

Issuance of Director General Circular Number 22 Date 9/3/2018 Related to the Regulation of Studies and Research in the Field of Mental Health and Psychosocial Support

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Related to the regulation of studies and research in the field of mental health and psychosocial support

Based on the decision number 141/4 related to the establishment of a mechanism for the accreditation of ethics committees for clinical trials and studies targeting humans,

As the Ministry of Public Health is keen on ensuring the safety and protection of persons living in Lebanon, particularly of vulnerable groups including displaced persons and refugees,

As the respect of ethics in research is a critical matter, especially in the field of mental health and psychosocial support and substance use, and particularly in the context of humanitarian crises during which participants in research may be in need of evidence-based mental health and psychosocial support interventions,

As the Ministry of Public Health, in particular its National Mental Health Programme, is keen on ensuring that any pilot or research study in the field of mental health and psychosocial support and substance use – including pilots of interventions and needs assessments pertaining to or comprising questions related to mental health (including around traumatic experiences) and substance use - conducted in Lebanon does not present any risk on persons participating in it and respects ethical guidelines,

In clarification of circular number 48 issue date 12 June 2017 related to the regulation of studies in the field of mental health and psychosocial support in Lebanon, we repeat and emphasize the following:

1. Regarding the requirements that apply to all mental health research regardless of its subject and independent of the body that is preparing it:
 - a. Prior informed consent must be obtained from participants in the study after they have received enough information about the study, its aims and its design, and the risks or disruption the study may subject them to; and the informed consent form must be written in a language that is understandable by the participant and read to him/her in a clear way.
 - b. Prohibiting the participation of children or persons who do not have the capacity to make decisions without the consent of their legal guardian and not coercing them to participate if they do not wish to do so;
 - c. Ensuring confidentiality of information on the participants acquired from the study and refraining from disclosing the information to any third party un-related to the study.

2. Regarding research related to mental health for displaced persons and refugees it is required to receive prior official approval from the Ministry of Public Health after the Ministry revises the following documents:

a. The official ethical approval for the study from an ethics committee that is affiliated to a university or hospital and that is officially authorized by the Ministry of Public Health (Institutional Review Board – IRB);

b. The final protocol of the study which should detail the following criteria and conditions:

- Details of a strict safety plan for persons at risk of self-harm participating in the research
- Mechanism for ensuring the access of persons participating in the study to appropriate mental health and substance use response services;
- Include a researcher and/or specialized professional in clinical mental health or substance use if the study deals with the clinical field.

c. The Ministry of Public Health shall review the documents within ten working days from the date of submission of the application and communicate to the research focal party the acceptance or rejection of the application or the need to make appropriate amendments to the above mentioned documents.

Note: discussing the concept note of the research with the National Mental Health Programme at the Ministry of Public Health before the official submission of the required documents contributes to expediting the procedure of obtaining the approval of the Ministry of Public Health.

3. Regarding research related to mental health in general, the Ministry of Public Health urges the concerned party to share a copy of the publications resulting from its research for documentation and coordination purposes.

The National Mental Health Programme is the reference body for the implementation of this circular and for receipt and processing of applications for study approval. The Programme can be contacted through:

- Email: mentalhealth@moph.gov.lb; nmhp@moph.gov.lb

- Phone: +961 1 611 672 ext.: 125

We ask all concerned parties, including local public and private universities and foreign universities with branches in Lebanon or who intend to conduct a research study on the Lebanese territory, United Nations organizations, research centres, international and local non-governmental organizations, foundations, and others, to abide by this circular.

Director General
Ministry of Public Health
Walid Ammar MD, Ph.D