Guidelines and Application Form

for

The Eastern Mediterranean Regional Office Special Grant for Research in Priority Areas of Public Health, 2016 - 2017

World Health Organization
Regional Office for the Eastern Mediterranean

منظمة الصحة العالمية
المكتب الإقليمي لشرق المتوسط

World Health Organization

Regional Office for
the Eastern Mediterranean
(WHO/EMRO)

1. INTRODUCTION

The research proposal guidelines have been developed to support health research initiatives in the countries of the Eastern Mediterranean Region (EMR), with a focus to promote health research as a tool for national development programming, and to increase the use of evidence based action and health planning for provision of equitable health care. The guidelines were first drafted in 2001 to support EMRO's initiative for Research in Priority Areas of Public Health. Based on extensive feedback from researchers, policy makers and experts in EMR health research, the new guidelines and application form are meant to be more user-friendly to encourage as many researchers from different EMR Countries to apply for the grant as possible.

Since the adoption of the new Sustainable Development Goals (SDGs) agenda, a growing emphasis on 'leave no one behind' requires that action be taken in the field of reducing inequities and protecting and promoting human rights and gender equality. Thus, when preparing your research proposals as per the priorities outlined under section "5" (entitled: Priority Areas for EM- RPPH Grant 2016 – 2017), please consider marginalized and underserved populations' health needs and risks; and disaggregation of collected data by sex, age and socio-economic quintiles in your analysis plan.

1.1 EMRO Special Grant for Research in Priority Areas of Public Health

In 2002, a new grant for research, **Eastern Mediterranean Regional Office Special Grant for Research in Priority Areas of Public Health (EMRPPH)**, was established by the Regional Office. Through a competitive process of selection, funds are provided to successful research proposals. The focus for this round is the five strategic areas identified by the Regional Director, WHO/EMRO in the 2012 strategic paper "Shaping the Future of Health in the WHO Eastern Mediterranean Region: reinforcing the role of WHO", namely: health system development and strengthening (HSD); emergency preparedness and response (EPR); communicable disease prevention and control (DCD); maternal, child health & nutrition (MCH); and prevention and control of non-communicable and mental health disorders (NMH) with special emphasis on cross-cutting initiatives as universal health coverage (UHC). Relevant technical units in EMRO were consulted in preparation of this Call for Proposals. The EMRPPH award amount will range from $ 10,000 - 15,000 for each proposal, and the proposed duration for which support is requested must not exceed 10 months.

The guidelines, priority areas and application form have been adapted through a comprehensive process. Thus, an in-house workshop was convened on 17 February 2016 on setting "Regional Health Research Priorities" to build consensus on a set of health research priorities based on views of representatives of different EMRO technical programmes. The set of health research priorities identified during the workshop are reflected in section "5".

OBJECTIVES:

General objective:

To promote EMR-based research in the 5 strategic areas of WHO/EMRO's work

Specific objectives:

The specific objectives of this call for proposals are to:

1. Generate local knowledge relevant to the 5 strategic areas;
2. Assist capacity building for research through learning by doing and hands on training;
3. Strengthen the link between evidence generation and health policy making; and
4. Enhance experience-exchange between the Region's member states

Only health-related research proposals meeting the following criteria are eligible for support:

1. The research proposal must be related to the priority areas specified by this call for proposals; and
2. The research proposal must not duplicate a proposal to another national or international agency for simultaneous consideration

1.2 EMRPPH Grant Application

The completed proposal with its annexes should be submitted through email (emrgorpd@who.int) including the following:

- Completed proposal form
- Data collection form(s)
- Research ethics checklist for principal investigators
- Informed consent forms (in English and local language)
- Support documents (provisional national/institutional ethical approval; short CVs of investigators)

The responsibility for proper citation rests with authors of the proposal (team of investigators) and their respective institution; all parts of the proposal should be prepared with equal care addressing this concern.

1.3 Eligibility of Applicants

Health related scientists, researchers and scholars based in EMR countries are encouraged to submit proposals. While postgraduate students are not encouraged to submit research proposals on their own, they could support teams of investigators, accordingly. The Principal Investigator (PI) must be a national of a member state of the WHO Eastern Mediterranean Region (EMR) and the research site should be in one of its Member States.

1.4 Individuals and Institutions

Individuals and institutions engaged in EMR health research are considered eligible for submitting proposals which include:

i. **Ministries, academic institutions, research institutes** in EMR countries.
ii. **Non-governmental organizations:** professional societies and civil service organizations involved in EMR health research activities.

1.5 Submission of Proposals

All proposals should be submitted in **English language only, along with the 'Research ethics checklist' – Annex II** via email at (emrgorpd@who.int). ***The applications must be signed by the Principal Investigator and the Head of the concerned institution.*** Unsigned copies will be considered incomplete and will not be processed.

2. INSTRUCTIONS FOR PROPOSAL PREPARATION

All proposals submitted in response to this call for proposals will be reviewed utilizing the merit review criteria, described in greater length in Section 3. Concise proposals would assist reviewers in effectively dealing with them. Therefore, **the Project Description should not exceed 10 pages (please follow instructions, accordingly)**.

The proposal document must be typed in MS Word using font size 12 "Times New Roman". All proposal pages must have 2.5 cm margins at the top, bottom and on each side. Line spacing must be 1.5.

3. PROPOSAL PROCESSING AND REVIEW FOR THE EMRPPH GRANT

Proposals received by the Research Promotion and Development Unit (RPD) of EMRO are immediately allotted a unique EMRPPH Grant Proposal Number which is referred to in all subsequent communications.

3.1 Review Process

The review process is carried out in two steps, i.e. initial screening followed by final selection review.

3.1.1 Initial Screening

All proposals received before the deadline and considered complete in all respects are carefully reviewed by WHO/EMRO experts. RPD-EMRO may contact the PI for further information. All proposals short-listed in the initial screening are provided to the Selection Committee for the final selection.

3.1.2 Final Selection (Technical and Scientific Review)

A Selection Committee formulated by WHO/EMRO will carry out the final selection review. The selection procedures usually consider the following:

- Merit of the proposal addressing a research area specified in this call for proposals with a clear national / regional perspective
- Observing gender, equity and human rights
- Applying quantitative / qualitative methodologies, as appropriate
- Observing ethical standards in research involving human subjects
- Outlining clear results' dissemination plan
- Multi-disciplinarily team composition
- Expertise / track record of the team of investigators
- Expected impact of the research outcomes on national and/or regional health profile

The proposals will be recommended for funding during the final meeting of the WHO/EMRO Selection Committee, the decision of which is considered final.

3.1.3 Award Recommendation

Based on the recommendations of the WHO/EMRO Selection Committee, RPD-EMRO decides whether a proposal should be recommended / declined for an award. The entire review and selection process usually takes 2-4 months from the closing date for receiving proposals.

3.2 Condition of a Compulsory Agreement

The PI(s) of the recommended proposals for funding are required to sign an agreement with WHO/EMRO before receiving the award (please see Section 4 for agreement conditions).

Applicants of EMRPPH are informed that only WHO/EMRO may make commitments, awards or authorize the expenditure of funds. An institution / PI providing financial / personnel commitments, in the absence of an agreement, would be doing so at own risk.

4. GENERAL CONDITIONS RELATING TO THE AGREEMENT CONCERNING EMRPPH GRANT

The following are general conditions which become effective if an agreement is signed between WHO/EMRO and the Institution of a PI whose proposal is recommended for funding by

the EMRPPH Grant. Applicants to the EMRPPH Grant are strongly advised to read these conditions before submitting a proposal, as in case their proposal is recommended for funding and their respective Institution signs an Agreement with WHO/EMRO, they will have to strictly abide by these conditions.

4.1 Principal Investigator and His / Her Employer Organization/ Institution

a. The Organization/Institution and the Principal Investigator (or Responsible Technical Officer), who must be an employee at the Organization/Institution, shall be jointly responsible for all the technical and administrative aspects of the work referred to in the proposal.

b. The Organization/Institution is required to notify WHO/EMRO immediately of knowledge that the Principal Investigator will cease or ceases to be an employee of the Institution or is no longer continuing the responsibilities described in the proposal. Under such circumstances WHO/EMRO has the right to:

    (i) Cancel the funding or
    (ii) Agree to continue the project under a new Principal Investigator proposed by the Organization/Institution and approved by WHO/EMRO.

4.2 Financial Arrangements

Payments shall be made into the bank account(s) of the Organization/Institution as specified in the Agreement and in accordance with the schedule of payments contained therein. The funds allocated to this agreement may not be used to cover any item that is not mentioned in the budget section of the application form and shall be expended only in accordance with its terms. In the event of this Agreement being cancelled under any circumstances, the Institution shall refund to WHO the balance of uncommitted funds.

4.3 Relationship and Responsibility of Parties

The relationship of the Organization/Institution to WHO/EMRO shall be that of an independent contractor. The employees of the Organization/Institution are not entitled to describe themselves as staff members of WHO/EMRO. The Organization/Institution shall be solely responsible for the manner in which work on the project is carried out and accordingly shall assume full liability for any damage arising from research or other technical services under this Agreement.

4.4 Equipment and Supplies

Unless otherwise agreed, and subject to subparagraph below, any equipment acquired under this Agreement shall become the property of the Organization/Institution. The Organization/Institution and the Principal Investigator shall be jointly responsible for the proper safeguard, maintenance and care of all equipment acquired under this Agreement.

4.5 Reports, Use of Results, Exploitation of Right and Publication

a. The Institution or Principal Investigator shall correspond with RPD/EMRO for any follow-up, submission of reports, requests for further release of funds, and any other technical matters.

b. The Principal Investigator shall submit technical and financial reports to WHO/EMRO in accordance with the following provisions:

   i. Technical reports shall be forwarded through and countersigned by the authorized official of the Institution or his/her authorized representative. ***The day the amount of the first installment of the fund is received by the Principal Investigator will be considered as the starting date of the project.***

   ii. Immediately after the first four-months of starting the project, a ***progress report*** should be submitted according to EMRO format of progress reports.

   iii. Before the expiry date of the project, a ***final report*** (technical and financial) should be submitted according to EMRO format of final reports.

   iv. Fiscal reports should be forwarded to WHO/EMRO after being jointly certified by the Institution's chief technical officer and the Principal Investigator.

   v. All financial and technical reports are subject to audit by WHO/EMRO, including examination of supporting documentation and relevant accounting entries in the Institution's books. The final technical and financial reports must be submitted before the expiry date of the project.

   vi. The results of the project may be freely used or disclosed provided that, without the consent of WHO/EMRO, no use may be made for commercial purposes and confidentiality shall be maintained with respect to results that may be eligible for protection by property rights. The Institution shall provide WHO/EMRO with the results, in the form of relevant know-how and other information, and to the extent feasible tangible products.

   vii. The industrial or commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from the project shall be designed to achieve, in so far as circumstances permit, the following objectives in the following order of priority:
      - the general availability of the products of creative activity;
      - the availability of those products to the public health sector on preferential terms, particularly to developing countries.

   viii. In any publication by the Institution or the Principal Investigator relating to the results of the project, the responsibility for the direction of the work shall not be ascribed to WHO/EMRO. ***All publications should include an acknowledgement note indicating that the underlying investigation received financial support from WHO/EMRO under the EMRPPH grant scheme, with reference to the project number.*** TWO reprints or copies of each publication should be sent to WHO/EMRO/RPD.

4.6. Research Involving Human Subjects

a. **Ethical Aspects:** It is the responsibility of the Institution and the Principal Investigator to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from the EMRPPH Grant, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Such funds may be used only to support investigation where:
    i. The rights and welfare of subjects involved in the research are adequately protected,
    ii. Freely given informed consent by participants has been obtained,
    iii. An ethical clearance is provided to the project by a local / national research ethics review committee and
    iv. Any special national requirements have been met.

b. **Protection of Subjects:** Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research.

4.7 Publicity

The Institution and the Principal Investigator shall not refer to the relationship of WHO/EMRO to the project or to products or processes connected with the project, in any statement or material of a publicity or promotional nature issued for commercial purposes, or with a view to financial benefit.

4.8 Litigation and Liabilities

WHO/EMRO will not be responsible for any litigation or liabilities that may stem from views and conclusions of the study by the Institution or the Principal Investigator.

5. PRIORITY AREAS FOR EMRPPH GRANT 2016 - 2017

The priority areas for this call for proposals include the five strategic areas identified by the Regional Director, WHO/EMRO in the 2012 strategic paper "Shaping the Future of Health in the WHO Eastern Mediterranean Region: reinforcing the role of WHO", namely: health system development and strengthening (HSD); emergency preparedness and response (EPR); communicable disease prevention and control (DCD); maternal, child health & nutrition (MCH); and prevention and control of non-communicable and mental health disorders (NMH); with special emphasis on cross-cutting initiatives as universal health coverage (UHC) in all five strategic areas. Relevant technical units in EMRO were consulted in preparation of this call for proposals (during the in-house 2016 prioritization exercise). Only high quality proposals with a national / regional perspective will be funded with a research grant ranging from $ 10,000 - 15,000 for each selected proposal.

The priority areas for this call for proposals are summarized below:

5.1 Communicable Disease Prevention and Control

- What operational models fit best for event-based surveillance systems for detection of unusual events in countries of the Eastern Mediterranean Region?
- Studies to adequately estimate country or regional burden of antimicrobial resistance (could be surveillance or modelling studies)
- What are the barriers for routine immunization in low and middle income countries in the region?

5.2 Non-Communicable Diseases & Mental Health

- What are the impacts of food regulation, legislation and taxes on promoting healthy nutrition including salt, fat and sugar intake reduction?
- What is the impact of alternative NCD financing arrangements on delivery of priority NCD interventions?
- What are the epidemiologic features of mental, neurological and substance use (MNS) disorders in the EMR? What are the best interventions to reduce the treatment gap for MNS disorders and promote mental health literacy / reduce the impact of stigma in EMR?
- What are the levels and sources of salt, fat and sugar intake using food consumption assessment or surveys at national or community levels?
- How can the national food systems / subsidies contribute to eliminate the consumption of unhealthy diet?

5.3 Health Protection and Promotion

- What are the main causes behind low coverage of children <5 years with suspected pneumonia receiving proper antibiotics?
- What are the main factors leading to a good coverage to basic and comprehensive emergency obstetric and newborn care in countries with emergency settings?
- How can primary health care services be designed to integrate the special health needs of adolescents?
- What are the main challenges for adopting the use of postpartum contraception among reproductive health aged women?
- What are the causes of high prevalence of cesarean section and what are its impacts on maternal and newborn health?

5.4 Health Systems Development

- How can we influence change behavior and build community awareness on consequences of over/under/abuse of antimicrobial medicines?
- What are the most effective regulatory measures necessary to address antimicrobial resistance in EMR from a health systems perspective?
- What is the magnitude and impact of health workforce mobility on the quality of health services in the EMR?
- What is the impact of dual practice on accessibility and quality of services? What type of regulatory interventions can be introduced?
- What are the approaches that can enable District Health Systems to respond to the needs of emergency preparedness and response in countries with crises?

5.5 Emergency and Humanitarian Action; Emergency Preparedness and Response

- What are lessons learnt from major national / regional crises (social, biological, technological)?
- What are examples of best practices of observing ethics in research targeting vulnerable groups during emergencies?
- What is the impact of preparedness on emergency response from an EMR perspective?
- What ethical framework may be developed to guide resource allocation in low resource countries?
- Which ethical issues are relevant to remote control operations and what guidance may be developed to aid practitioners?

- **APPLICATION FORM**

The Eastern Mediterranean Regional Office Special Grant for Research in Priority Areas of Public Health 2016 - 2017

COVER SHEET OF APPLICATION FORM

SHADED AREA FOR OFFICIAL USE ONLY	
DATE RECEIVED (dd/mm/yy)	WHO/EMRO PROPOSAL ID NUMBER **RPD/EMRPPH 16/**……..
NAME OF COUNTRY OF APPLICANT	HAS THIS PROPOSAL BEEN SUBMITTED TO ANOTHER AGENCY FOR FUNDING YES ☐ NO ☐
NAME OF ORGANIZATION/INSTITUTION	IF YES, WRITE NAME OF AGENCY WITH ACRONYM
TITLE OF PROPOSAL (120 characters maximum):	
WHAT IS THE PRIORITY AREA ADDRESSED BY THIS PROPOSAL? ☐ Communicable Disease Prevention and Control ☐ Non-Communicable Diseases & Mental Health ☐ Health Protection and Promotion ☐ Health System Development ☐ Emergency Preparedness and Response Please indicate the detailed priority area (from section 5): _____	
NAME OF PRINCIPAL INVESTIGATOR (PI)	
LAST NAME:	FIRST NAME(S):
TITLE:	
POSTAL ADDRESS:	
TEL . MOBILE:	FAX:
E-MAIL 1:	E-MAIL 2:
NAME OF PI's INSTITUTIONAL HEAD:	
TITLE	
ADDRESS	
TEL . MOBILE:	FAX:
E-MAIL 1:	E-MAIL 2:
☐ UNIVERSITY ☐ GOVERNMENTAL ORGANIZATION ☐ NON-GOVERNMENTAL ORGANIZATION ☐ OTHER	
REQUESTED AMOUNT (USD ……)	PROPOSED DURATION (9 MONTHS MAX):……..
SIGNATURE OF THE PRINCIPAL INVESTIGATOR	SIGNATURE (AND STAMP) OF INSTITUTIONAL HEAD
NAME & DATE:	NAME & DATE:

1. PROPOSAL SUMMARY

Please provide one page executive summary, **up to 500 words**. The summary should include (i) rationale (ii) objectives, (iii) methods, (iv) expected outcomes (national / regional perspective)

2. BACKGROUND

Please provide a **2-page background**. Background includes literature review of previous studies on the subject (global / regional / national), stating its public health importance and rationale of proposing the study this time at this place on this population, considering gender, equity and human rights (please quote references using a standardized citation style)

3. OBJECTIVES

3.1 General objective: the overall aim expected to be achieved from this research

3.2 Specific objectives: 2-3 clearly stated SMART specific objectives (specific, measurable, achievable, relevant to EMR, time-bound), which break-down the general objective

1.

2.

3.

4. METHODOLOGY

An appropriate clear description of activities and information on the general plan of work should be provided here. The methodology section should describe;

4.1 Study design (observational / experimental, mentioning specific type, accordingly)

4.2 Study setting / data sources (clearly indicating where the study will be conducted: country, city, institution(s), department(s), etc.). This includes settings for primary data collection, and specific sources of secondary data (e.g. medical records; health registers; insurance registers; national census records, etc.)

4.3 Study population (study subjects and their respective characteristics)

4.4 Sample size (sample size assumptions / estimate)

4.5 Sampling method (method to be used to select subjects ensuring a representative sample of the target population; inclusion and exclusion criteria)

4.6 Data collection (data collection method(s) and tool(s) as appropriate: ***data collection tool(s) to be annexed to the proposal*** but sections / variables described under this section; focus group/interview guidelines; checklists; anthropometric measurements (e.g. weight, height, circumference, BMI, WHR, etc.) with reference to measurement / estimation method; biological measurements (laboratory investigations with reference to measurement / estimation method / kit); relevant definitions of exposure(s) and outcome(s) as appropriate to proposal; background / number of data collectors, etc.

4.7 Data management plan (A clear plan of data coding, entry, cleaning, and analysis to be used, considering disaggregation of collected data by sex, age and socio-economic quintiles. Please mention specific statistical tests and references software)

4.8 Coordination, monitoring and quality control (plan for field work supervision to ensure proper / scientific data collection, data management, quality control indicators, etc.)

4.9 Ethical considerations:

All research proposals submitted for the EMRPPH grant must adhere to ethical conduct of research on human subjects. This commitment will be ensured by the WHO/EMRO Selection Committee. The PIs are required to obtain clearance from an official Ethical Review Committee / Institutional Review Board ***before*** submitting the proposal, which is a ***condition*** for consideration for funding. Litigation involving human research must be accompanied by: (a) copy of ethical clearance certification and (b) the informed consent documents (in English and local language).

Please describe your proposal:

1. Does this research involve human subjects?

Yes □ No □

2. If yes, have you received an ethical approval for this research?

Yes □ No □

3. Is there a research ethics committee or institutional review board at your institution which reviews research on human subjects?

Yes □ No □

4. If yes, has this committee given ethical approval for the conduct of this research?

Yes □ No □

5. Will you ensure that confidentiality of collected information (e.g. medical records, biological samples) obtained from subjects be protected in this research?

Yes □ No □

6. Have you received any training on ethics of biomedical research?

Yes □ No □

5. TIME FRAME OF PROPOSED ACTIVITIES (Gantt chart)

Please indicate the activities to be conducted and check the corresponding timing by marking (X) or shade the appropriate cell(s). Overlap is expected (i.e. more than one activity in certain months)

Starting Month:_____ ***Year***:_____

Activity	1st QUARTER			2nd QUARTER			3rd QUARTER		
	M 1	M 2	M 3	M 4	M 5	M 6	M 7	M 8	M 9
Submission of the Progress Report*					**X**				
Submission of the Final technical and Financial Report*									X

*mandatory

6. BENEFICIARIES OF RESEARCH RESULTS (who are the direct / indirect beneficiaries of the study, what are the benefits both groups [direct / indirect] are likely to accrue in the short or long term)

8. REFERENCES CITED

Any references cited should be listed here, using standardized citation style (e.g. Vancouver Style). This includes citations for scientific papers, books, reports, laboratory methods, standardized questionnaires / check-lists, biostatistical software, etc. References should be listed in numerical ascending order with corresponding citations in the text, marked as shown [#].

Examples of citing references in this section are given below:

- Journal articles should start with name of author (with suffix et al, if more than six authors), followed by title of study, name of journal, volume, page numbers and **year** of publication (in bold at the end).
- Books should start with the title, followed by Editors, Publishers, and **year** of publication (in bold at the end).
- Reports should start with title, followed by name of writer, reference to organization for which it was written, reference number of report if any and **year** of reporting (in bold at the end)

9. PROPOSAL BUDGET WITH JUSTIFICATIONS

Budget breakdown should be provided in a tabular format, as shown below, with the full term of requested budget from EMRPPH Grant. The award will range from **$ 10,000 - 15,000**. The breakdown should be restricted to 2 pages.

Instructions for budget items:

i. Personnel

WHO/EMRO expects that the PIs and Co-Investigators will be faculty / researchers at eligible institutes, with research as one of their normal functions. EMRPPH funds **may not be used to pay salary or augment the total or part of the salary** of PIs and Co-Investigators. Personnel costs therefore include compensation for data collectors, field workers, lab technicians, data managers, etc.

ii. Material and Supplies

The budget must indicate the general types of expendable materials and supplies required, with their estimated costs. The breakdown should be more detailed when the cost is substantial.

iii. Equipment

EMRPPH Grant does not support general purpose equipment, such as a personal computers, telephone sets, photocopying / facsimile machines etc.

iv. Human Subjects

The needs for requiring direct compensation of participants (which is not generally recommended) must be fully justified (e.g. transportation, hot meals, etc.)

v. Travel

Travel and its relation to the proposed activities must be specified and itemized by destination and cost. EMRPPH Grant does not support foreign travel (travel outside the Applicant's country)

vii. Field Work

Funds may be requested for field work necessary for data collection other than the personnel cost.

viii. Training

Training expenses should be minimized to only specialized training needed for staff using related research equipment or improving research skills

ix. Dissemination of Results

The cost involved must be in accordance with the proposed dissemination plan such as local conferences, publications and dissemination workshops.

x. Other Costs

The budget must identify and itemize other anticipated costs not included under the headings above. Examples include telecommunications and photocopying. Reference books, periodicals and other scientific literature may be charged to the Grant only if they are specifically required for the project.

OUTLINE OF THE BUDGET (in USD)				
Total Amount Requested: US $:				
Budget Breakdown				
No	**ITEM OR ACTIVITY**	**Amount Requested from EMRO Grant**	**Amount available from other Sources**	**JUSTIFICATION**
1.	Personnel* - -			
2.	Materials & Supplies - -			
3.	Equipment - -			
4.	Local Travel - -			
5.	Field work - -			
6.	Training - -			
7.	Dissemination of results** - -			
8.	Other Costs*** - - -			
	Total US $			

***Up to 20 % of total budget; **Up to 10 % of total budget; ***Up to 5 % of total budget**

10. APPENDICES

Please provide as appendices:

- Data collection form(s)
- Research ethics checklist for principal investigators
- Informed consent forms (in English and local language)
- National/institutional ethical approval
- CVs of investigators

DEADLINE FOR SUBMISSION OF PROPOSALS

The deadline for submission of proposals is 15 December 2016. Proposals received after the deadline shall not be considered in this round. Applicants should allow 2-4 months for review and processing.

The completed Application Package for the Eastern Mediterranean Regional Office Special Grant for Research in Priority Areas of Public Health 2016-2017 (as described under section "10") should be emailed to:

Coordinator, Research Development & Innovation
World Health Organization
Regional Office for the Eastern Mediterranean
Abdel Razzak Al Sanhouri Street
Nasr City, PO Box 7608, Cairo 1137, Egypt
Fax: (+202) 2670 24 92/94; (+202) 2276 54 20
E-mail: emrgorpd@who.int

ANNEX I

Certification for Proposal

I certify to the best of my knowledge that:

i. All statements in the proposal entitled

"……

……"

(excluding scientific hypotheses and scientific opinions) are true and complete, and

ii. The text and graphics herein as well as any accompanying publications or other documents, unless otherwise indicated, are the original work of the signatories or individuals working under their supervision.

I agree to accept responsibility for the scientific conduct of the project and to provide the required project reports, if an award is recommended from the EMRPPH Grant, as a result of this proposal.

NAME (TYPED)	Signature	Date (dd/mm/yy)
PRINCIPAL INVESTIGATOR		
CO-INVESTIGATOR-1		
CO- INVESTIGATOR-2		
CO- INVESTIGATOR-3		

INSTITUTIONAL HEAD OR HIS/HER AUTHORIZED REPRESENTAVE		
NAME (TYPED)	Signature	Date (dd/mm/yy)
TITLE		

TELEPHONE NUMBER	FAX NUMBER	E-MAIL ADDRESS

THIS RESEARCH ETHICS CHECKLIST IS BASED ON THE WHO HQ 'GUIDE FOR PRINCIPAL INVESTIGATORS', 'STANDARDS AND OPERATIONAL GUIDANCE FOR ETHICS REVIEW OF HEALTH-RELATED RESEARCH WITH HUMAN PARTICIPANTS' AND THE WHO EMRO (SERIES 30) 'A PRACTICAL GUIDE FOR HEALTH RESEARCHERS'

ANNEX II

RESEARCH ETHICS CHECKLIST
GUIDE FOR PRINCIPAL INVESTIGATORS

INTRODUCTION
CONDUCTING ETHICAL RESEARCH

WHO follows the World Medical Association Declaration of Helsinki (1964), amended in 2000, and further revised in 2008, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects published in 2002 as well as the WHO Standards and operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011. During the ethical review of a protocol, the WHO/EMRO ERC evaluates the risks and benefits to the research participants and research communities in the following domains:

- ***Respect for persons***
- ***Justice***
- ***Autonomy***

The table below lists examples of the potential risks/harms and benefits that may accrue to research participants as a result of taking part in research.

Risks/Harms	***Benefits***
Physical harm	Access to treatment/ Free treatment
Social harm/social risk	Emotional support
Emotional harm/risk	Psycho-social support
Stigmatization	Humanitarian
Loss of privacy	Contribution to society
Insensitivity to vulnerabilities, exposing individuals to various types of harms/risks	Others
Sharing of confidential information resulting in tangible or intangible losses	
Perpetuation of gender and other biases	
Others	

Purpose of the Research Ethics Checklist

This checklist has been adapted by the WHO/EMRO ERC to help to ensure that all the elements necessary for the development of a complete and ethically sensitive protocol are covered. The checklist consists of a series of questions that address key considerations in the design of research protocols, development of informed consent forms and recruitment/information material. It is divided into 2 sections: Section 1 raises key questions related to scientific and technical issues of the protocol; and Section 2 consists of questions around key ethical issues that should be addressed in the protocol, as well as informed consent forms and recruitment/information material for participants.

The Annex provides further details on the issues mentioned in the sections below.

As this checklist functions as a 'self-checklist', check boxes have been included to help researchers flag areas that require more attention. Please note that not all the elements described here are relevant to all protocols. Please ensure that those items which correspond with the research you are conducting are included in your submission to WHO/EMRO because they will be assessed by WHO/EMRO Ethics Review Committee reviewers.

THIS RESEARCH ETHICS CHECKLIST IS BASED ON THE WHO HQ 'GUIDE FOR PRINCIPAL INVESTIGATORS', 'STANDARDS AND OPERATIONAL GUIDANCE FOR ETHICS REVIEW OF HEALTH-RELATED RESEARCH WITH HUMAN PARTICIPANTS' AND THE WHO EMRO (SERIES 30) 'A PRACTICAL GUIDE FOR HEALTH RESEARCHERS'

SECTION 1

PROTOCOL (SCIENTIFIC AND TECHNICAL ISSUES)

The ethical acceptability of research is dependent on its scientific validity (i.e. its design and methodology). Consequently, the following section includes key questions on scientific and technical issues that should be included in the research protocol.

This section is not intended to provide guidance on how to design a study, but rather raises key technical and scientific issues that need to be well explained in study protocols. For guidance on how to design a research study, please consult the following link:
http://www.emro.who.int/publications/pdf/healthresearchers_guide.pdf

The WHO website also has additional guidance documents on writing research protocols and informed consent forms, available at the following link:
http://www.who.int/rpc/research_ethics/format_rp/en/index.html

	YES	NO	N/A
Background information			
Is the rationale for the study clearly stated in the context of present knowledge?			
Is the review of literature with references included?			
Is the study setting described?			
Goals and objectives			
Are the objectives and/or hypothesis to be tested clearly stated?			
Study Design			
Is a clear description of the study design (e.g. whether it is basic science research, social science research, or epidemiological - observational or intervention - research) and the study participants, outcomes and intervention and control groups (if relevant) provided?			
Methodology			
Is an estimate of sample size provided, along with the assumptions on which it is based?			
Are the inclusion and exclusion criteria clearly stated?			
Are the procedures for participant recruitment, admission, follow up and completion fully described?			
Are the laboratory tests and other diagnostic procedures fully described?			
Does the protocol include information on procedures that are experimental and part of the research, as opposed to those that are part of routine care?			
Does the protocol describe how the specimens and/or data will be coded/anonymized?			
If the study is an intervention study, including placebo controlled trials, is justification for the control group provided?			
If the study is an intervention study, are the types and methods for subject allocation to intervention and control group clearly explained?			
Participant safety			
Have any risks to participating in the research been identified and does the protocol state how these will be minimized?			

If the research involves new drugs or vaccines, is clearance from the national drug regulatory authority attached?			
If the research involves new drugs or vaccines, is the Investigator's Brochure (including safety information) attached?			
If the study is an intervention study, is a Data Safety Monitoring Board (DSMB) envisaged? If yes, is information about the DSMB included (ex. terms of reference & list of members)?			
If an intervention study, is a plan for adverse event reporting included in the protocol?			
Data Management and Statistical Analysis			
Does the protocol include a discussion on the quality assurance mechanisms for data collection, storage and analysis?			
Is the plan for statistical analysis provided?			
Expected outcomes and dissemination of results			
Does the protocol indicate how the study will contribute to advancement of knowledge and how the results will be utilized?			
Does the protocol include a plan for the dissemination of results, not only to the research community (through open access online publication, and other journal publications) but also to policy makers (through meetings, reports etc) and back to the research participants & research communities (through community meetings, flyers, leaflets etc)?			
Gender issues			
Does the protocol discuss how the research contributes to identifying and/or reducing inequities between women and men in health & health care or does not perpetuate gender imbalances?			
Project Management			
Does the protocol state the expected duration of the project?			
Does the protocol describe the role and responsibility of each member of the team?			
Study instruments			
Where questionnaires, diary cards and other materials are used, are these relevant to answer the research questions?			
Are the study instruments provided in English? (translations should be submitted after an English version has been approved by the WHO/EMRO ERC)			
Are study instruments written in lay language, worded sensitively & easily understood?			
If applicable, have Case Report Forms, Adverse Event forms etc. been prepared & included?			
Ethical issues (see section 2 for detailed guidance on addressing ethical issues in the study protocol)			
Does the protocol include a discussion of ethical issues? (See section 2)			
Have consent forms been prepared? Are these included? (See Section 3)			
Have assent forms been prepared for children aged 12 - 18 years? Are these included?			
Please provide comments as required:			

SECTION 2

PROTOCOL (ETHICAL ISSUES)

Please ensure that your protocol minimizes harms and maximizes benefits to the research participants, and *discuss under ethical issues how this has been achieved*. The sections below outline key ethical considerations and are included to assist you in identifying and addressing the ethical issues that may be posed by your research.

	YES	NO	N/A
Risks and benefits			
Have individual risk vs. the potential benefits from the study been adequately addressed?			
Does the protocol describe whether and how communities from which the participants are to be drawn are likely to benefit from the research?			
Is the research outcome also likely to benefit communities beyond the research population?			
Study population			
Is a vulnerable population being studied (i.e. any of the following - pregnant women, children, adolescents, elderly people, people with mental or behavioral disorders, prisoners, refugees, those who cannot give consent (unconscious), others)?			
If a vulnerable population is being studied, is the justification adequate?			
Have adequate provisions been made to ensure that the vulnerable population is not being exploited?			
Autonomy/Incentives/Coercion			
Does the design of the study include inducements (financial or free medical care, etc) to participate in the research?			
If yes, is the rationale described in the protocol?			
Are the research participants free not to participate or to leave the research at any time without penalty?			
Privacy/Confidentiality			
Does the study outline the procedures for the protection of the privacy and psycho-social needs of the participants?			
Are there mechanisms to ensure the confidentiality of the data?			
Monitoring safety/protection			
Do provisions exist in the proposals to deal with adverse reactions associated with the research (medical/physical/emotional/psychological) as well as coincidental findings during the course of the research (e.g. through blood tests etc)?			
When appropriate, do provisions exist for counseling research participants prior to, during and after the research?			
Are there issues that may affect the safety of the researchers involved in the study? How are these being addressed?			
Process for gaining informed consent			
Is the process, through which informed consent will be obtained, described?			

Where written consent from participants is not possible, have you explained the reasons for this and how the agreement of participants will be recorded?			
Is this a cluster randomized controlled trial?			
If so, has the process of taking consent for clusters to be included in the trial described?			
If this is not possible, is information provided to all communities participating in the trial?			
Is the process of taking consent from individuals in the clusters before they participate in any study procedures or data collection described? *			
Please provide comments as required:			

***** Community leaders cannot give 'consent' on behalf of individuals in communities to participate in randomized controlled trials, but rather permission to approach individuals in communities to invite their participation.

SECTION 2 (*continued*)

INFORMED CONSENT FORMS (ICFs)

Informed consent forms must be submitted to the ERC along with the study protocol. The ERC has developed templates of informed consent forms in order to assist the Principal Investigator in designing ICFs. However, it is important that the Principal Investigators adapt their own ICFs to their particular study and include the relevant information for participants. In addition, the logo of the collaborating institution must be used on the ICF and not the WHO logo. ICF templates are available at the following link:
http://www.who.int/rpc/research_ethics/informed_consent/en/

Some additional questions are included below to provide guidance on addressing key issues in the content and format of information sheets and consent forms.

	YES	NO	N/A
General format and content of the ICF			
Does the informed consent form make it clear that the participant is being asked to participate in research?			
Is the information sheet free of technical terms & written in lay-person's language, easily understandable & appropriate to the educational level of the community concerned?			
Does it describe why the study is being done & why the individual is asked to participate?			
Does it provide participants with a full description of the nature, sequence and frequency of the procedures to be carried out, including the duration of the study?			
Does it explain the nature and likelihood of anticipated discomfort or adverse effects (including psychological and social risks) if any, and what has been done to minimize these? Does it state the action to be taken should these occur?			
Does it outline the procedures to protect the confidentiality of data, and if confidentiality is not possible due to the research design, has this been conveyed to all relevant persons?			
Does it inform the research participants that their participation is voluntary and they are free to decide whether or not to participate, or to withdraw at any time and for any reason without further penalty either personal or professional or affecting their future medical care?			
Does it describe the nature of any compensation or reimbursement to be provided (in terms of time, travel, man-days lost from work, etc)?			
Does it outline how participants will be informed of the progress & outcome of the research?			
Does it provide the name and contact information of a person who can provide more information about the research project at any time?			
Has a provision been made for subjects incapable of reading and signing the written consent form (e.g. illiterate patients)?			
Does a provision exist for participants incapable of giving personal consent (e.g. because of cultural factors, children or adolescents less than the legal age for consent in the country in which the research is taking place, participants with mental illness, etc) to express their decision?			
Questionnaires			
If questionnaires will be used for the research, does the information sheet and consent form			

describe the nature and purpose of the questions to be asked, and if applicable, state if some questions may prove embarrassing for the participant?			
State that the participant is free to not answer any question?			
Where applicable, make it clear that the interviews (in-depth or focus group discussions) are likely to be audio or video taped?			
Where applicable, mention how and for how long are the tapes going to be stored?			
Human biologic materials (tissues, cells fluids, genetic material or genetic information)			
If human biologic materials are to be collected, does the information sheet and consent form describe in simple language the nature, number and volume of the samples to be obtained and the procedures to be used to obtain them?			
Indicate if the procedures for obtaining these samples are routine or experimental and if routine, are more invasive than usual?			
Describe the use to which the samples will be put both in the study & in the longer term?			
Does it include a provision for the subject to decide on the use of left over specimens in future research of a restricted, specified or unspecified nature?			
State for how long the specimens can be kept and how they will finally be destroyed?			
Mention that genetic testing/genomic analysis will be carried out on the human biologic materials, where applicable?			
Participant Recruitment Material (If you plan to use participant recruitment material (e.g. advertisements, notices, media articles, transcripts of radio messages) please review the material in light of the following questions)			
Is the information provided in both English and in the local language?			
Can you support the claims made?			
Does the material make promises that may be inappropriate in the research setting (e.g. provide undue incentives, emphasize remuneration)?			
Please provide comments as required:			

This guidance is complementary to information and advice provided by the WHO/EMRO technical unit or available on the department specific website. For additional guidance materials on preparing a research proposal that satisfies ERC requirements, as well as the process of ethics review please see the WHO link ***http://www.who.int/rpc/research_ethics/guide_rp/en/index.html***

GLOSSARY

Adopted from the WHO 2011 document 'Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants' - Standard 7: Ethical basis for decision-making in research ethics committees

Scientific design and conduct of the study

Research is ethically acceptable only if it relies on valid scientific methods. Research that is not scientifically valid exposes research participants or their communities to risks of harm without any possibility of benefit. The ethics review committee also assesses how the study will be conducted, the qualifications of the researcher(s), the adequacy of provisions made for monitoring and auditing, as well as the adequacy of the study site (e.g. availability of qualified staff and appropriate infrastructures).

Risks and potential benefits

In ethically acceptable research, risks have been minimized (both by preventing potential harms and minimizing their negative impacts should they occur) and are reasonable in relation to the potential benefits of the study. The nature of the risks may differ according to the type of research to be conducted. Risks may occur in different dimensions (e.g. physical, social, financial, or psychological), all of which require serious consideration. Further, harm may occur either at an individual level or at the family or population level.

Selection of study population and recruitment of research participants

Ethically acceptable research ensures that no group or class of persons bears more than its fair share of the burdens of participation in research. Similarly, no group should be deprived of its fair share of the benefits of research; these benefits include the direct benefits of participation (if any) as well as the new knowledge that the research is designed to yield. Thus, the protocol should clearly indicate whether the population that will bear the risks of participating in the research is likely to benefit from the knowledge derived from the research. In addition, ethically acceptable research includes recruitment strategies that are balanced and objectively describe the purpose of the research, the risks and potential benefits of participating in the research, and other relevant details.

Inducements, financial benefits, and financial costs

It is considered ethically acceptable and appropriate to reimburse individuals for any costs associated with participation in research, including transportation, child care, or lost wages. However, payments should not be so large, or free medical care or other forms of compensation so extensive, as to induce prospective participants to consent to participate in the research against their better judgment or to compromise their understanding of the research.

Protection of research participants' privacy and confidentiality

Invasions of privacy and breaches of confidentiality are disrespectful to participants and can lead to feelings of loss of control or embarrassment, as well as tangible harms such as social stigma, rejection by families or communities, or lost opportunities such as employment or housing. The protocol should clearly state the precautions taken to safeguard participants' privacy and confidentiality.

Informed consent process

The ethical foundation of informed consent is the principle of respect for persons. Competent individuals are entitled to choose freely whether to participate in research, and to make decisions based on an adequate understanding of what the research entails. Decisions for children or adults who lack the mental capacity to provide informed consent should be made by an authorized surrogate decision-maker.

The protocol should outline the process through which informed consent will occur, as well as the information that will be provided. While informed consent to research is important, the fact that a participant or surrogate may be willing to consent to research does not, in itself, mean that the research is ethically acceptable.

Community considerations

Research has impacts not only on the individuals who participate, but also on the communities where the research occurs and/or to whom findings can be linked. Duties to respect and protect communities should be mentioned in

the protocol and, as far as possible, are aimed at minimizing any negative effects on communities such as stigma or draining of local capacity, and promoting, as relevant, positive effects on communities, including those related to health effects or capacity development. Researchers should actively engage with communities in decision-making about the design and conduct of research (including the informed consent process), while being sensitive to and respecting the communities' cultural, traditional and religious practices.