuce.
TYPE 4	This includes all other harmful procedures to the female genitalia for non-medical purposes, e.g. pricking, piercing, incising, scraping and cauterizing the genital area.

It is important, therefore, to use accessible language while also seeking clarity of meaning. The DHS uses standardized terminology such as "removal of flesh". While this terminology may not be specific in terms of typology, it does ensure accessible language and concepts, and comparability across settings. With qualitative research involving discussions with community members, local terms relating to FGM should be used, while also sensitively seeking clarification as to their precise meaning.

Equally important is the need for research participants to be able to participate in a language in which they feel comfortable talking about FGM. Therefore, research tools and consent forms need to be available in local languages. The translation process needs to ensure that the specificity of the question is not lost in translation and is accurately reflected in the local languages. Back translations can be used to ensure accuracy of language. The literacy complexity and vocabulary used in translation should also be appropriate to the research participants, distinguishing between language used with health professionals, for example, as opposed to community members. It is better to avoid using non-specific terms – such as "sunnah" – and researchers should seek further clarification on what the research participant means when using a specific term.

Equally important is the need for effective training of research team members, including on pretesting the tools, so that they feel comfortable using the selected terminology, understand its precise meaning, and are able to clarify where appropriate.

HYPOTHETICAL SCENARIO B

Use of standardized language

BACKGROUND:

A research team is conducting a population-based study in an emergency setting with displaced persons to understand the health and psychosocial needs of the population being served in this setting. The researchers suspect that many of the women have experienced multiple forms of trauma and they would like to assess the constellation of their experiences, including FGM, to ensure that programmes and services are appropriately responding to their needs. Since FGM is one of many topics of interest, the research team is exploring how to ask about FGM status.

ETHICAL CHALLENGE:

The phrasing of questions to assess FGM status can have implications for the validity of the data. Researchers who are not familiar with the topic or who may be inquiring about FGM status as a secondary topic in a survey might opt for a more general question, such as, "Have you ever undergone female genital mutilation or cutting?" This question can lead to underreporting if women do not consider the procedure they underwent to be FGM. Carrying out research that underestimates prevalence rates of FGM because of inadequate measurement is unethical because it will adversely affect resource allocation due to biased results.

How can questions about a woman's FGM status be asked sensitively while also providing accurate and comparable information?

PROPOSED SOLUTION:

The DHS and the MICS, two population-based surveys, include modules on FGM that are administered in countries where FGM is practised. These modules are considered valid and reliable measures of self-reported FGM status. The questions ask women about the extent of their FGM experience, including a question on whether their genitals have been cut, whether flesh has been removed and whether they have been stitched closed. The advantage of these standardized questions is that responses can be compared across settings and they are considered valid measures of reporting.

The use of local terminology familiar to the study population can be a sensitive way for interviewers to introduce the topic of FGM. Wherever possible, researchers should then use standardized terminology to clarify the responses to increase the accuracy and comparability of the data.

3.4 COMMUNITY ENGAGEMENT

Research or other engagement with practising communities around cultural practices that are considered harmful by human rights standards might be perceived as a form of cultural imperialism, with researchers or advocates being seen as outsiders bringing in external agendas not aligned with local values, attempting to persuade communities to abandon local practices.

Much of the research on FGM takes place in a community setting. The level of community engagement in community-based research on FGM varies considerably. Since 2016, there has been a call for increased community engagement in research on health-related issues (CIOMS, 2016) (also see section 2.2 on page 8 on CIOMS guidelines).

CIOMS GUIDELINE 7 emphasizes the value of community engagement in the research process.

"***Community engagement*** is a means of ensuring the relevance of proposed research to the affected community as well as its acceptance by the community. In addition, active community involvement helps to ensure the ethical and social value and outcomes of proposed research." (CIOMS, 2016, p. 25)

"***Active engagement with community members*** is a mutually educative process, which both enables researchers to learn about communities' cultures and understanding of research-related concepts, and contributes to research literacy by educating the community about key concepts critical for understanding the purpose and procedures of the research." (CIOMS, 2016, p. 26)

This type of engagement, through focusing on raising awareness and encouraging community dialogue, rather than on educating communities, is essential for topics such as FGM. It must be sustained throughout the research process from conceptualization through to the data analysis, interpretation and dissemination of results (Johnson et al., 2009; Gopichandran et al., 2016; Contreras-Urbina et al., 2019; Barrett et al., 2020).

The advantages of ensuring community engagement from the outset of the study include:

- mutual learning between the research team and the community stakeholders developing trust and shared commitment to the research (CIOMS, 2016);
- community stakeholders providing insights to the research team regarding the community's culture, structures and dynamics (Johnson et al., 2009; CIOMS, 2016, guideline 4);
- community stakeholders understanding key concepts of ethical research (e.g. informed consent and confidentiality) and supporting the application of these throughout the research process;
- active engagement of the community leaders, religious leaders and other opinion formers in relation to FGM who may be gatekeepers to community members participating in the research (Gopichandran et al., 2016);
- shared understanding of the research findings by the research team and the community stakeholders;
- strengthening the social value of research, leading to increased use of the study findings to inform the development of evidence-based programmes and interventions to end FGM (CIOMS, 2016, p. 30).

3.5 RESEARCH CAPACITY-BUILDING

CIOMS supports the establishment of collaborative partnerships to build local research capacity, stating that: "Health-related research often requires international collaboration and some communities lack the capacity to assess or ensure the scientific quality or ethical acceptability of health-related research proposed or carried out in their jurisdictions. Researchers and sponsors who plan to conduct research in these communities should contribute to capacity-building for research and review." (CIOMS, 2016, p. 29)

CIOMS suggests that collaborative partnerships may present ways of managing power inequalities between external and local research teams and may promote inclusion, mutual learning and social justice. Three steps are suggested: determining the local research agenda; determining capacity needs or priorities among partners of international health research; and creating a memorandum of understanding or other agreement (CIOMS, 2016, p. 30). Collaborative partnerships should lead to joint publications, wherever possible using open-access publication platforms to extend the accessibility of research findings.

Capacity-building among community members to gain skills to engage in research is an element of CBPR, which involves an iterative process of analysis of the challenges in relation to FGM, data collection, and engaging in the data analysis and interpretation of findings. This in turn feeds back into enhanced interventions at the community level (Johnson et al., 2009).

CIOMS GUIDELINE 8 particularly emphasizes the responsibility of people conducting research to build research capacity as part of the research process (CIOMS, 2016, pp. 29–31). Data on FGM can be complex and open to misinterpretation. Community-based organizations (CBOs) have a role to play in informing research questions, and as key stakeholders, they should be consulted by research teams during the research process. They are also well placed to generate or interpret evidence on their programmes, although they may lack the skills to carry out research. Capacity-building of local organizations – particularly on interpreting research and conducting evaluations – could potentially enhance the translation of research findings for practical purposes (Askew, 2005).

3.6 OBTAINING INFORMED CONSENT

Obtaining informed consent for any research involving human subjects requires ensuring adherence to the concepts of sharing information, of comprehension and of voluntariness, while considering the capacity of the participant to consent (WHO, 2018a).

The sensitivities around FGM and the potential for harm create unique challenges in applying these concepts. The privacy of research participants – including community members, health workers and FGM practitioners – should be respected, meaning they should be able to choose the level of disclosure they are comfortable with and be able to withdraw at any stage without question (Santi, 2016). In this way, informed consent is best described as an ongoing process during the research process, rather than a single event (CIOMS, 2016). Informed consent is usually given by research participants in writing. However, in contexts where agreements tend to be made orally, rather than in writing, or where potential research participants do not read and write with confidence, verbal consent – which is then recorded by the research team – may be more appropriate.

Information – Potential research participants should be provided with sufficient information to make an informed decision about their consent to participate in the study. The *International ethical guidelines for health-related research involving humans* (CIOMS, 2016) provide a checklist of the types of essential information that should be shared during the consent process to ensure that potential participants make an informed decision. These types of information include the purpose of the research, what participation would involve, the voluntariness of participation, any money or other resources provided in return for participation, any potential individual risks or benefits of participating, the potential benefits of the research to society, provisions to maintain confidentiality and any limitations to these provisions, how the data will be stored and used, and how the findings will be disseminated. With clinical research, patients should be aware of their right to see their clinical records, and there should be a full disclosure of the risks of any treatment and the potential for compensation in the event of adverse effects.

Comprehension – Comprehension is about ensuring that the information is given in a language and manner that is accessible, with appropriate opportunities for participants to ask questions and confirm their understanding. Occasionally, specific information about the study might be withheld from potential research participants for two reasons. First, to avoid social desirability bias, the consent process should include enough information about any sensitive topics to be covered but not the specific research questions to be explored. Second, to protect respondents from potentially harmful questioning by their peers; for example, in a community in which talking about FGM is taboo, a general term like "women's health" rather than FGM might be used when introducing the research to a group in a school or health centre or even when describing it to a community (WHO, 2001). The precise nature of the research would then need to be explained as part of the individual process of obtaining informed consent.

Voluntariness – Potential research participants, regardless of study design, should be aware that participation is voluntary, that there will be no repercussions if they choose not to be involved, and that they can withdraw at any time without being required to give a reason.

The following are examples of ensuring voluntary participation.

- In health facility–based research, patients need to have confidence that there will be no repercussions in terms of the type or quality of care they receive if they decline to participate in a study or withdraw after a period of time.
- In research involving health workers as research participants, they need to be confident that there will be no professional repercussions, regardless of whether they agree or decline to participate, or choose to answer only some questions.
- In population-based household surveys, where questions about FGM might become more personal in nature as the interview progresses, research participants need to be aware that they can decline particular questions or halt the interview at any time without question.
- In focus group discussions, participants need to be aware that they can choose which parts of the discussion they contribute to and are not placed under any pressure to contribute at any time.

Capacity – For potential research participants to be able to give informed consent personally, they must have the maturity to understand the nature of the research, be fully aware of the voluntariness of their participation, and be able to weigh up any benefits or potential disadvantages of participating. People without the capacity to give informed consent, either on the basis of age or mental capacity, should not be included unless an appropriate guardian has given informed consent on their behalf and they have indicated their assent to participate (CIOMS, 2016).

Age, assent and informed consent – Most existing data on FGM prevalence among children are reported by women about their daughter's FGM status during population-based household surveys, such as the DHS and MICS. The active participation of children and adolescents as research participants on FGM provides an important perspective as they are the cohort in whom changes are most likely to be observed and they are the decision-makers of the next generation.

CIOMS (2016) and the WHO *Guidance on ethical considerations in planning and reviewing research studies on sexual and reproductive health in adolescents* (WHO, 2018a) indicate that in most cases young people under 18 years old are unable to give informed consent to participate in research. Prior to their involvement as research participants, informed consent is required by the parent or guardian in addition to assent by the young person. The CIOMS section on assent explains that for a child or adolescent to give assent means that he or she is "meaningfully engaged in the research discussion in accordance with his or her capacities", that "the researcher must involve the child or adolescent in the actual decision-making process and use age-appropriate information", and that the assent processes "must take into account not only the age of children, but also their individual circumstances, life experiences, emotional and psychological maturity, intellectual capabilities and the child's or adolescent's family situation" (CIOMS, 2016, p. 67).

There are circumstances in which it is considered acceptable for young women to be considered to be emancipated minors, "freed from parental custody or control, and empowered to make autonomous decisions in particular contexts" (WHO, 2018a, p. 7). Examples include data collection for the DHS and MICS where female household members between the ages of 15 and 49 years are interviewed. There are also circumstances in which the guardians might not necessarily have the best interests of the young woman in mind, as illustrated by Contreras-Urbina and others (2019) when researching violence against women and girls in South Sudan, as many of the parents were absent and guardians might have been abusers or did not necessarily have the best interests of the young women in mind. Similarly, where a young woman, 15–18 years of age, has children with a partner, it might be inappropriate, and even pose a risk, to seek informed consent from her partner. In each of these situations, informed consent should be obtained through the same process used for those 18 years of age and over following the principles described above.

The research brief from the United Nations Children's Fund (UNICEF)*, Inclusion with protection: obtaining informed consent when conducting research with adolescents,* supports the recognition of emancipated minors, stating that, "Informed consent can often be obtained directly from adolescents, particularly for minimal risk studies" and "wherever possible, adolescents should be able to consent independently if they are capable of understanding the nature and consequences of the research or service and are able to assess their own best interests" (Santelli et al., 2017, p. 15).

CHECKLIST

STUDY DESIGN

Research teams and research ethics committees have responsibility for the following aspects of ethically conceptualizing, designing and justifying research on FGM.

Positioning the study in the wider research context:

- ○ The research builds on existing knowledge and previous research on FGM and addresses specific knowledge gaps.
- ○ The research is grounded in a theory of change model.
- ○ The research is expected to result in new knowledge and/or understanding about FGM.
- ○ National stakeholders on FGM have been appropriately involved in the conceptualization of the study.
- ○ The local, national and international benefits of undertaking this research are articulated in measurable terms.

Engagement with the community – understanding the local context and engaging local stakeholders:

- ○ Local stakeholders and opinion formers on FGM have been involved in the conceptualization of the research.
- ○ Local stakeholders have been actively involved in the assessment of potential benefits and risks of undertaking this research and have agreed that the potential benefits outweigh the risks of harm.
- ○ The capacity-building of local organizations has been incorporated into the research process.

Minimizing risks to research participants:

- ○ The range of potential risks to research participants (physical, psychological and psychosocial) of participating in the research are identified, including the potential sanctions to which community members opposing social norms might be subjected.
- ○ Active measures have been incorporated in the study design to minimize the risks of harm for all research participants.
- ○ Appropriate support and referral services are available and/or individuals have been identified and adequately trained to provide support and protection.
- ○ Accurate information on FGM, and related protection and support services are provided, and any participant requiring additional support as a result of study participation will have access to these services, including participants in control arms.
- ○ Systems are incorporated into the study design to monitor risks to participants throughout the research process.

Methodology:

- The methodology takes into account cultural sensitivities in relation to FGM in the research settings.
- The study design places justice at its core, ensuring the balance of benefits and risks at the level of the individual and the group as well as the overall study.
- The sampling strategy is appropriate for the research question(s).
- Any information given or questions asked are explicit, unambiguous and use appropriate local language.
- Sensitive and standardized processes are in place to protect privacy and to obtain informed consent, including for participants under 18 years of age.
- Systems and protocols are in place to manage confidentiality throughout the research process.
- Research tools and techniques are developed collaboratively with appropriate local stakeholders and are adequately piloted.
- Dissemination processes at local and national levels are included in the research design.
- Regardless of whether FGM is the primary or secondary aspect of the research, appropriate systems and processes are in place to ensure adequate training and support on FGM for the research team members.

Selection, training and support for research team members:

Research team members are principal investigators, data managers, statisticians, research assistants and research coordinators. Data collectors are generally not considered part of research teams, although in small-scale studies, research team members might do some or all of the data collection.

- Appropriate procedures are developed for the selection of research team members and data collectors, and ensure the appropriate skill mix while also reflecting the participating communities and stakeholder groups.
- Any potential conflicts of interest of the research team are declared and resolved.
- Adequate training and ongoing support for all the members of the research team and the data collectors are incorporated into the planning process, with particular emphasis on the sensitive nature of research on FGM.
- Data collection among women and girls on FGM-related topics, such as personal beliefs and experiences related to FGM, should be conducted by female data collectors, unless the participant is selected because of their professional role (e.g. health-care provider, policy-maker), in which case the sex of the data collector does not need to be restricted.
- The range of potential risks to data collectors and research team members (physical, psychological and psychosocial) of participating in the research have been identified, including any potential sanctions or adverse consequences for community members involved in data collection.
- Active measures have been incorporated in the study design/protocol, to minimize the risks of harm for all involved in the research.
- Appropriate debriefing will be available to all research team members and data collectors, and support will be available to any individuals adversely affected by their engagement in the research study.

4 STUDY IMPLEMENTATION

4.1 SAMPLE SELECTION

Selection of sites, whether they are communities or facilities, and selection of individual research participants should be based on a clearly stated methodology and selection process, appropriate to the study design. As with any sensitive topic, individuals who are most willing to talk about FGM, or who are put forward to talk about it, might not be representative of the population of interest. Research teams should avoid allowing sampling decisions to be influenced by power dynamics, which could bias the results due to non-representativeness, and which could limit the application of research findings to excluded groups.

4.2 RISKS TO RESEARCH PARTICIPANTS AND RESEARCH TEAM MEMBERS

Research participants and research team members may be exposed to a range of physical, psychological and psychosocial risks by engaging in research on FGM. Managing these potential risks is a key element in ensuring the overall beneficence of the research.

RESEARCH PARTICIPANTS:

Undergoing FGM is for many girls and women a traumatic experience. The retelling of these experiences is deeply personal and affects different people in different ways. For some, the retelling, or hearing others relating their experiences, can restimulate their original trauma. For a few, they might realize for the first time that they have gone through FGM, or that they underwent a more severe form of FGM than they had previously realized. For others, if handled sensitively, having the opportunity to share their experiences of undergoing FGM can be a validating experience, confirming that what they went through was harmful and a violation of their rights.

Women and girls might become distressed at retelling their personal experience of undergoing FGM, or reveal deeply held senses of life chances lost through FGM, or bitterness at those who made decisions on their behalf or those who did not protect them from harm. Girls who have not experienced FGM may be traumatized by hearing the details from others through the research process or from friends confiding in them after being interviewed.

Men and boys might become distressed at hearing experiences of FGM, or from a realization of the trauma that those close to them have undergone. They might be unaware of what had taken place in the past or about how harmful the practice is to the health and well-being of women and girls.

Teachers might become distressed at being made more aware of the experiences of girls and young women in their classes undergoing FGM, or feel a sense of regret that they failed to protect or support them adequately. Tensions might also increase between teachers with different views on FGM, which may have been exposed or triggered through the research process.

Where confidentiality is not fully respected and maintained by research team members and other research participants, research participants might be subjected to psychological or physical abuse as a result of information being disclosed outside the research context. Focus group discussions can be challenging to manage when discussing sensitive topics such as FGM and should be used with caution due to the sensitivities around disclosure and confidentiality in a group setting. The responsibility of maintaining confidentiality in focus group discussions is shared between the research team and the participants. The research team is responsible for confidentiality in relation to the storage of the data and their use in reports and the dissemination of findings. It is equally important that the focus group participants take responsibility for confidentiality within the community. Information revealed in focus group discussions may increase tensions in the community, if different views are expressed on FGM or personal experiences are shared.

In addition to triggering feelings of distress, anxiety or guilt about FGM, the research process might result in the disclosure of an individual's FGM status that they had previously chosen to keep secret. They, or their family, might be subjected to sanctions imposed by the community on people who do not conform to the community social norms on FGM. These sanctions might include a reduction in a girl's marriage prospects, or the community stigmatizing a family and refusing to interact with them, or professional consequences.

In communities where the majority of girls and women have undergone FGM, those who have not undergone the practice experience the greatest social sanctions and stigma. However, where a community is in the process of abandoning FGM, there are accounts of girls and women who previously underwent FGM, or who underwent a more severe type of FGM than is now practised, being subjected to discrimination and reduced marriage prospects (Newell-Jones, 2017, p. 27).

RESEARCH TEAM:

Research team members and data collectors researching sensitive topics such as FGM may be subjected to pressure, threats or even abusive behaviour because of their involvement in the research, given the taboo nature of the topic or strongly held beliefs among community members. The research team can take measures through dialogue, transparent engagement and collaborative planning from the outset of the research.

Data collectors and research team members – particularly those with personal experiences of the practice – may experience vicarious trauma or secondary trauma from reliving their own experience. As explained by Contreras-Urbina et al. (2019), "while emotional engagement can be a tool for researchers to provide a safe and comforting environment for participants, it can also carry an emotional cost for the researcher" (p. 9). Researching any sensitive topics can result in significant personal distress.

The personal safety of data collectors, especially women, should be taken into account throughout the research process, especially where research includes individual interviews.

Data collectors from within the community or a neighbouring community being researched may be perceived as trying to bring about change that undermines local culture. Data collectors from outside the community that is being researched might be considered outsiders trying to introduce external agendas. These concerns can affect the safety of the data collectors as well as the accuracy of the data collected, demonstrating the need for gaining endorsement from the participating communities and following safety protocols at all stages of the research.

HYPOTHETICAL SCENARIO C

Protecting confidentiality in group settings

BACKGROUND:

A research team is undertaking an observational study to measure the impact of an alternative rites-of-passage (ARP) programme. The ARP programme replaces the traditional FGM ceremony with an activity that celebrates girls' passage from girlhood to womanhood through dance, song and learning about local cultural practices, without the girls undergoing FGM.

In addition to carrying out a survey to measure changes in attitudes and practice in relation to FGM among families participating in this programme, the research team intends to conduct focus group discussions with some of the mothers whose daughters participated in the ARP programme.

ETHICAL CHALLENGE:

Focus group discussions can be an excellent way to understand the perceptions and views of participants when the groups are well structured and moderated. However, personal and confidential information might be shared in the focus groups. This information could result in the stigmatization of individuals and their families if shared beyond the focus group discussion.

How might the research team minimize the risk of confidential information being shared outside the focus group discussion?

PROPOSED SOLUTION:

1. Consider key informant interviews instead of, or as well as, focus group discussions. Focus group discussions provide opportunities to explore attitudes, reactions, social norms and community dynamics, whereas key informant interviews provide a more confidential space within which to explore personal experiences and behaviours.

2. If focus group discussions are used:

   - the composition of focus groups should bring together people who would feel comfortable in dialogue with each other, and the composition of the groups should be as homogenous as possible;

   - the moderator should ask focus group members to keep information disclosed to the group confidential and remind them that the research team cannot ensure the confidentiality of information that they choose to disclose in the presence of others.

4.3 LINKAGES TO REFERRAL SERVICES

Research teams should be prepared to provide information on:

- FGM types, legal status, health complications;
- referral resources to support individuals at risk of undergoing FGM; and
- resources to support those who have undergone FGM.

Ensuring that appropriate support or referrals are available is an important element of beneficence (minimizing the harm and maximizing the benefits of the research).

Data collectors should not provide FGM-related information and support directly to research participants as this might compromise their impartiality, but they should be able to direct individuals to appropriate referral services. These services should be available throughout a research study and ideally be continued afterwards.

Referral services should include:

- contextually relevant resources on FGM;
- counselling support to manage distress and trauma;
- medical support on managing the health complications of FGM;
- information on local and national organizations working to end FGM; and
- information on how to engage the authorities, including where such authorities might not represent safe spaces for girls and women.

All support should be equally accessible to research participants, data collectors and research team members, regardless of their literacy level.

4.4 SELECTION, SUPPORT AND TRAINING OF RESEARCH TEAM AND DATA COLLECTORS

The composition and diversity of the research team and the data collectors will impact the way in which the study is undertaken and how the research team is perceived by the research participants. Most research participants will feel more comfortable being interviewed by someone similar to them. When discussing participants' FGM status, female data collectors should be employed. Considerations should be given to the ethnic and linguistic characteristics of data collectors and research participants. When data collectors are known to a study community, care should be taken to avoid social desirability bias and to reassure participants about any concerns they have regarding confidentiality.

Training and support of research teams and those collecting data are essential to ensure a common understanding of the purpose, methodology and challenges of the specific research project. This support needs to be ongoing throughout the research process, adapting to any needs and challenges that arise.

Data collectors need to have adequate training in ethical research, including in participant selection, developing rapport and creating safe spaces for interviews, interviewing techniques, consent,

confidentiality, and data collection. Additional project-specific training needs to include opportunities for all research team members to:

- talk about their perceptions about FGM
- deepen their understanding of how FGM is spoken about locally
- develop their confidence and skills in talking about FGM sensitively and directly.

Piloting of the questionnaires and/or interview guides by the data collectors provides additional opportunities to practise obtaining informed consent, interviewing using appropriate language, and collecting data, while establishing rapport with research participants.

HYPOTHETICAL SCENARIO D

Privacy and safe spaces

BACKGROUND:

A research team wishes to interview women seeking routine health-care services about FGM to assess the quality of care received by women and how effective the health-care providers are in providing services related to FGM prevention and care. Some of the questions that women are asked are related to their FGM status and their opinions about the practice. The research team needs to protect the privacy of the participants by providing a safe space to conduct the interview in a busy clinic setting.

ETHICAL CHALLENGE:

Conducting research on sensitive topics requires a private and safe space to ensure that respondents feel sufficiently comfortable to respond truthfully and accurately and are assured that their responses will be kept confidential. Data confidentiality is a standard aspect of data collection, but privacy during data collection can also affect confidentiality, and researchers must ensure that responses cannot be overheard or observed in writing.

How can researchers ensure this level of privacy in a busy clinic setting and how should they proceed if they cannot guarantee privacy?

PROPOSED SOLUTION:

The research team must make arrangements to ensure the availability of a private space for data collection at the health facility, whether this is an empty office, an extra consultation room or a dedicated space allocated for the study.

If a safe and confidential space cannot be guaranteed for the data collection then the research team should not proceed. Privacy and confidentiality are essential elements of research and the research team cannot compromise on these conditions. Without privacy and confidentiality guaranteed, the validity of the findings would be compromised as respondents might not respond accurately if they fear their responses could be overheard or observed.

CHECKLIST

STUDY IMPLEMENTATION

Research teams and research ethics committees have responsibility for the following aspects of the ethical implementation of research on FGM.

Research team members:

- ○ The research team members are fully aware of and comfortable in their respective roles and in talking about FGM.
- ○ The data collectors have received appropriate training in participant selection and using the research tools.
- ○ Measures are in place to minimize any risks to the safety of data collectors and other research team members.
- ○ Debriefing and ongoing support are available to all research team members, both in carrying out the research and in managing any vicarious trauma they might experience.

Community mobilization and participant selection:

- ○ The appropriate authorities and/or community leaders are aware of the research and, where appropriate, have approved the involvement of their organization/community, and are fully aware of the data-collection process and its requirements.
- ○ The concept of confidentiality is fully understood by the authorities and/or community leaders.
- ○ Robust and clear procedures are in place for the selection of research participants.

Conduct of individual interviews and/or focus group discussions:

- ○ The purpose of the research and how the findings will be used and disseminated are explained in clear and straightforward language, and participants have opportunities to ask questions.
- ○ Strategies are in place to protect the privacy, safety and confidentiality of all research participants:
  - ○ The informed-consent process is ongoing throughout their participation;
  - ○ Protocols are in place to support research team members to manage signs of anxiety or distress;
  - ○ Research team members are equipped to refer research participants for further support or information on FGM.

Ensuring data security and confidentiality throughout the research process:

- ○ Protocols are in place to ensure data are kept secure at the time of data collection, data transfer, data management and analysis.
- ○ Anonymization of data takes place at the earliest opportunity.
- ○ Protocols are in place for data storage at the appropriate points in the research process.

Minimizing risks to participants:

- Measures to reduce the risks to the participants are included in both research protocols and in training/ preparation for research team members.
- Community leaders are aware of the risks to participants and willing to take steps to minimize these.
- Referral services are identified and all research team members are made aware of the referral resources for appropriate support.
- Systems are in place to provide information on FGM and to provide referrals, as appropriate.

Minimizing risks to the research team members:

- Standard operating procedures are established to record and review any adverse events and unintended consequences on participants.
- Measures to reduce the potential risks to data collectors and research team members are included in standard operating procedures and during training.
- Support for the data collectors and research team is available as needed.
- Debriefing sessions are conducted to provide opportunities for all research team members to talk about the impact of their involvement in the research process.
- Support structures and mental health referrals are available to research team members who may be adversely affected by the research, including through vicarious trauma.

5 ANALYSIS AND DISSEMINATION

As stated in *Putting women first* (WHO, 2001), "Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development" (p. 11). This is echoed by CIOMS (2016), which calls for research to be translational and recommends that community engagement continues through all stages of the research, including during dissemination.

5.1 ANALYSIS AND INTERPRETATION

STUDY LIMITATIONS:

All research studies have limitations and these should be disclosed when presenting the findings, whether these relate to sample size, lack of generalizability of findings, measurement limitations, lack of controlling for confounding, or other risk of bias. The validity of findings depends on the accuracy of the responses and the analysis and interpretation of the data.

These limitations are particularly relevant for FGM research because there is potential for the underreporting of experiences of FGM, especially in contexts where the practice is illegal, or when there is a lack of clarity over what constitutes FGM. Use of validated questionnaires and measurement tools, plus good training of providers and ensuring privacy and confidentiality during data collection, can improve measurement and reduce the risk of bias and other limitations.

Research teams also need to be aware of their own positionality and remain objective in the testing of hypotheses and the analysis and interpretation of data. Protocols should be peer reviewed and receive ethical approval from research ethics committees. The publication of research protocols in peer-reviewed journals also enhances transparency.

AVOIDING STIGMATIZATION:

Measures should be taken when presenting data on sensitive issues such as FGM, to avoid stigmatizing specific individuals and communities (see **HYPOTHETICAL SCENARIO E**), especially when these might reinforce negative stereotypes of specific ethnic or religious groups.

Data on individual research participants should be de-identified to avoid breaches of confidentiality and privacy. Names of research participants should be removed from all databases and should not be used in any reports or case studies.

Appropriate disaggregation of data is key to understanding differences among different subgroups and how they respond to interventions differently. However, presenting disaggregated data can inadvertently stigmatize particular individuals or groups. Care should be taken when disseminating findings related to specific groups to protect their confidentiality. For example, a midwife or nurse might have talked about the pressures they have been under to perform FGM on girls in their community, or they might have explained that they have performed FGM, or asked a colleague to perform FGM on their daughter. The consequences of their identity being revealed could have severe consequences for them professionally and personally.

Where comparisons are made between the prevalence or practice of FGM in different subgroups, any differences should be reported factually and, where possible, the reports should include communities' own explanations of findings around attitudes and behaviours in relation to FGM without stigmatizing them and without creating tensions between groups or within communities.

5.2 DISSEMINATION OF RESEARCH FINDINGS

The dissemination of research findings requires a range of approaches appropriate to different audiences who benefit from knowledge transfer, whether they are policy-makers, donors, programme planners, advocates, research participants or other stakeholders. Depending on the audience, relevant channels include peer-reviewed publications, project briefs, reports, infographics and presentations to key stakeholders. Engagement can also be through non-print media and other channels appropriate to the audience as well as stimulating dialogue and promoting knowledge transfer at international, national, subnational and community levels.

CONTRIBUTING TO THE POLICY-MAKING DISCOURSE:

Findings from peer-reviewed publications can be supplemented by concise policy briefs, infographics and/or case studies, which can be more accessible to policy-makers and other stakeholders than academic papers and project reports.

Opportunities for policy-makers to engage in dialogue about the findings of research – with either the research team or representatives from the target communities – can be valuable in understanding the methodological limitations of the research as well as the key findings. These dialogues can ensure that policy changes reflect the body of evidence on a particular topic and that the results of a single study are interpreted within that context.

CONTRIBUTING TO ONGOING ADVOCACY AND PROGRAMMATIC ACTIVITIES:

Improving FGM programming is an important rationale for conducting research on FGM. Specified resources are required to ensure that dissemination to and engagement with relevant stakeholders takes place, and that the findings are presented in accessible ways and in a timely manner. This might require translating key findings into local languages, organizing workshops or other events for community members, and engaging with CBOs, nongovernmental organizations (NGOs) and community leaders to discuss the implications of the findings for programmes to end FGM.

Research dissemination can also bring together stakeholders across different sectors, including from education, health and legal sectors, for cross-sectoral dialogue to explore potential interventions and increase collaboration.

HYPOTHETICAL SCENARIO E

Avoiding stigmatization through dissemination

BACKGROUND:

A research team is conducting a secondary analysis of a population-based survey. The team is particularly interested in understanding the factors that are associated with FGM by analysing how different sociodemographic characteristics are associated with FGM. They plan to disseminate these findings in the national media.

ETHICAL CHALLENGE:

During the analysis, the research team finds that one minority ethnic group in the country, which is regularly the focus of negative media coverage, has higher rates of FGM and higher rates of gender-based violence. Releasing the findings has the potential to cause further alienation of children from this ethnic group who already face discrimination and bullying at school.

PROPOSED SOLUTION:

The research team should consider convening relevant national stakeholders, including representatives from the affected community, to discuss the range of findings, including other explanatory factors, and to decide jointly how to ensure that the research findings are used to improve programming without further stigmatizing members of this group.

HYPOTHETICAL SCENARIO F

Research to action

BACKGROUND:

A research team decided to investigate the impact of providing alternative incomes, in the form of conditional cash payments, to FGM practitioners to stop them performing FGM on girls in their community, with the intention of scaling up the approach if the findings were positive. The research team engaged in consultation with relevant government departments and NGOs that supported the research. They identified a group of 15 traditional FGM practitioners and, using a mixed-methods approach, collected baseline data before giving them an amount of money equivalent to the cost of 10 FGM ceremonies to offset their lost income. The FGM practitioners also attended a series of sessions on the harms of FGM. The research team collected follow-up data from them in the form of questionnaires and in-depth interviews, and found that 12 of the 15 FGM practitioners reported they were no longer performing FGM.

The government departments and NGOs that supported the research are keen to scale up the project nationally.

ETHICAL CHALLENGE:

The research team has identified a positive change in the behaviour of FGM practitioners, in one specific context, over a relatively short time frame. Despite the inclusion of key stakeholders from the outset of the study and both baseline and follow-up assessment, the research leaves many unanswered questions, including which aspect of the intervention was associated with the change observed (the awareness raising on the harms of FGM or the cash transfer), and whether observed change could be attributable to some other factors since there was no control group. In addition, understanding whether families were seeking FGM from other practitioners instead remains unknown.

PROPOSED SOLUTION:

While the quantitative results from the questionnaires show change in the right direction, the qualitative data can enhance the interpretation of the findings by explaining some of the contextual factors and mechanisms of change. Understanding the perspectives of the practitioners about how and why they responded to the programme, or not, is a critical component of understanding the findings of this small-scale study. If possible, additional follow-up and additional interviews with key stakeholders should take place to understand how the community responded to the programme, and its potential sustainability.

If this approach is shown to be effective in promoting the abandonment of FGM over the long term, implementation research might be appropriate to explore challenges in implementation or how it works in different contexts.

Scale-up should occur only when there is clear evidence of effectiveness.

CHECKLIST

DATA ANALYSIS AND DISSEMINATION

Research teams and research ethics committees have responsibility for the following aspects of data analysis, interpretation and dissemination of findings of research on FGM.

Minimizing risks to participants:

- ○ The confidentiality and safety of all research participants is maintained in the analysis and presentation of data through anonymity, especially when presenting disaggregated results.

Authenticity:

- ○ Limitations of the methodology and sampling processes and the risk of bias are fully recognized in the interpretation of the findings.
- ○ Descriptive accounts related to individuals or communities are accurately and sensitively portrayed.
- ○ Quotations are used in the context in which they were provided.

Local ownership and dissemination of findings and capacity-building:

- ○ When research is a collaboration between local researchers and external partners, local research teams should be responsible for engaging in dialogue about the findings in the local context.
- ○ Research participants and communities are given an opportunity to learn about the research results before they are disseminated more widely.
- ○ Stakeholders (e.g. health facility leaders, NGO/CBO members) have opportunities to engage in dialogue about the findings and can consider data-to-action workshops to identify how to feed results into policy and programmatic processes.

Publication in a range of formats and styles:

- ○ The findings are available in relevant languages in a range of formats appropriate to different audiences, including peer-reviewed publications, research reports, policy briefs, infographics, radio programmes and in other accessible formats.
- ○ Any conflicts of interest of researchers are declared and resolved.

Dissemination locally, nationally and internationally:

- ○ Findings are disseminated locally to actively encourage dialogue and discussion around policy and programming.
- ○ Findings are disseminated through national and international forums.

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ANNEX 1

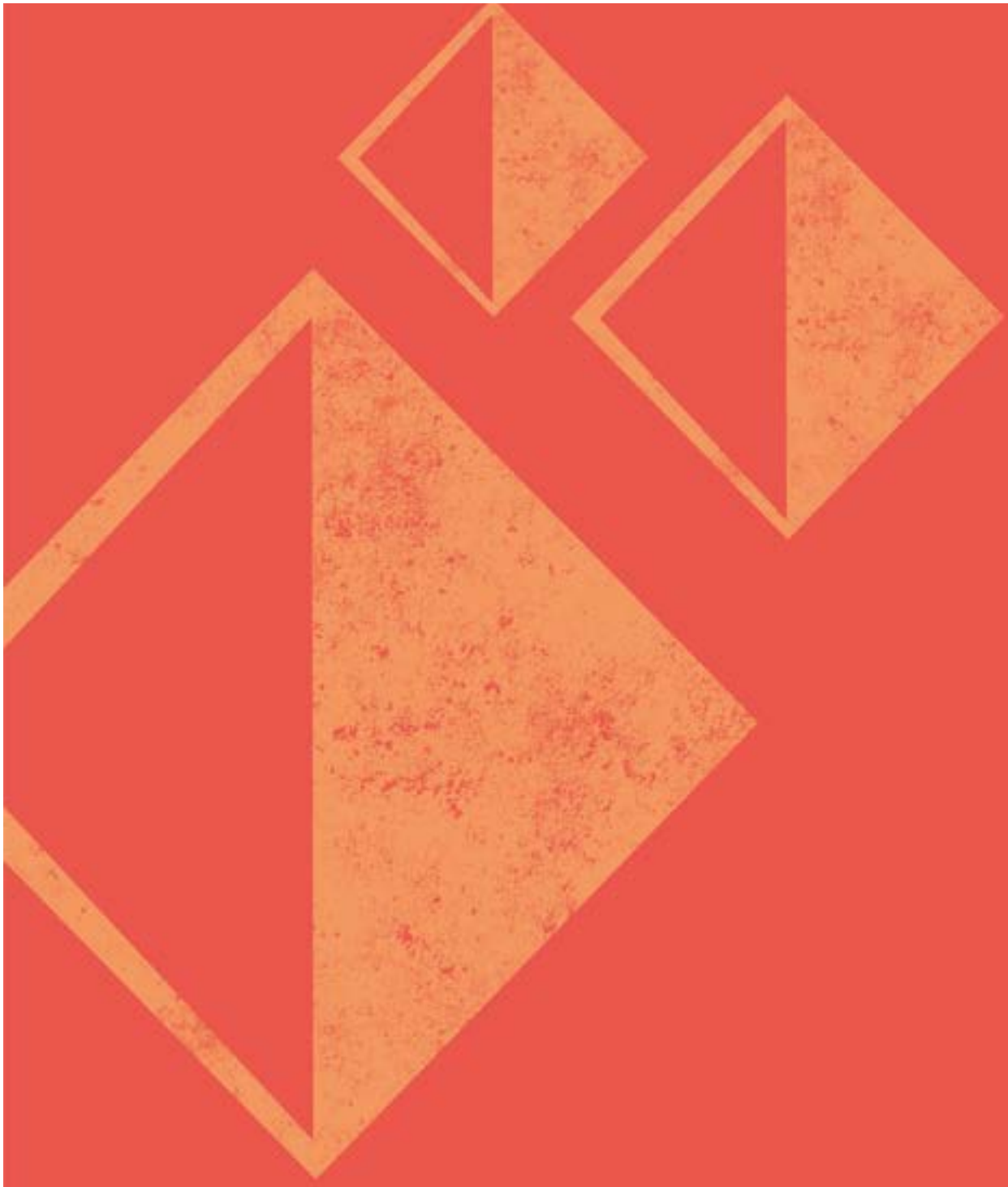
SUMMARY OF RECOMMENDATIONS FOR ETHICAL RESEARCH INTO VIOLENCE AGAINST WOMEN AND GIRLS FROM EXISTING GUIDANCE

- Study design
- Study implementation
- Analysis and dissemination

Putting women first: ethical and safety recommendations for intervention research on violence against women **(2001)**	*WHO ethical and safety recommendations for interviewing trafficked women* **(2003)**	*WHO ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies* **(2007)**	*Ethical and safety recommendations for intervention research on violence against women* **(2016)**
1. The safety of respondents and the research team is paramount and should guide all research decisions.	**1.** Do no harm.	**1.** The benefits to participants or communities of documenting sexual violence must be greater than the risks to participants and communities.	**1.** The safety of respondents and the research team is paramount and should guide all project decisions.
2. Prevalence studies need to be methodologically sound and to build on current research experience about how to minimize the underreporting of violence.	**2.** Know your subject and assess the risks.	**2.** Information gathering and documentation must be done in a manner that presents the least risk to participants, is methodologically sound, and builds on current experience and good practice.	**2.** Prevalence studies need to be methodologically sound and to build on current research experience about how to minimize the underreporting of violence.
3. Protecting confidentiality is essential to ensure both women's safety and data quality.	**3.** Prepare referral information – do not make promises that you cannot fulfil.	**3.** 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.	**3.** Protecting confidentiality is essential to ensure both women's safety and data quality.

Putting women first: ethical and safety recommendations for intervention research on violence against women **(2001)**	*WHO ethical and safety recommendations for interviewing trafficked women* **(2003)**	*WHO ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies* **(2007)**	*Ethical and safety recommendations for intervention research on violence against women* **(2016)**
4. All research team members should be carefully selected and receive specialized training and ongoing support.	**4.** Adequately select and prepare interpreters and co-workers.	**4.** The safety and security of all people involved in information-gathering about sexual violence is of paramount concern and, in emergency settings in particular, should be continuously monitored.	**4.** All research team members should be carefully selected and receive specialized training and ongoing support.
5. The study design must include actions to reduce any possible distress caused to the participants by the research.	**5.** Ensure anonymity and confidentiality.	**5.** The confidentiality of individuals who provide information about sexual violence must be protected at all times.	**5.** The study design must include actions to reduce any possible distress caused to the participants by the research.
6. Fieldworkers should be trained to refer women requesting assistance to available local services and sources of support. Where few resources exist, it may be necessary for the study to create short-term support mechanisms.	**6.** Get informed consent.	**6.** Anyone providing information about sexual violence must give informed consent before participating in the data-gathering activity.	**6.** Fieldworkers should be trained to refer women requesting assistance to available local services and sources of support. Where few resources exist, it may be necessary for the study to create short-term support mechanisms.
7. Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development.	**7.** Listen to and respect each woman's assessment of her situation and risks to her safety.	**7.** All members of the data collection team must be carefully selected and receive relevant and sufficient specialized training and ongoing support.	**7.** Researchers and donors have an ethical obligation to help ensure that their findings are properly interpreted and used to advance policy and intervention development.
8. Questions about violence should only be incorporated into surveys designed for other purposes when ethical and methodological requirements can be met.	**8.** Do not re-traumatize a woman.	**8.** Additional safeguards must be put into place if children (i.e. under 18 years of age) are to be the subject of information-gathering.	**8.** Questions about violence should only be incorporated into surveys designed for other purposes only when ethical and methodological requirements can be met.

Putting women first: ethical and safety recommendations for intervention research on violence against women **(2001)**	*WHO ethical and safety recommendations for interviewing trafficked women* **(2003)**	*WHO ethical and safety recommendations for researching, documenting and monitoring sexual violence in emergencies* **(2007)**	*Ethical and safety recommendations for intervention research on violence against women* **(2016)**
	9. Be prepared for emergency intervention.		**ADDITIONAL RECOMMENDATIONS** **1.** Intervention studies need to be methodologically sound and build on the current evidence base of interventions and intervention research experience.
	10. Put information collected to good use.		**2.** Processes and criteria for participant recruitment should be carefully considered to avoid excluding women who may not initially disclose experience of violence.
			3. Participant randomization should be transparent and described in a way that can be easily understood by those involved in the research.
			4. The provision of services to participants in the control group should maintain a minimum standard of care.
			5. Measuring and monitoring harm related to the research should be incorporated into safety protocol procedures.



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