Health Sector Research and Assessment Committee

Terms of Reference

Background: Coordination is an essential part of the humanitarian response, with the aim of avoiding unnecessary duplication of service delivery and identifying gaps where services are most needed. With the Syrian crisis in its fifth year, the evolving humanitarian context poses new demands on health systems in Jordan and consequently on the Health Sector, and there is a need to strengthen planning and coordination even further to ensure an appropriate response. This includes improve collection and analysis of data and dissemination of information. Thus, the formation of a Health Sector Research and Assessments Committee (HSRAC) was proposed in order to better identify directions for researches and coordinate sector needs assessments.

Function: The function of the HSRAC is to provide technical and strategic support to ensure that refugee rights are recognized and the particular vulnerability of refugees is considered in the planning design and conduct of assessments and research and to ensure a coordinated approach.

Objectives:

1- Review planned assessments for justification and indications, methodology, ethical principles, and coordination with existing or planned assessments;
2- Review proposed research relating to health amongst refugees and ensure agreed criteria are met.

Membership: Membership is voluntary, and the committee will have between 3 to 4 members (in addition to MOH and sector chairs). They should be familiar with the main current health issues facing populations and health systems in Jordan and the ways they are being addressed. The members will not act in the interest of their own organization but rather use their broadly-based experience in the interest of the Health Sector as a whole.

Members: To be nominated and selected, with the possibility of rotational membership every 6–12 months. Current members are MoH, UNHCR, WHO, UNICEF, UNFPA and USAID.

Method of Work:
Health Sector Research and Assessments Committee (HSRAC) will be chaired by MOH and Health Sector Leads. The Committee will meet at least once a month and when required to review applications and give timely feedback to the applicants. Members are requested to attend the meetings in person, or send a suitable representative.

The role of the Research and Assessments Committee in reviewing and approving Needs Assessments and Research relating to health and provide recommendation to MOH and does not replace the Governments core function in providing approvals.

Application Process:

In order to ensure appropriate coordination of assessments, an agency wishing to conduct an assessment should go through the following process:

1. Define the objective for the assessment, and how the information will be used;
2. Upload the proposed assessment data onto the Needs Assessments Registry; http://data.unhcr.org/syrianrefugees/country.php?id=107
3. Inform geographic coordination structures (Camp Management, or urban coordination systems);
4. Inform geographic sector Working Groups, where applicable;

5. Inform country-level sector Working Groups;
6. Complete and submit Form for Research Project Proposals (Annex1) with sector chair for HSRAC committee review.
7. Within one week HSRAC Committee will review assessment and share recommendation to MOH, give feedback to the requester and mark assessments as 'approved' in the Needs Assessments Registry (for primary data collection only);
8. Apply for MOH approval (see Annex 2: MOH requirements for research approval
9. Obtain MOH and ethical committee approval (see annex 3: "Research Ethics Summary for the Humanitarian Response" for further guidance)
10. Some assessments and researches that include field work and/or home visit activities would need Ministry of Interior approval (seek MOH advice).
11. Provide plan of work and coordinate with relevant fields for data collection.
12. Share the assessment findings with corresponding coordination mechanisms (both geographic and sector-based).

Annex1: Health Sector Working Group Form for Research Project Proposals Amongst Refugees in Jordan

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1. Project Title:

2. Name of Institution(s) leading the research:

3. Name and address of agency with which collaboration is proposed, and name of contact person in collaborating agency:

4. Name of researcher(s) with designation, experience, address and telephone/fax, and e-mail:
5.

6. Please submit any documents that indicate clearance from ethical committee(s) if already obtained:

    - from country of origin
    - from Jordan

7. Research objectives:

8. Projected dates and duration of data collection:

9. Proposed methodology and data collection methods including confidentiality and data storage procedures:

10. Sites of research, how have these sites been chosen and how will the participating community be approached about study participation?

11. Target population and proposed sample size:

12. Informed consent processes – how will consent be obtained and recorded?

13. Expected benefits to the target population:

14. Anticipated risks to the target population and strategies to monitor and manage risk:

15. Expected Outcomes:

16. Proposed dissemination plan. How will results be communicated back to others working in the relevant setting/ thematic area and to the participating community?

Annex2: Ministry of Health requirements for research approval

Each researcher should submit the following documents to the Directorate of Human Resources Development/Planning Department in the Ministry of Health. The research proposal will be presented to the Ethics Committee for scientific research. The decision would be either approved or request modification before approval or rejection

1- Provide a full research protocol and preferably attach a soft copy in addition to the hard copy. Including the ethical aspects of the scientific research
2- The research should include the following information:-

   a) The time frame for data collection
   b) Explain the mechanisms to abide by to maintain confidentiality and patient privacy
   c) Explain the mechanisms to abide by to maintain respect to the participant's cultures, customs, traditions and religions.
   d) Explain the benefits of the patients' participation in the research and the potential risks if found.
   e) Determine the interviews' location at the hospital or the health center
   f) Identify the method of obtaining consent.
   g) Provide researcher curriculum vitae.
   h) Present certified copy of the scientific degree.
   i) Provide a written pledge and a copy of the research and results before publishing to the human resources development department and Chairperson of the Ethics Committee of scientific research

3- Provide a letter from the sponsoring organization for the research submitted to the Director of Human Resources Development/Ministry of Health

4- Provide a written pledge to provide the necessary material for the research

5- Share data collection tools

6- Indicate if the research was presented to other committees? If "Yes" identify where and the result of the presentation

_____
Full name_____
E-mail_____
Mobile number_____
Home number _____
Work number _____ Extension:_____
Address _____
Nationality:- Jordanian Other

Name:- Signature:-

Annex3: Health Sector Working Group Jordan

Research Ethics Summary for the Humanitarian Response

Background

There is a need to further develop the evidence base of the effects of humanitarian situations on health and wellbeing and the outcomes of programmatic interventions. Indeed work in progress aims to provide a rigorous assessment of the quality and depth of the evidence-base that informs humanitarian public health programming globally[1].

However, there is a lack of guidance on the ethics of conducting such research in humanitarian affected populations. Despite the fact that Ethical Review Boards exist in many countries additional safeguards are needed for refugees and internally displaced populations and when undertaking research in a humanitarian context.

Jordan has been a refugee hosting country for many years including large influxes of Iraqis and now Syrians. Requests to the Health Sector Working Group to conduct research are frequent and often based on the needs/interests of researchers and not on research gaps identified by operational agencies. Furthermore, to date, there have been few measures beyond standard ethical review procedures to ensure that specific protection or ethical concerns relating to refugees are considered in planning and conducting and reporting research.

Why the need for these guidelines?

1. Refugees have fewer defined political rights than host community citizens
    - Refugee Convention established only basic standards for treatment of refugees.
    - Refugees may stand outside the regulatory protection of host country legislation.

2. Research in midst of complex emergencies or humanitarian situations may mean inadequate safeguards are in place to protect the population of refugees or internally displaced persons.

3. Little technical guidance is available from the existing international instruments on biomedical ethics (Declaration of Helsinki or guidelines from the Council for International Organizations of Medical Sciences). Although these instruments examine issues of vulnerability (as arising with prisoners, children, or the mentally impaired) they do not

[1] http://www.elrha.org/r2hc/evidence-review

address the special circumstances of enlisting refugees or the internally displaced in research.

4. The physical layout of camps and population density are very amenable to rapid systematic sampling and data collection making research in camp situations logistically appealing. However, research conducted in refugee camp settings must not be founded upon convenience alone; to conduct research on this basis amounts to exploitation.

5. High profile humanitarian situations attract many institutions and individuals wanting to undertake assessments or research. While there have been positive examples of convergence of information needs of operational agencies with interests of academic researchers this is not always the case. Even if well-meaning, research may not always offer direct or even indirect benefit to refugees or the affected populations.

6. The multitude of organizations collecting data for different reasons including advocacy, assessments, monitoring and evaluation, operational research mean that households and individuals can be assessed or studied multiple times resulting in "survey fatigue".

7. There are challenges obtaining informed consent in populations who may be in need of protection and assistance. Refugee populations may feel that continued assistance or protection is contingent on their participation in the research and therefore may be reluctant to decline to be involved.

8. Dissemination of information collected in the field (e.g., pictures), can inform the outside world and mobilize support. However, photographs also can bring humiliation or stigma, and violate the rights to privacy. Images may reinforce the image of the subjects as victims, rather than as resilient individuals. Even in the case in which consent to publish or use a picture is given, subjects may not fully understand the number of people who would see their picture, in what context their picture might be viewed, or the implications for themselves.[2]

9. Confidentiality is more difficult to maintain in refugee settings.

10. Beneficence—in whose interest is this research being done, and who will benefit from the results? The mobility and fluidity of many refugee populations make it difficult to ensure benefit to the specific individuals enrolled or to the community to which he/she belongs.

Research Procedures in Refugee Context in Jordan

[2] Allden et al. Mental Health and Psychosocial Support in Crisis and Conflict: Report of the Mental Health Working Group. July-August 2009 http://pdm.medicine.wisc.edu Prehospital and Disaster Medicine

Due to the above concerns the Health Sector Working Group in Jordan would like to safeguard the rights, safety, and wellbeing of refugees participating in any research, study or survey. In doing this reference will be made to the *Basic Values Underlying Research Ethics* (Annex 2.a) and the *Proposed Guidelines for Research in Refugee and Internally Displaced Populations (Annex 2.b*). Persons or organizations wishing to conduct research in Mental Health or Psychosocial Support should also seek guidance from the *Mental Health Inter-Agency Guidance Note for Mental Health and Psychosocial Support in Jordan - Response to Displaced Syrians - November 2012* in *Section 6.3. Conducting MHPSS Assessments, Monitoring and Evaluation* and where relevant follow the *WHO Ethical and Safety Recommendations for Researching, Documenting and Monitoring Sexual Violence in Emergencies. WHO 2007*[3]*:*

When do these Guidelines Apply?

The requirement for ethical review depends on the research methodology and the specific population involved. This would vary depending on whether the research involves routine monitoring and evaluation, operational research (investigations or studies that are not routine and undertaken to inform programmatic planning or to address identified programmatic problems), hypothesis testing, or clinical research.

1. Most actors in the health sector in Jordan have conducted baseline assessments and continue to conduct monitoring and evaluation, including surveys which may not fall under the umbrella of "research". Therefore, they may not require institutional review board approval or need to apply to the Health Sector Working Group for approval. However, they should consider the same ethical questions below when planning and conducting programmatic monitoring and evaluation. Confidentiality issues, anonymity of personal identity within datasets and the right to refuse participation are all ethical principles which cannot be compromised.[4]

2. Operational research and hypothesis testing. Any non-routine study undertaken to inform programmatic planning or test a hypothesis even if using existing data sets will need approval of the Health Sector Working Group.

3. Clinical research will not be conducted in refugee settings as (with very rare exceptions) it can be conducted in other populations.

The conduct of Needs Assessment is also guided by the Standard Operating Procedures for Needs Assessments developed by the Inter-sector Working Group http://data.unhcr.org/syrianrefugees/working_group.php?Page=Country&LocationId=107&Id=60

Approval Process

[3] http://www.who.int/gender/documents/OMS_Ethics&Safety10Aug07.pdf

[4] Nathan Ford, Edward J Mills, Rony Zachariah and Ross Upshur. Ethics of conducting research in conflict settings. Conflict and Health 2009, 3:7

All proposed research as above must be submitted to the Health Sector Working group for approval. Please submit to Ibraheem Abusiam abusiam@unhcr.org or Felicia Jones jonesf@who.int

What the Health Sector Working Group Will Assess:

- the rationale of the research
- the scientific design and methodology, including the skills and any additional training of the research team to conduct research in humanitarian settings
- the recruitment of research participants, including inclusion and exclusion criteria, list of participants, and means by which full information is to be conveyed to potential research participants or their representatives
- relevance of the research in the refugee population and in the wider context of public health evidence building in humanitarian settings
- evidence that the research could not be conducted in non-refugee populations
- the research benefits to the participant group and all refugees
- evidence that the research will pose "minimal risk" to the participants and research team, and the way in which potential risk is to be managed
- appropriate referral mechanisms are in place for those identified during the research to be in need of further care or support
- evidence that the refugees are free to participate and withdraw at any time
- Assurance that confidentiality of participants is ensured
- Assurance that the results will be disseminated amongst the agencies working in the same domain to avoid duplication of efforts, promote use of the results and reduce undue burden on research subjects.
- Assurance that the manner in which the results of the research will be reported and published is appropriate

Documentation that the research proposal meets appropriate Ethical Review Board requirements in Jordan will be required later.

For further information please contact Ibraheem Abusiam abusiam@unhcr.org or Felicia Jones jonesf@who.int

ANNEX 3.a: Basic values underlying research ethics:

Autonomy, Beneficence and Justice

1. Autonomy

The research participant should make an autonomous decision, have the right to reject participation without explanation at any stage of the research. It is underlying that sufficient information adapted to the cultural context is given to participants.

Informed consent

- each person has a right to reject interventions to his/her own body or mind
- primary aim is adequate understanding and voluntary consent
  'informed" means that individual has an understanding of a study's purpose, who are the targeted beneficiaries, and the implications of involvement; "Informed" also means that the information is communicated in a form appropriate to the culture, age, and educational level of that individual.
- "Consent" refers to an active agreement for participation in research, with the understanding that the participant has the right to refuse any question and to stop participation or withdraw at any time.
- Refugees must understand that their participation or not in the research will have no influence on their right to access assistance or protection.
- Documentation required is a signed consent form or oral consent in front of a witness
- consent of parents / legal guardian in case of minor or mental illness

2. Beneficence and Non–maleficence

– avoidance of inappropriate risks to participants and the research team
– benefits for the group in which the research take place
– acceptable risk / benefit rates
– processes to monitor and assess risks, with strategies to respond to high risk

3. Justice

- equitable selection of research participants according to the scientific design and methodology of the study
- clear explanation of the availability of treatment / intervention to the population involved in the study and beyond

Annex 3.b: Proposed Guidelines for Research in Refugee and Internally Displaced Populations[5]

- Undertake only those studies that are urgent and vital to the health and welfare of the study population

- Restrict studies to those questions that cannot be addressed in any other context

- Restrict studies to those that would provide important direct benefit to the individuals recruited to the study or to the population from which the individuals come

- Ensure the study design imposes the absolute minimum of additional risk

- Select study participants on the basis of scientific principles without bias introduced by issues of accessibility, cost, or malleability

- Establish highest standards for obtaining informed consent from all individual study participants and where necessary and culturally appropriate from heads of household and community leaders (but this consent cannot substitute to informed consent)

- Institute procedures to assess for, minimize and monitor the risks to safety and confidentiality for individual subjects, their community, and for their future security

- Promote the well-being, dignity, and autonomy of all study participants in all phases of the research study

Additional considerations in humanitarian populations include[6]:

1. Research should provide a benefit to the studied population;
2. If the primary purpose is to assist those being studied, research should:
    a. address important unknowns that affect the nature of humanitarian assistance (program design and planning); and
    b. evaluate benefits/risks of interventions when these are also unknown;
3. Research also may facilitate progress in the field of humanitarian assistance (i.e., improved services after future disasters); and
4. There should be a generalizable benefit, if possible.

[5] Leaning J: Ethics of research in refugee populations. Lancet 2001, 357:1432-1433.

[6] Allden et al.

5. If the research is determined to be of no benefit to the local population, then it should not be carried out