Lebanese Republic
Ministry of Public Health
Mental Health Programme

Application to Conduct Research in Mental Health and Psychosocial Support and/or Substance Use in Lebanon involving refugees and/or displaced populations

In line with the Ministry of Public Health Circular number 22 Date 9/3/2018[1] related to the regulation of studies and research in the field of mental health and psychosocial support and substance use, research in this field in Lebanon involving displaced persons and refugees is required to receive prior official approval from the Ministry of Public Health of Lebanon. This includes pilot or research studies – including pilots of interventions and needs assessments pertaining to or comprising questions related to mental health (including around traumatic experiences) and substance use.

Please fill this application form and submit it along with the below indicated documents to the National Mental Health Programme at the Ministry of Public Health on the following email address: mentalhealth@moph.gov.lb

Document Submission Checklist:

☐ The official ethical approval for the study from an officially authorized ethics committee (Institutional Review Board-IRB) by the Ministry of Public Health or IRB in Lebanon or an IRB that is affiliated to a university or hospital that is officially authorized[2].

☐ If the study is conducted in collaboration with a university outside Lebanon, the official ethical approval for the study from the ethics committee (Institutional Review Board-IRB) of that university.

☐ The complete study protocol including all relevant/related documents (consent documents, research instruments (interview guide, survey, etc.), flyers, advertisements, etc.) in the language in which they will be administered. Key elements that need to be detailed in the protocol where relevant are:

- 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;
- Declaration if any biological samples will be collected from the study participants, and if so, specifying the answers to the following: What are the samples to be collected? Why will they be collected? Will the samples be exported for testing outside the country? [3]

☐ If the study is an INTERVENTIONAL[4] study, a proof of submission to the Lebanese Clinical Trials Registry (LBCTR) where it should be registered. Submission is conducted on the website of the LBCTR: http://lbctr.emro.who.int/. The study will only be officially registered at the LBCTR after it is cleared from the National Mental Health Programme.

[1] Link to Circular number 22 Date 9/3/2018: English / Arabic
[2] Link to List of authorized IRBs: English/ Arabic
[3] If biological samples are to be collected from study participants, and to be shipped outside Lebanon for testing, approval for exportation has to be obtained from the MOPH. Studies that involve collecting genetic samples might need further approvals from the Lebanese Ethics Advisory Committee for Health and Life Sciences (Website: http://ccnle.org.lb/about-us/members).
[4] Interventional studies are those that intend to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, process-of-care changes and others. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Contact Person *(i.e. Focal person from the research team the MOPH can contact to follow-up on application form submitted)*
Name:
Title:
Phone number:
Email address:

1. Type of Research:

Check which of the following categories applies to your study:
☐ Randomized Controlled Trial
☐ Quasi Experimental Study
☐ Descriptive/ Exploratory (Case series, needs assessment, epidemiological description, descriptive cross-sectional study or community survey, etc.)
☐ Grounded Theory
☐ Observational or Correlational Study (Case reports, cross-sectional survey, cohort study, case-control study, etc.)
☐ Other: Specify

The study is conducted as part of:
☐ University Departmental Research
☐ Graduate Study Research
☐ Undergraduate Study Research
☐ Organisation Research
☐ Project report
☐ Others *(Please specify)* _____

2. Research Project Information:

2.1 Project title:

_____
_____

2.2 Key Personnel:

	Full name	Affiliated institution	Department	Degree	Affiliation *(University Faculty, Graduate Student, Staff, Undergraduate Student, Visiting Scholar, Other*	Title	Phone number	Email address
Principal Investigator (*(The researcher leading the study and is responsible for conducting the research team)*								

Co-investigator(s) *(Key research team member, engaged in design, recruitment, consent process, data collection, and/or data analysis)*								
Collaborator (s)								

Name of the Support staff/ Research staff _____
(Personnel implementing more basic duties)
Affiliated institution: _____
Department: _____
Degree: _____
Affiliation: ☐ University Faculty ☐ Staff ☐ Graduate Student
☐ Undergraduate Student ☐ Visiting Scholar ☐ Other:
Title: _____
Role in Study: _____
Phone number: _____
Email address: _____
Provide the same information for additional Support/Research staff members

3. Research Location:

Describe all the research sites for this research project, specify whether the site has given you permission to conduct your research
1._____
2._____
3._____
4._____

4. Research Duration:

Proposed Project Start Date and Duration, including recruitment, collection and data analysis.
_____
_____

5. Participants/Subjects:

Describe the participant/subject population
_____
_____
_____
_____

Vulnerable/protected populations included among target population (Check all that applies)
- ☐ Children (less than 15 old)
- ☐ Adolescents (between 15 and 24 years old)
- ☐ Children living in adverse circumstances
- ☐ Older adults (more than or equal to 65 years old)
- ☐ Adults with legal guardians

- ☐ Persons with disabilities (including mental and physical)
- ☐ Persons in Prisons
- ☐ Palestinian Refugees
- ☐ Displaced persons
- ☐ Pregnant/lactating women
- ☐ Terminally ill participants/subjects
- ☐ Persons receiving palliative care
- ☐ Survivors of torture
- ☐ Survivors of sexual and gender-based violence
- ☐ Foreign domestic workers
- ☐ Persons from the LGBT community
- ☐ Women with substance use disorders
- ☐ Other: ……..

What precautions have you included in your protocol to protect the rights and welfare of the vulnerable population?

_____
_____
_____
_____

6. Research Procedure:

Discuss any aspects of the study that need special consideration due to their sensitivity, any issues that require flexible interpretation.

_____
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_____

Please specify if your study involves deception/withholding information that would normally be provided to research participants. Clarify if any possible risk are related to the deception

_____
_____
_____

If yes, explain the nature and the reason why deception / withholding is necessary to your study. Describe any alternative research strategy that has been considered to achieve the objectives of the research.

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