IASC

Inter-Agency Standing Committee

IASC Reference Group for Mental Health and Psychosocial Support in Emergency Settings

RECOMMENDATIONS FOR CONDUCTING ETHICAL MENTAL HEALTH AND PSYCHOSOCIAL RESEARCH IN EMERGENCY SETTINGS

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RECOMMENDATIONS FOR CONDUCTING ETHICAL MENTAL HEALTH AND PSYCHOSOCIAL RESEARCH IN EMERGENCY SETTINGS

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1 INTRODUCTION

Mental health and psychosocial support (MHPSS) is a priority component of any emergency response. MHPSS should be based on knowledge, available resources and effectiveness of interventions. To achieve this research has a key role to play.

ETHICAL RECOMMENDATIONS

Ethics *can be defined as: a system, or code of moral principles, to guide us to determine what behaviours or actions are helpful or harmful.*

Recognizing the complexities of emergencies and the need for ethical recommendations to support MHPSS research in emergency settings, the Inter-Agency Standing Committee (IASC) Reference Group on MHPSS agreed on specific guidance to:

- Ensure MHPSS research in emergencies benefits affected people;
- Design research to fill knowledge gaps in MHPSS theory and practice in emergencies;
- Avoid bad practice, such as research without satisfactory consent of participants; and
- Better understand how to manage ethical challenges in MHPSS research during emergencies.

Ethical research principles stem from universal guidelines[1], but do not address the unique challenges of conducting MHPSS research in emergency settings. This document aims to fill that gap, providing recommendations to ensure ethical principles and to promote standards of best practice for MHPSS data collection during emergencies. Considering the reality of research conducted in emergencies, including the inability to guarantee the successful implementation of all principles into every study, this document nevertheless aspires to the widespread practice of the recommendations. The recommendations are relevant

across multiple disciplines, and operate alongside action sheets 2.1 and 2.2 of the *IASC MHPSS Guidelines* on planning, assessment and Monitoring and Evaluation cycles of MHPSS programmes and services during emergencies (IASC, 2007).

2 KEY CONCEPTS

What is meant by "emergencies"? As defined by the IASC, an emergency is: *"a humanitarian crisis in a country, region or society where there is total or considerable breakdown of authority...and which requires an international response that goes beyond the mandate or capacity of any single agency and/or the ongoing United Nations country programme"* (IASC and OCHA, 2008). The term "emergencies" covers natural disasters, man-made disasters (including conflict) and epidemics.

Emergencies may be characterized by:

- Extensive injury and loss of life
- Damage to societies and economies
- Requiring humanitarian assistance
- Displacement
- Potential violence and hindrance of humanitarian assistance
- Potential security risks for humanitarian workers

What is meant by 'research'? Research is the systematic collection and analysis of data. It applies to qualitative or ethnographic data (for example, data collected using focus group discussions, open-ended interviews or observation) or quantitative data (for example, data collected using structured interviews such as diagnostic interviews and symptom checklists). This includes needs assessments; psychiatric epidemiology (study of distribution and cause of mental illness); monitoring and evaluation; social sciences research; as well as data collected for advocacy purposes.

Who are the recommendations for? People who play various roles in emergencies: MHPSS practitioners or programme staff; people designing research protocols; field staff; ethical review boards; emergency officers; funders; and decision makers (UN, nongovernmental organizations (NGOs) and government stakeholders) who commission, authorize, conduct and/or evaluate research.

Scope of the recommendations These recommendations provide specific ethical guidance for conducting MHPSS research in emergencies. They are based on existing knowledge from a review of multidisciplinary academic and practice literature. They are to be used in conjunction with existing resources for MHPSS programme planning, assessment, research and monitoring and evaluation in emergency settings, including: internationally agreed ethical guidelines on research involving human subjects; professional codes of conduct for medical, researcher and humanitarian aid workers; international human rights standards; local ethical and legal procedures and standards.

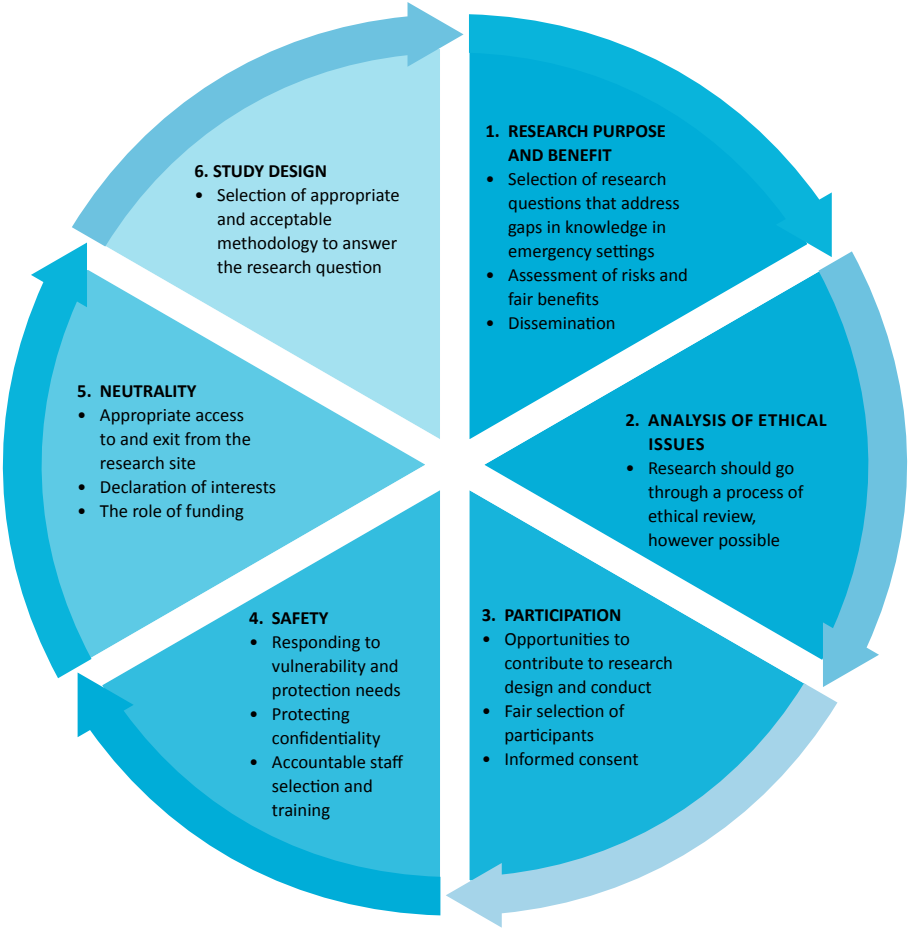
Note: These recommendations focus on research with adults. At the end of each section are key considerations on research with children and adolescents (referred to as "children"), in  *text boxes.*

How are these recommendations presented? The recommendations cover six key areas: (1) research purpose and benefit; (2) analysis of ethical issues; (3) participation; (4) safety; (5) neutrality; and (6) study design (see Figure 1).

These recommendations also include case studies provided by members of the IASC MHPSS Reference Group or drawn from existing literature which illustrate practice-based examples of applying ethical principles in the field, including positive and negative outcomes and lessons learned.

The recommendations are interrelated. Each principle contributes to a comprehensive framework. Decisions relating to one principle may affect another.

Figure 1. Six key areas covered by the recommendations



3 ETHICAL RECOMMENDATIONS

1. RESEARCH PURPOSE AND BENEFIT

1.1 Ethical research addresses questions and topics that respond to a recognized gap or need

MHPSS research in emergencies is conducted when it is the *only* way to gain knowledge. Research needs to make a meaningful contribution to MHPSS theory and/or practice in emergency settings and generate new knowledge. If the research question could be answered in a non-emergency setting, then it should not be answered in an emergency setting.

- Stay informed to avoid duplication of research (see Box 1).
- Formulate your research question so that results lead to fair benefits (see 1.2).
- Engage communities and local service providers to identify research topics and questions (see 3.2).

Box 1. Where can I learn about existing research knowledge on MHPSS in emergencies?

www.mhpss.net – resources section
www.alnap.org – humanitarian evidence and learning site: resources section
www.clinicaltrial.gov – registry of clinical trials conducted worldwide. Researchers are encouraged to register their trial with this site.
www.pubmed.gov – allows searches for relevant peer-reviewed journal articles. Abstracts can be viewed freely, but some full-text content requires payment or subscription.
Websites of journals, such as Plos Medicine or Intervention, have many articles that are open access or free to view, but some require payment or subscription.

To learn about studies (including needs assessments) proposed or ongoing, contact coordination bodies in the field, or local academic institutions and researchers.

1.2 Ethical research ensures fair and direct benefits and minimizes research risks

Research in emergencies may present risks to the participants, including: to their personal security; being exposed to stigma attached to mental health; or social, economic or political impacts. Despite risks, it is important to carry out MHPSS research in emergencies to inform MHPSS services. Researchers have a duty to identify and respond to risks. When possible, link research with programmes for participants and/or ensure that research participants have access to services. Care and support strategies need to address risks presented and vulnerability of the target population:

1. Conduct risk and benefit assessments. Outline a risk management plan in research protocol.
2. Identify and share potential risks and benefits with participants (see 3.5).
3. Share knowledge of risks and benefits during staff recruitment (see 4.5).

4. Prior to starting research, ensure procedures to respond to participant discomfort or adverse reactions, including training (e.g. Psychological First Aid[2]) to assist distressed participants and referral pathways to mental health, psychosocial and other services.

Fair benefit to participants and community The phrase "no survey without service and no service without survey" (HHI, 2009) means research should deliver direct benefits (see Box 2) to the study population, and all services are based on evidence and monitored during implementation. Consult local community and service providers over whether payments or compensation should be given to participants. Ensure that offered services are appropriate, available and accessible.

To be ethical, research benefits:

- Must provide appropriate compensation but not excessive reward
- Maintain confidentiality
- Avoid intensifying tensions in the community

In research design, it is important to address *who* is to benefit and *in what way* (see Box 2). What are *fair benefits* is best defined, negotiated and agreed with the participating community, collaborating service providers, researchers and funders, prior to starting research. Document and include agreements in research protocols.

Box 2. Determining fair and direct research benefits

Who will benefit? Can include:
- Direct study participants
- Families and caregivers of study participants
- Local community members
- Whole villages or camp settings
- Populations affected by humanitarian crises

In what way they will benefit? Benefits could include:
- Access to services during and after research
- Training and capacity-building of research teams or health-care staff
- Improved sustainable facilities at health-care centres, such as new equipment.

1.3 Dissemination of research findings to participants, collaborators and others

Should include information on study design and conduct. Findings should include: both negative or non-significant and positive or significant findings.

Who should receive information about the results of research? includes: the participating community; collaborators; care providers; local and international decision makers; and the academic and practice community. Disseminating results to the participating community ensures the participants' right to information is respected. When disseminating findings to funders, protection of participant confidentiality/anonymity is essential. Dissemination to others (such as humanitarian agencies) can inform and improve emergency response, and inform appropriate targeting of funding. Dissemination to the academic and practice community ensures lessons are shared and utilized.

What is the most effective format for each audience? messages should be tailored for each target audience (see Box 3). Findings should be publicly accessible. Presentations, social media, summaries and reports, workshops, and conferences are all useful.

Box 3. Tips for effective dissemination

All dissemination outputs should:

- Use non-technical language or clearly define technical terms using non-technical language
- Be written in the language of the reader (i.e. local community, international readership, for the hearing and visually impaired, etc.)
- Use a writing style appropriate to the literacy and education level of the reader
- Provide key messages about the research methods, tools and findings

Recommended publicly accessible platforms for dissemination include:

- Health or Protection cluster meetings in emergency settings
- Online platforms i.e. www.mhpss.net; www.alnap.org; www.urbangoodpractitces.org
- Open access journal publications
- Community meetings

What are the potential risks in dissemination? Data ownership and confidentiality/anonymity of participants must be protected. In emergency settings dissemination may have unintended results and findings may be manipulated or abused by various actors. Other risks include: reinforcing stereotypes, contributing to learned helplessness, or negative impact on aid. Discuss findings with the community and local partners before external dissemination. When using social media to promote findings, it is critical to protect anonymity/confidentiality at *all* times.

How can collaborators and co-authors best be acknowledged? Study protocols should document agreed authorship. Ensuring local counterparts and national partners are included as co-authors in *all* disseminated findings recognizes the role of public acknowledgement in capacity-building, and fairly distribute benefits.

Plan and budget for dissemination: Include a dissemination plan in the research protocol with a budget and timeline. For example, cost of open access journal fees, language editing, community dissemination meetings and staff costs. Feeding back research findings to participants and their communities is usually overlooked in dissemination planning. It is important to include this in the research design and budget.

- Protect the confidentiality/anonymity of child participants and caregivers.
- Dissemination of findings needs to be tailored to participating children, caregivers, schools or community centres. Consider the appropriate format, length and language.
- Provide opportunities for participating children to be involved in the dissemination of findings, where this does not lead to increased risks.

2. ANALYSIS OF ETHICAL ISSUES

All research protocols involving primary data collection for publication in a scientific medium (e.g. journal, book, conference) must undergo *a process* of ethical review, before research starts, to address potential ethical issues (see Box 4). In the case of monitoring and evaluation that is for internal use, external dissemination and audit, ethical review is not a formal requirement but can be seen as a best practice, whenever conditions allow. Ethical review is still to be sought for monitoring and evaluation or audit involving primary data collection for publication in a scientific medium. An ethical review requires a written protocol that can be independently reviewed. Requirements vary. For biomedical research, the entire process should be detailed for ethical approval. For social sciences research, the protocol will be broader, potentially with ethical review provided in stages as research progresses. Reviews of secondary data may not have to go for ethical review.

It is understood that if rapid assessments are subject to ethical review procedures this could result in unacceptable delays to research conduct and potential harm to participants. Therefore, it is recognised that in these situations ethical review may be omitted, unless expedited procedures exist.

Box 4. What should an ethical review consider?

Ethical review includes making sure that research:

- Addresses important gaps in humanitarian evidence
- Uses appropriate and acceptable methodologies
- Includes opportunities for community participation throughout the research process
- Respects autonomy and capacity in informed consent
- Protects confidentiality and anonymity during research and dissemination
- Actively considers participant and research team safety, including:
  - Identifying and responding to participant vulnerability and protection needs
  - Having in place strategies to manage and respond to research team safety including researcher self-care and exit plans
- Provides opportunities for reflecting upon study conduct
- Maintains neutrality through appropriate entry to and exit from the research site, while considering issues of gatekeeper power
- Coordinates with other organizations and researchers in the setting
- Declares all researcher and funder interests prior to research starting
- Delivers direct benefits to participating communities
- Disseminates widely findings and methodological and ethical learning

Undergoing ethical review offers researchers, communities and reviewers the opportunity to engage with practice-based research ethics. Include ongoing oversight, such as safety monitoring, to address adverse reactions to research.

Reviewers can be internal (the team conducting the study), or external (ethical review bodies or safety monitoring boards). For example, Médecins Sans Frontières (MSF) requires Institutional Review Board (IRB) oversight for studies that present risk of psychological harm. These include clinical trials, studies on interventions of unknown effectiveness, studies that involve taking blood or tissue samples, and monitoring and

evaluation (including descriptive studies). There are two levels of review: full review with all IRB members for high levels of risk (i.e. clinical trials); and expedited review with two or three IRB members for studies that present minimal risk (such as monitoring and evaluation) (Schopper et al., 2009).

It is critical that researchers adhere to local and international standards of ethical review, and that approvals are obtained *before* research starts. Adhere to any approval mechanisms established as temporary measures in emergency settings (see Case Study 1).

Case Study 1. Adhere to temporary measures in emergency settings

The Health Sector Working Group (HSWG) in Jordan received repeated requests to conduct research on displaced populations. Many of these requests were based on the needs and interests of researchers, and procedures in Jordan were unable to ensure ethical concerns were addressed.

To address this gap, the HSWG developed a review process to ensure the rights, safety and well-being of participants. This included guidelines and a form for submitting research proposals. These measures do not negate approval from other appropriate ethical review boards, but are an additional step to ensure the vulnerabilities of refugees are recognized and protected.

Learning for future studies:

- It is important to be informed about local research review procedures operating in specific humanitarian settings.
- Research must be reviewed and approved by all relevant bodies, including ethical review boards, before the project starts.

Required approvals can include: multiple levels of ethical approval from funders, academic institutions, and in-country bodies. Ethical merit should be considered from both a contextual (local) and a technical or scientific perspective. Should an in-country review body not have appropriate technical expertise, or have broken down in emergencies, local ethical review boards should be strengthened and additional

local or international review may be required. For example, researchers should identify appropriate local representatives to conduct an assessment.

Ensuring local review is vital to respecting local ethical and cultural norms. If conflicting approaches arise through reviews by different bodies, explore *why* these have arisen and find an appropriate compromise. This process is a chance to engage and apply standards of ethical research practice, including the way potential ethical issues are managed. The aim of this process is to enhance the ethical merit of the research, benefitting participants, researchers and funders alike.

- Ensure children are represented in any community review of research involving children.
- Acknowledge, value, and accommodate the opinions of children reviewing a study.

3. PARTICIPATION

3.1 Participation in research demonstrates respect for individual and community autonomy and self-determination.

An active role in research design, conduct and dissemination recognizes community and collaborators expertise, and helps to build effective partnerships.

3.2 Ethical research practice includes community participation throughout

Written research protocols should identify opportunities for participation, including the scope of participation. Stakeholders invited to participate could include: affected populations; community members; existing MHPSS resources (e.g., religious and traditional healers); and national academic and government stakeholders. As well as co-learning, community engagement produces more reliable findings, focuses on issues important to local populations, and helps to ensure research

recommendations are put into practice. It also builds the capacity of communities to critically assess, join, or lead studies, and may be the first step in identifying and selecting research teams (see 4.5).

- The research process should respect the right of children to be heard.
- Participation can include children as researchers collecting data, or participating on a community advisory board.
- Involving children as researchers requires careful consideration of the risks it may present.

3.3 Collaborating and coordinating with others in the setting

It is very important that researchers cooperate with those coordinating emergency response (service providers), target communities, and local academics, researcher or practitioner groups. This is essential to the safety of both the research team and participants.

Collaborative partnerships include sharing responsibility and are based on mutual respect during all stages of research.

Effective collaboration prevents duplication of research, wasting of resources, and provides opportunities to share knowledge. Being networked into existing systems enables identifying and linking with other services and safety procedures. Early collaboration creates opportunities to jointly identify research topics and questions, and to design studies that meet practical clinical care and theoretical research objectives. Collaboration can also raise issues of power dynamics that can lead to barriers in coordination. It provides opportunities to plan how to feedback findings sensitively, and how to respond to poor standards of care or any discrimination uncovered.

3.4 Fair selection of participants

Objectives of the research necessitate its conduct during an emergency and participants must always be selected according to these scientific objectives. When selecting study participants, researchers are implicitly or explicitly sending a message about who is being heard and whose

needs are being prioritized. This can increase the potential for conflicts as a result of perceived discrimination, injustice or jealousies. Selecting a population for research may expose them to increased risk. Sensitive topics such as HIV, substance use, human trafficking, gender-based violence or political persecution must be conducted sensitively and participants approached discretely.

The role of gatekeepers includes negotiating access to communities via "gatekeepers" such as a community leader. This can deliver benefits, such as advice on consent practices and where research approvals should be sought. However, gatekeepers may also be part of power structures, controlling the benefits or costs of participation for some and not for others (see Case Study 3).

Case Study 2. Ensure fair selection of research participants that follows the scientific objectives of the research

A University in Lebanon conducted research with volunteers based on the need to "do something". No ethical approval was obtained as the study was classified as a needs assessment. Study participants were IDP's in centres managed by warring factions. Centres were included on the basis of access. The original sampling frame, designed to ensure fair representation in the study sample, was not followed.

Learning for future studies:

- The fair selection of participants was compromised because of reliance on gatekeepers to access research participants.
- Gatekeepers distorted the research design by controlling who researchers were and were not able to access. This undermined the validity of results.
- Researchers must ensure the need to "do something" does not overwhelm the importance of ethical research practice. This means not conducting research if it cannot be conducted ethically.

*(Source: Yamout and Jabbour "Complexities of research during war: lessons from a survey conducted during the Summer 2006 War in Lebanon" **Public Health Ethics; 3**(3); pp. 293-300)*

When accessing communities it is important to remain aware of *whom* is "speaking for" a particular group of people, and whose voices are not being heard or actively silenced. It can help to ask:

- What does the gatekeeper gain from assisting with the research?
- From what gender or nationality/ethnic/religious group is the gatekeeper, and what are the different (social) groups that the study aims to reach?
- Is the gatekeeper actively controlling participation in the research, for example by systematically excluding a certain group or imposing power structures?
- Which sections of the population may be being excluded from the research?

Ensure decisions about who is heard and what knowledge is included are recorded. Decisions should be made according to the scientific objectives of the study. In conflict contexts, there may be competition over involvement, due to perceived status. Access via one gatekeeper may signal agreement or support of that group. This can put researchers and participants at risk of reprisals.

3.5 Robust and reliable informed consent processes

Informed consent is critical to ensure ethical research practice. A decision to participate or not is made after a process of respectful and truthful information exchange about the research aims, process, and potential risks and benefits (see Box 5). It is recommended that informed consent processes follow the 3 C's:

- ✓ Clear
- ✓ Concise
- ✓ Continuous

Box 5. What should informed consent cover?

- The nature and purpose of the study
- Who the funders / sponsors are
- Who the researchers are and the institutions they are associated with
- The relationship between the research and collaborating organizations (i.e. separating research from service delivery)
- The anticipated use of data
- Why and how the individual has been approached to participate in the study
- A full explanation of what participation entails – i.e. time input, any follow-up contact, participating in an intervention or service, etc.
- Details of likely benefits and potential risks
- Data ownership, storage and security procedures
- How confidentiality will be maintained, including:
  - Anonymity procedures and disclosure of potentially identifiable forms of data collection such recording devices or photographs
  - Outlining limits to confidentiality e.g., cases of imminent suicide risk or child protection
- Procedures for dissemination, including how participants will be informed of research findings
- What long term engagement means in practice (specific to anthropological research)
- The right to withdraw from research at any time, to decline to answer individual questions or participate in specific stages of data collection, or to limit the use of data provided

There are different models for implementing informed consent. Most common is an individual written informed consent form. Other practices include: verbal consent; witnessed consent (someone other than the researcher signs); or the participant signs a separate sheet to indicate consent, ensuring their name is not linked to the study (for sensitive or taboo topics). In covert research, consent is not obtained from individual participants.

Case Study 4. Informed consent should be contextually appropriate while maintaining ethical standards

A study conducted in Swat region of Pakistan, following armed conflict, to determine the prevalence of psychological distress in perinatal women. Due to conservative and religious norms, community health workers (CHWs) initially approached participants. An example of the flexible, informed consent procedures that followed is outlined below.

Learning for future studies:

- Accessing participants appropriately through appropriate gatekeepers (in this case CHW's)
- Having separate researchers conduct informed consent to ensure participants do not feel pressured to participate
- Collecting consent from families as well as individuals, showing respect for local cultural and religious norms
- Repeated verbal checking to confirm women were still comfortable with participating or not, providing continuous consent and an opportunity to ask questions or withdraw.

In emergencies researchers must have rigorous but flexible consent procedures (see Case Study 4). Discuss with the local community or local collaborators how to approach participants for consent that will respect local norms and help to develop locally appropriate consent processes. This local input into the consent process will be expedited or can be omitted for rapid assessments and routine monitoring and evaluation, but informed consent should always be obtained in research.

3.5.1 Providing information about the research and ensuring it is understood

Research information must be written clearly and accessibly in the language of participants, and explained in familiar terms, using accessible language. Some professional translations may be too formal or academic for community use. Best practice is for translated documents to be reviewed by a community member. Information sheets must be written objectively. The use of persuasive language or emphasizing benefits and downplaying risks is unethical. In some settings, the spoken language is unwritten, or illiteracy high. In this context, each participant should be given the same clear explanation of the study.

Simply providing information is not sufficient for informed consent. It is a *process* of information exchange. Present risks and benefits in a neutral way, and pay attention to cultural, linguistic, economic, educational, perceived social status and other barriers that may affect information exchange. Rephrase or re-explain aspects that have not been fully understood. Repeat until satisfied that the participant can make an informed decision.

It is possible that researchers become aware of misunderstandings about research once it has started (see Case Study 5). In such situations, efforts should be made to address misunderstandings at both the individual and community level. This is important for participants' and researchers' safety.

Case Study 4. Ensure that research information has been fully understood and correct misunderstandings

A study conducted in Swat region of Pakistan (see Case Study 4 for details). Rumours spread that the research team was passing information to the Pakistani intelligence authorities. Community members made threats against the research team. Research was immediately halted. The study lead met with those families making threats and re-explained the research, with an emphasis on the right to decline, to withdraw, and to refuse to answer any questions. Also, the research purpose and who had access to the data collected was covered. As a result, the threats were withdrawn and support given. When research started again, information was repeated to individual participants, reconfirming consent verbally. This strategy was effective in preventing further threats.

Learning for future studies:

- Monitoring community views of research and addressing rumours through community consultation ensures consistent and reliable information, and understanding.
- It is an ethical duty to ensure the safety of research participants and team.
- It is important to ensure research data is unbiased. If participants think their responses may be passed to intelligence authorities, they are likely to self-censor.

Carry the study information sheet and consent form at all times, provided this does not present risks. Include contact information for the research team. This is particularly appropriate for ethnographic or anthropological research where the research unfolds informally, but informed consent processes must be upheld. Researchers must also consider how to document consent and how to protect this data (see 4.4 and 4.5).

Increasingly, technology plays a role in informed consent processes. Tablet computers with pre-loaded information videos or slide shows are seen as a way of delivering reliable information. Researchers must consider

safety issues and participants' potential unfamiliarity with technology, as this may either discourage or encourage study participation.

It has been proposed that *researchers* also provide informed consent prior to participating in data collection during emergencies. This can be part of the recruitment process and is recommended practice.

Case Study 5. Ensure that research participants are able to exercise their right to make a voluntary decision about research participation, free of coercion (force) or external influence

A University in Lebanon conducted research with volunteers (for details see case Study 3). Members of different political factions introduced researchers to participants and remained during the consent process. They were the sole authorities in the centres, providing access to shelter and basic services. Researchers later reported that participants potentially viewed their involvement in the study as a condition to continue to receive shelter and assistance.

Learning for future studies:

- When gatekeepers introduce participants to researchers this might lead to confusion about who is conducting the research, and if participation is required to please gatekeepers.
- In this example, some participants may have thought participation was a requirement to continue to receive services and shelter, and therefore their decision about participation was not voluntary: it was not free from external influence.
- Research participants may provide answers to please the gatekeepers, rather than their true opinions. Thereby, the validity of the final research data was thrown into question.

(Source: Yamout and Jabbour "Complexities of research during war: lessons from a survey conducted during the Summer 2006 War in Lebanon" ***Public Health Ethics; 3****(3); pp. 293-300)*

Voluntariness Participation must be voluntary. In emergency situations, or where participants are dependent, the extent to which they are free to agree or to refuse can be questioned (see Case Study 5). Community

participation and identifying contextual factors that may affect voluntary consent (see Box 6) will help to ensure that explicit or implicit coercion to participate are avoided.

Box 6. What can affect making a voluntary decision to participate in research?

- Unequal power relationships. This can lead to:
  - Raised expectations of the benefits of participation such as access to services or aid or
  - Consenting to research because of perceived power of the person taking consent, e.g., a medical professional
- Fear of outsiders, e.g. not understanding why or by who the research is being conducted which can lead to refusal to participate.
- The level of incentives or compensation to populations living in a dependent status, this can lead to participation for material benefit alone.
- Research embedded within services, this can lead to concerns that services will be withdrawn if they decline to participate or participants may think that their answers may affect service provision.
- Cultural and religious values such as hospitality norms or cultural norms that promote saying yes.

- Ensure consent is in line with local and international legal standards for children, including obtaining parental / legal guardian consent.
- If there is doubt about a parent or legal guardian acting in the best interests of a child, then this child should not participate.
- Additional consent or approval may be required from those in authority when conducting research at community centres, health centres or schools.
- The rights of children to actively consent to participate should be respected.
- Informed consent from parents or legal guardians and informed consent from children requires balancing two ethical duties. Be prepared to manage conflicts.
- Multiple versions of research information will be needed, including: age appropriate for children; for parents or legal guardians and for community organizations.
- Voluntary consent of children can be impacted by: their parent's consent or dissent; peer-pressure; potential stigma resulting from refusal to participate.

3.6 Reflecting on the study conduct for collective learning on ethical research practice

Increases transparency and learning, and should include how ethical challenges were managed. Critical reflection should be carried out through ongoing study monitoring or research advisory boards, not only at the end. It is important to include relevant stakeholders in this process (see 3.2), as reflection helps to identify ways to achieve and maintain ethical standards.

- Children should be provided opportunities to reflect on their participation.
- This can contribute to knowledge about research methods and study designs that children enjoy and that gather reliable data.

4. SAFETY

4.1 Participant and researcher safety are overriding priorities in emergency settings

Entering emergencies without sufficient safety planning is unethical and violates the principle of "do no harm". All research must include procedures for monitoring and responding to participant and researcher safety.

4.2 Responding to participant vulnerability and protection needs

Meeting participant protection needs *always* takes priority over conducting research. Here, vulnerability means individuals or groups at risk of: physical, sexual and emotional violence and/or abuse, exploitation or mistreatment, and those who lack power and/or resources to speak out and/or make voluntary choices.

Participants' have protection needs that may overlap with individual vulnerabilities. Protection needs can include: severe mental disorders; suicidal ideation; physical, sexual and emotional abuse or exploitation; female heads of households without support networks; unaccompanied children; people with specific health problems (e.g., HIV / AIDS); those involved in illegal activities (e.g., drug use or prostitution); or groups vulnerable to stigma or targeting. Emergencies may also bring MHPSS impacts for individuals, including: family separation; disruption of social networks; destruction of community structures and resources; increased gender-based violence; grief; non-pathological distress; and depression and anxiety disorders (IASC, 2007). It is important to identify these groups without further excluding, stereotyping or stigmatizing.

Ethical research requires that individuals and groups perceived as vulnerable or high risk are involved in research to ensure findings are applicable to these individuals and/or groups. Individual assessments enable an informed decision regarding participation, show respect for autonomy, and help to identify protection measures. Ongoing research monitoring may be needed. Have strategies to reach groups

and individuals who may self-exclude, be hidden or are hard to access. Collaboration with formal and informal community networks and groups can help.

Referrals to mental health care and other services: All staff must be trained in clear protocols to make referrals for further support where needed. This is an important benefit to participants (see Box 2), and a referral guide is essential. When including services for referrals, researchers must conduct an assessment of legitimacy, suitability and accessibility. Discuss inclusion with service providers (see Case Study 6). Where services do not exist, or service capacity is in question, researchers must make a decision whether they can ethically conduct their study. Independent reviewers will consider this decision through the ethical review process. Researchers must also consider the way referrals are offered to participants. For example, for victims of trafficking or sexual violence, or for mental health conditions that may be stigmatized, provide referrals to services in a manner that respects confidentiality.

Case Study 6. Identify and assess services to be included in referral guides for participants prior to starting research

An International NGO wanted to conduct a prevalence study of common mental disorders in a new refugee camp. They approached the International Medical Corps (IMC) to see if they could refer cases in potential need of mental health support. However, with the large sample size of participants and estimated high number of cases experiencing symptoms of common mental disorders, the capacity of IMC's team would have been quickly overwhelmed. This request was therefore declined by IMC.

Learning for future studies:

- Assessing services and discussing their inclusion in referral guide, prior to research starting, are essential to ensuring services are available to participants.
- If services are not available or accessible, a decision must be taken whether it is ethical to conduct research at all. This decision should be outlined in the research protocol for review.

- Researchers have a responsibility to ensure the protection of children participating.
- Do not arbitrarily exclude children. This leads to feelings of injustice or exclusion.
- Identify appropriate services for referrals, including child protection concerns. Assess the suitability and safety of services.
- When determined that a referral is required, this must be discussed with the parent / legal guardian for consent and cooperation.
- When children are researchers, ensure that they are aware of how to report concerns about another child to the study lead, who has the responsibility to respond.

4.3 Assessing and responding to participant autonomy and capacity

Autonomy refers to the right of competent individuals to make informed decisions about things that will affect them. Capacity refers to the ability to understand and be able to make an autonomous decision. Informed consent assumes participant autonomy. For children, people experiencing severe mental disorder and those who are unable to consent for themselves researchers will require alternative mechanisms for obtaining consent. This may include seeking consent from legal guardians, using in-country laws on proxy-consent, and ensuring these meet international human rights standards. If there are concerns that the legal guardian may not be acting in the best interests of the participant, then proxy-consent from them is unreliable. In such cases this is a valid reason for not conducting research with this population.

- Child legal standards require consent from legal guardians for a child to participate.
- It is important that the right of children to make autonomous decisions about participating is respected at all times, including their refusal. This right is emphasized in the UN Convention on the Rights of the Child[3], Articles 12 and 13.

4.4 Ensuring confidentiality, anonymity, and the right to privacy

Protect against privacy breaches by not excessively targeting a population group or using information provided by one participant to encourage information from another. For each research topic / question / population a decision needs to be made whether to hold interviews in public spaces (that cannot be overheard), or in private, including how privacy can be assured (see Case Study 7). This decision should be informed by the sensitivity of the research topic, and the potential risk to the participants if they are identifiable.

Be aware when being seen with a researcher exposes participants to risk. Research must not identify participants in a way that could lead to stigma or victimization.

Determine if it is possible to negotiate with family or communities to conduct interviews in private, or if the interview questions and study design have to be adjusted to fit local norms surrounding privacy (see 6.2). Have a short set of diversionary questions on a non-sensitive subject to refer to in order to diverge from the original question should interview conditions become unsafe, or privacy interrupted. This is best practice when interviewing participants who have been trafficked, experienced domestic abuse, or who are stigmatized.

Case Study 7. Holding research interviews in private locations where they cannot be overheard

A University in Lebanon, conducted research with volunteers (for more detail, see case Study 3). Members of political factions controlling the centres remained present during the interviews. Researchers reported that participants appeared to self-censor. Private locations to conduct interviews were unavailable.

Learning for future studies:

- Interviews in the presence of officials are likely to produce information to please officials, rather than representing the true opinions of participants. This data is unreliable and unethical.
- Conducting interviews in the presence of officials puts participants in a disempowering position. Prior to starting data collection, researchers should identify private locations for interviews. This can require negotiating with gatekeepers or officials.
- There are exceptions here: for example, if a study has been designed to be conducted in the presence of a family member or friend, or in a focus group, then research questions must avoid putting participants in a position where they may not be able to provide honest answers.

(Source: Yamout and Jabbour "Complexities of research during war: lessons from a survey conducted during the Summer 2006 War in Lebanon" ***Public Health Ethics; 3****(3); pp. 293-300)*

Researchers must be clear about the limits of confidentiality when conducting research. For example, in the case of harm to oneself or to others confidentiality will have to be broken to ensure that protection needs are being met. This break in confidentiality must be clearly conveyed during informed consent.

Making data anonymous is important to protect participant confidentiality. Involving communities in decisions regarding anonymity procedures is recommended. This includes sharing the ways participants will be referred to, and allowing the community to select their preferred option (see Box 7), which can increase agency and ownership.

Box 7. How can research data be made anonymous?

- Use pseudonyms (alternative names)
- Identifying participants by Unique Case Numbers (UCNs) instead of names, and not storing names and the identifying number together (IRCT, 2012)
- Creating composite persons, where a person is "made-up" based on features of different people and assigned a pseudonym (alternative name)

Written research protocols must include data management and security procedures to ensure confidentiality. Researchers are encouraged to map the physical "journey" that data will go on and how it will be protected at each stage (see Box 8).

Box 8. Protecting the security of research data

Recording devices: a person's voice may be recognized. Data must be protected on the initial device and on any computer files

Photography: taking photographs can be viewed as an attempt to document wrongdoing. Ensure consent is given prior to taking pictures of someone. Photos must be protected both when stored on cameras (digital or film) and on other devices such as computers

Notebooks (paper and electronic): if names or interview notes are stored in notebooks and these are stolen or confiscated, what risks are presented to research participants? Should names be recorded? Backing up data: Has the data been backed up and is the back-up saved on a safe device?

Data encryption / USB pens: Is electronic data encrypted (i.e. on computers and on pen drives)? Is all data on one pen?

Filing cabinets: If premises were raided and files searched, what is the likelihood that participants would be identified and therefore at risk? Who holds the keys to filing cabinets? Does having keys present a risk to staff members? How can this be minimized?

It is important to consider the increased risks of passing through security check points or conducting research in conflict contexts. Data should be carried in hand luggage when travelling.

All members of staff including interviewers, interpreters, data in-putters and auxiliary staff must be trained to protect confidentiality.

- Researchers must be clear about the limits of confidentiality when conducting research with children. If immediate safety concerns about a child's physical or psychological welfare are raised, researchers have a duty to act. This will break confidentiality and must be clearly conveyed during informed consent.
- Data collection methods should be discussed with the community in the study design phase to ensure they are compatible with local practice and norms. For example: children may prefer being interviewed with a friend, or a family member may be required to be present.
- When conducting research with children protecting anonymity and confidentiality is especially important.

4.5 Accountability through fair selection and specialist training of research teams and auxiliary staff

Research must be accountable to the community involved, to donors and to wider academic, practitioner and public audiences. Accountability requires ethical research practice.

Staff selection: researchers and auxiliary staff must enter emergencies mentally, physically and materially prepared. They must be fairly selected and undergo proper training. This is achieved through clear procedures to identify knowledge, skills, attributes and prior experience of the team and staff (People in Aid, 2003). It is important to address matching researchers and participants where this is culturally appropriate (see Case Study 8, 9, and 10). Potential implications for confidentiality and anonymity must be considered when staff are recruited from within the community where research will occur.

Case Study 8. Staff selection based upon objective criteria and a fair recruitment process

A University in Lebanon conducted research with volunteers (for detail see case Study 3) who were activists and students, and not selected on the basis of objective staff criteria.

Learning for future studies:

- Staff selection was based on being willing volunteers and therefore not accountable.
- As activists and university students they were likely to have brought their own interests to data collection, for example seeing involvement in the research as a way to gain credit.
- When including voluntary staff in data collection, they should be provided the same training and support as paid staff, provide informed consent and compensation for expenses.

(Source: Yamout and Jabbour "Complexities of research during war: Lessons from a survey conducted during the Summer 2006 War in Lebanon" Public Health Ethics; 3(3); pp. 293-300)

Staff Training: Adequate time and support must be given for staff training needs. The aim of initial training and ongoing mentoring is to build skills in ethical research practice. It is particularly important to develop local capacity.

Case Study 9. Fair staff recruitment and specialist training

Study conducted by two international principal investigators assisted by two locally hired co-investigator consultants. The team included 20 psychosocial workers and five supervisors. Specialist training was provided to the Psychosocial Workers collecting data, but did not include how to respond to complex psychological suffering of interviewees.

Learning for future studies:

- Staff selection included partnership between local and international investigators, a number of internal organizational staff and specifically recruited local experts. This approach resulted in a good balance and effective collaborative work.
- Data collectors were recruited from within existing project staff. This enabled building local capacity through specialist training while service delivery continued as normal.
- When asking staff to take on additional data collection or research roles, ensure they are free to decline and that this will not affect employment. Staff must be selected on objective criteria.
- As well as training in collecting information, it is important to include responding to participant distress and making direct referrals.

Recommendations for staff training are provided in Box 9. It is also important that researchers adhere to standards of accountability in humanitarian practice (e.g. Sphere Handbook) (The Sphere Project, 2011). Researchers should practice implementing skills being taught. Training should continue until the trainer is confident that staff have understood, that research will be conducted ethically, and methods implemented well.

Box 9. What should research staff training cover?

- Ethical research practice (including these recommendations);
- Cultural competencies;
- Collaborative and team working skills;
- Basic helping skills (such as Psychological First Aid);
- Safety including emergency preparedness and field coordination practices;
- Social and psychological risks of working in emergency settings;
- Self-care strategies (see 4.6);
- Background knowledge of the research topic and the emergency;
- How to recognize, establish and maintain professional boundaries;
- Understanding and maintaining participant confidentiality and anonymity throughout the research process;
- How to manage issues participants may present that are not directly related to research or that researchers may be unable to respond to, such as applications for refugee status or problems relating to housing or employment;
- How to identify at risk or vulnerable participants;
- Referral guides for responding to participant distress, vulnerable participants or protection needs;
- Risk management, including ongoing risk monitoring procedures
- Data management including safe data storage;
- Dissemination arrangements;
- Specialist training in informed consent procedures to ensure clear, concise and continuous explanations of research;
- Specialist training in any tools, instruments, documents, and forms required by the researchers role;
- Specialist training for interviewers i.e. developing rapport with participants and active listening skills;
- Specialist training when working with interpreters or translators, emphasizing confidentiality and power relationships

(Source: WHO, 2012; IOM, 2010)

Whenever possible, research supervisors and/or the study lead should accompany researchers to the field and remain on-hand for support (see Case Study 10). Study leads/supervisors should conduct regular

debriefings to monitor study conduct. All members of the team should have identified field mentors and should have in place clear processes for raising concerns. It is preferred that researchers work in pairs to ensure actions of one researcher are monitored by another and can offer peer support and advice. Ensure participants are comfortable with *why* there are two researchers before starting research. If a researcher is working alone, it is essential they are fully trained and competent.

Case Study 10. Staff training should include classroom based active learning and ongoing support during field data collection from study leads

Study conducted in Puttalam, Sri Lanka measuring the prevalence of common mental disorders among internally displaced Muslims, a population closed to outsiders. This was addressed by recruiting research assistants (RA's) from within the community and gender matching interviewers and interviewees. Research training lasted five days, with two days dedicated to ethical research practice. Training was active and involved role-play. During initial informed consent, the research lead remained to answer questions. This increased the capacity of RA's to answer questions themselves and the lead was able to observe each RA's initial interview with participants to monitor that methods were implemented well.

Learning for future studies:

- Staff selection was based on study needs, including the acceptability of RA's to the community.
- Training covered all aspects of ethical research relevant to the role of the RA's. Practice implementing these principles and using the study tools allowed RA's to build confidence, and the study lead to address any shortcomings in implementation.
- The presence of the lead in the field reassures RAs that support is available if required. This encourages ethical research practice and the identification of potential training needs.
- Field mentoring of all staff ensures ethical informed consent and data collection tools.

(Source: Siriwardhana et al., 2013 "Ethical challenges in mental health research among internally displaced people: Ethical theory and research implementation" BMC Medical Ethics, 14 (13) – open access)

- Researchers' primary accountability duty is to children themselves.
- Conducting research with children requires extensive specialist training developed in accordance with specialist, technical advice.
- If there are any concerns about the ability of researchers to implement the methods well that person should be removed from the research team, or research should not be conducted at all.
- Research training must include: issues of power and vulnerabilities of children; limits of the researcher's role and how to intervene appropriately to bullying, jealousy or stigma; identifying, establishing and maintaining professional boundaries, appropriate to the local cultural context; and extensive role-play and case study scenarios.
- When involving children as researchers:
  - Appropriate payment/compensation must be agreed with the community.
  - Research training must be age appropriate, involving participatory methods and clear explanations of key principles. Training should continue until the study lead is confident that children will implement the methods well.
  - They should always work in pairs with age-appropriate supervision and leads should always be present in the field to provide immediate support and supervision.

4.6 Staff care

Staff care should take place on different levels: personal level (self-care), team level (peer support); supervision (guided by an appointed supervisor); inter-vision (Inter-collegial); and on management level (policy) (Antares Foundation, 2012). Working in emergency environments can be stressful and exhausting, so all staff should practice care and support strategies. Good staff care protects against and responds to negative reactions, which can include: grief, stress, anger, inability to sleep, loss of appetite, excessive alcohol consumption, over-involvement, or a sense of duty towards participants. Negative

thoughts include suspicion or worries about being a failure, and can result in being isolated or withdrawing from usual activities. Being exposed to participants' lives or histories of extreme suffering increases the chance of negative reactions. Providing opportunities for concerns to be raised allows researchers to seek support. Frequent supervision is recommended.

- If involving child researchers:
  - During training, children should identify strategies to relax;
  - Regular group activities are recommended;
  - Inform parents or guardians about potential negative reactions, so they can monitor child researchers' self-care.

4.7 Environmental, political and health security

Emergencies present a range of risks to both researchers and participants. Depending on the emergency, this can include the presence of armed actors, unpredictable events and engaging with communities who have been displaced. Learning about potential safety considerations prior to entering the field is essential (see Box 11).

Box 10. Learning about safety when working in emergencies

- This is an important aspect of being prepared to conduct research in emergency settings.
- Recommended resources include:
  - United Nations Field Security trainings (this training is free but you will have to register)[4]
  - Organizational trainings
- Once in the field researchers must coordinate with those managing the emergency response, such as coordinators of an MHPSS Working group and Health or Protection Clusters.

Having safeguards, security measures and exit strategies prior to starting research is central to ethical research practice. This requires coordinating

with agencies managing the emergency response. Given the changing nature of emergencies, it is essential to monitor and respond to changing security contexts, including suspending or terminating research (see Case Study 4).

- If involving children as researchers, it is essential that researchers have emergency contact details for parents or legal guardians.

5. NEUTRALITY

Ethical research should maintain 'equity' (treating all humans as equal) and 'impartiality' (not taking sides or passing judgement).

5.1 Ensure non-discrimination and non-alignment (not taking sides) in conflict settings

The way research is presented to the community impacts perceptions of researchers' neutrality. They must remain non-aligned in conflicts and practice non-discrimination in participant selection. This includes remaining impartial to social inequalities and social characteristics including: age, gender, religion, ethnicity, and political affiliation. Social science research may be designed to explore the perspectives of a particular social group or experiences of a military faction.

5.2 Access to and exit from the study site

The way the study is positioned in relation to the emergency requires critical consideration. This includes implicit messages, such as which communities are targeted, and could the target community be seen as chosen due to easy accessibility? Explicit messages are, for example, do questions focus only on child soldiers? Coordination with organizations on the ground can also have implications, as they may be perceived to have agendas. Choice of accommodation, transport and people you associate with publicly also sends messages.

In written research protocols, it is important to identify circumstances where research might be limited, suspended or stopped. Researchers should plan how to ethically exit, with honest explanations to communities and stakeholders providing support.

5.3 Declare researcher interests

Researchers, participants, ethical review bodies, and partner organizations all bring their own interests and agendas to the research process and have an ethical duty to declare these. Transparency about interests includes being open about research that is commissioned or supported by delivery organizations or private (pharmaceutical) companies, or is conducted to influence policy or for advocacy.

5.4 The role of funding

The role of research funders in influencing or setting research agendas and conduct also carries ethical implications. Funding connected to donor's priorities or goals, may constrain research and steer it in a specific direction. Be prepared to negotiate with funders over the management of ethical issues, including educating funders on the importance of spending time on community participation or specialist training of staff. Anticipate the funding implications of ethical research, with budgets included in the research protocol. These budgets must be transparent. Researchers should also engage with funders to advocate for the importance of methodological and ethically rigorous MHPSS research during emergencies.

- These recommendations apply equally to research with children.

6. STUDY DESIGN

6.1 To be ethical, research must be well designed

To ensure a positive contribution to MHPSS services in emergency settings, research must be well designed and address contextual factors,

including sociocultural considerations, patterns and dynamics of conflict, economic inequalities, poverty, and unequal access to health-care.

6.2 The research methodology must be appropriate to the research question and target population

Poorly designed research is unethical. Unreliable methods risk promoting unreliable knowledge and may cause harm to participants. A general tenant of research is: *no data is better than bad data.* It is worth thinking about simplicity and feasibility in design, not only to increase chances of success, but of subsequent work being successfully achieved. For example, this might include simple (statistical) analysis of data, rather than needing specialist technical expertise or software. Box 12 identifies some considerations to help ensure research is well designed.

Box 12. Methodological considerations for well-designed research

- Clear scientific rationale for why research must be conducted in an emergency;
- Explanation and justification of the methods (i.e. interviews, questionnaires, randomized control trials, ethnographic methods such as participant observation) including how tools and methods will be adapted to the local context;
- Employing a study design and methods that can answer the questions/hypotheses posed by the study, and are feasible for the study team to achieve;
- Ensure that data is collected to a high standard through regular review of data;
- Description of the sampling approach;
- Clear definitions of key concepts, variables, and the central research hypothesis;
- Evidence how contextual norms have been addressed;
- Ensure transparency on how strengths and limitations of the methods and results will be evaluated throughout research design, implementation and dissemination.

Be aware that some research methods may be similar to other processes. This could lead to confusion about whether interviews are for research purposes or for "official" applications. Avoid labelling or stigmatizing participants and avoid using concepts which are understood differently in different cultures (such as "childhood"), or terms that could be seen as aggressive or undermining of resilience. Be sure to involve communities to verify concepts, language used and the phrasing of questions (IASC and UNICEF, 2011). Pilot all tools to ensure questions are being understood and are collecting reliable data. Methodologically sound research requires that methods are practiced well (see 4.5).

- It is important to have specialist technical support to design research to be:
  - Appropriate to the age and developmental stage of participating children;
  - As participatory as possible;
  - Culturally appropriate. Consider restrictions to mixing genders or activities that require touch between children not known to one another;
  - As non-invasive and stress free as possible.

FEEDBACK

We welcome and encourage your feedback and experiences of applying and using these recommendations in your data collection activities. We hope that discussions on ethical MHPSS research will continue across different agencies and disciplines, which will help to further refine what ethical MHPSS research practice "looks like" during emergencies.

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FURTHER RESOURCES ON ETHICAL GUIDANCE:

International declarations on ethical research:

Council for International Organisation of Medical Sciences (CIOMS)
2002 *International ethical Guidelines for Biomedical Research involving human subjects:* http://www.cioms.ch/publications/layout_guide2002.pdf

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1979 *Ethical Principles and Guidelines for the Protection of Human Subjects of Research. April 18, 1979:* http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

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Endnotes

1 Please see international declarations on ethical research above for examples (p. 50)

2 http://www.who.int/mental_health/publications/guide_field_workers/en/

3 http://www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx

4 https://trip.dss.un.org/dssweb/WelcometoUNDSS/tabid/105/Default.aspx?returnurl=%2fdssweb%2f

Mental health and psychosocial support (MHPSS) are an integral part of any emergency response. Research knowledge is a fundamental factor in the design and implementation of effective MHPSS programs. Therefore, research in all its forms is key to informed MHPSS emergency responses. This document provides an overview of principles, practices and examples to support researchers, practitioners, managers, emergency officers and communities to implement MHPSS research in emergency settings that is ethical.