**Guidelines and Application Form**

**for**

**The Eastern Mediterranean Regional Office Special Grant for**

**Research in Priority Areas of Public Health, 2022-2023**





**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 increasing 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 (RPPH). Based on extensive feedback from researchers, policymakers, 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 2022), 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 strategic directions identified by the Regional Director, WHO/EMRO in “EMR Vision 2023”, including expanding universal health coverage, addressing health emergencies, and promoting healthier populations. Relevant technical units in EMRO were consulted in the preparation of this Call for Proposals. The EMRPPH award amount will range from **$8,000-$10,000** for each proposal, and the proposed duration for which support is requested must not exceed 10 months.

The guidelines, priority areas, and application forms have been adapted through a comprehensive process. Thus, an in-house workshop was convened on 21 February 2022 on setting “Regional Health Research Priorities” to build consensus on a set of health research priorities based on the views of representatives of different EMRO technical programmes. The set of health research priorities identified during the workshop is reflected in section “5”.

**OBJECTIVES**:

**General objective:** to promote EMR-based research in the 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 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 policymaking; 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)
* Completed ethics review checklist
* 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 the authors of the proposal (team of investigators) and their respective institutions; all parts of the proposal should be prepared with equal care to address 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:

1. **Ministries, academic institutions, and research institutes** in EMR countries.
2. **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 SID- 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/SID-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 (priority)
* Involving academic institutions and policy makers (priority)
* Involving more than one institution and/or more than one country (priority)
* 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/SID-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 its own risk.

# 4. GENERAL CONDITIONS RELATING TO THE AGREEMENT CONCERNING EMRPPH GRANT

The following are general conditions that 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

1. 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.
2. 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:
3. Cancel the funding or
4. 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 canceled 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

1. The Institution or Principal Investigator shall correspond with SID/RPD/EMRO for any follow-up, submission of reports, requests for further release of funds, and any other technical matters.
2. The Principal Investigator shall submit technical and financial reports to WHO/EMRO in accordance with the following provisions:
3. 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.***
4. Immediately after the first four months of starting the project, a ***progress report*** should be submitted according to the EMRO format of progress reports.
5. Before the expiry date of the project, a ***final report*** (technical and financial) should be submitted according to the EMRO format of final reports.
6. Fiscal reports should be forwarded to WHO/EMRO after being jointly certified by the Institution's chief technical officer and the Principal Investigator.
7. 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.
8. 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.
9. 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.
10. 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 acknowledgment 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/SID.

## 4.6. Research Involving Human Subjects

1. **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:
	1. The rights and welfare of subjects involved in the research are adequately protected,
	2. Freely given informed consent by participants has been obtained,
	3. An ethical clearance is provided to the project by a local / national research ethics review committee and
	4. Any special national requirements have been met.
2. **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 2022-2023**

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

***5.1 Non-Communicable Diseases & Mental Health***

# Interventions to improve breast cancer survival in the EMR

# Pilot testing of mobile phone surveys to strengthen NCD risk factors surveillance in EMR countries

# Identifying and testing delivery strategies for evidence-based interventions to reduce stigma and discrimination against Mental, Neurological & Substance Use (MNS) disorders

# Attributes of a programme for successful and sustainable community based mental health care delivery

# Implementation of research to inform cervical cancer interventions in the region

***5.2 Universal Health Coverage (UHC), Primary Healthcare, Health Systems***

# Role of PHC in COVID-19 in EMR and how it could be strengthened by building resilient PHC at national and sub-national levels.

# Role of community engagement in implementing Integrated People Centered Health Services

# Establishing country relevant “Models of Care” to enhance service coverage on the path to UHC

# Making UHC happen at country level: push and pull factors

# Integrating Essential Public Health Functions in PHC in EMR

***5.3 Healthier Populations***

# Determinants and gaps in quality of care for newborns and child health care at the facility level

# Assessment of maternal and perinatal deaths surveillance system (MPDSR) at the country level

# Effect of adopting the WHO ten group classification system in preventing unnecessary use of cesarean section

# Burden of two and three wheelers related traffic injuries in the Eastern Mediterranean Region

# Indoor air quality in public places and its impact on health

***5.4*** ***Science, Information, and Dissemination***

# Influence of COVID-19 on the transformation of health professionals’ education towards the use of digital technologies, including challenges faced and coping strategies during the transition and transformation

# Assessing the degree and extent of use of evidence in national policymaking for health

# Case study to assess research governance (priorities, funding, ethics, standards) at the national level

# Developing and assessing the performance of quantitative indicators that can measure the status of research governance and ethics in countries of different context

# Case studies of institutional processes to enhance multi-concept evidence-informed policy-making processes (as introduced in RC2019)

***5.5 Country Health Emergency Preparedness & International Health Regulations***

# Assessing emergency care systems’ quality of care services in LMIC in EMR

# Responding to and deploying interventions that protect against infodemics and mitigate their harmful effects

# Systematic review of Disaster Risk Reduction (DRM) policies; obstacles to risk mitigation in EMR countries

# Factors to consider in selection and timing of public health measures in the region (impacts of time lag to implement response measures: when should be done/actually implemented)

# Role of the IHR Monitoring and Evaluation tools and the Universal Health and Preparedness Review in assessment of countries’ capacity for public health emergencies preparedness

# *5.6 Infectious Hazard Preparedness*

# Burden of disease assessments for typhoid / other water-borne diarrhoeal diseases

# Threat of emerging and re-emerging zoonotic diseases in EMR: country response and lessons learnt

# Intervention community field studies to improve uptake of Risk Communication & Community Engagement (RCCE) for outbreak response

# Enhancing critical/ICU care capacities and life-saving skills among front-line healthcare workers in Fragile, Conflict-Affected and Vulnerable (FCV) countries

# Barriers and enablers of use of seasonal influenza vaccines among healthcare workers

# *Health Emergency Information & Risk Assessment*

# Landscape assessment of the surveillance systems in EMR countries to identify the opportunities, gaps, and ways forward for the establishment/strengthening of Event-Based Surveillance

# Epidemiological modelling of infectious diseases to support public health responses to managing disease outbreaks and reducing the burden of disease in the EMR.

# APPLICATION FORM

# The Eastern Mediterranean Regional Office Special Grant for

# Research in Priority Areas of Public Health 2022-2023

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| --- |
|  COVER SHEET OF APPLICATION FORM |
|  |
| **SHADED AREA FOR OFFICIAL USE ONLY** |
| DATE RECEIVED (dd/mm/yy) | WHO/EMRO PROPOSAL ID NUMBER**SID/EMRPPH 20/**…………….. |
| 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: |

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| **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. |

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| **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?1. 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? 1. Yes € No €

6. Have you received any training on ethics of biomedical research?1. Yes € No €
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**5. TIME FRAME OF PROPOSED ACTIVITIES** (Gantt chart)

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| **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 |
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| ***Submission of the Progress Report\**** |  |  |  |  |  X |  |  |  |  |
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| **Submission of the Final technical and Financial Report\*** |  |  |  |  |  |  |  |  | X |

\*mandatory

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| **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) |

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| **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)

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**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 **$8,000-$10,000**. 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.

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| **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 30 June 2022.** 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 2022-2023 (as described under section “10”) should be mailed to:**

Coordinator, Research and Innovation

Science, Information, and Dissemination

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:

1. All statements in the proposal entitled “……………………………………………………………………………………………………………………………………………………………………………………………………………………………………”

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

1. 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 |
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**ANNEX II**

**RESEARCH ETHICS CHECKLIST**

GUIDE FOR PRINCIPAL INVESTIGATORS

Please ensure that your protocol minimizes harm and maximizes benefits to the research participants. *Please 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.

# INTRODUCTION

**CONDUCTING ETHICAL RESEARCH**

WHO follows [World Medical Association Declaration of Helsinki (1964)](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/), amended in 2000, and further revised in 2008, [Universal Declaration of Bioethics and Human Right 2005](http://portal.unesco.org/en/ev.php-URL_ID%3D31058%26URL_DO%3DDO_TOPIC%26URL_SECTION%3D201.html), [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html), the [CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects](https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/) published in 2016 as well as the [WHO Standards and operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011](https://www.who.int/publications/i/item/9789241502948).

**Definition of Human Biomedical Research**

Human Biomedical Research refers to any research performed for the ultimate purpose of studying, diagnosing, treating or preventing any disease, injury, disorder, or condition of the human mind or body, and which entails the involvement of humans, human biological materials or information derived from humans or human biological materials. Also included is research on human physiological processes, and in epidemiology or public health. During the ethical review of a protocol, the WHO/EM- RERC evaluates the risks and benefits to the research participants and research communities in the following domains:

* + **Respect for persons**
	+ **Beneficence**
	+ **Justice**
	+ **Solidarity**
	+ **Autonomy**
	+ **Proportionality**
	+ **Sustainability**
	+ **Research integrity**

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 | Contribution to society |
| Emotional harm/risk | Psycho-social support |
| Stigmatization | Humanitarian  |
| Loss of privacy | Others |
| Insensitivity to vulnerabilities, exposing individuals to various types of harms/risks |  |
| Sharing of confidential information resulting in tangible or intangible losses |  |
| Perpetuation of gender and other biases |  |
| Specify potential risks induced by the research protocol |  |
| Others |  |

# Purpose of the Research Ethics Checklist

This checklist has been adapted by the WHO/EM-RERC to help ensure that all necessary requirements for the development of a complete and ethically sensitive protocol are covered. The checklist consists of a set of specific 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 relevant questions around key ethical issues that should be addressed in the protocol. Sections 3 and 4 are related to 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 the elements described here are not all relevant to all protocols. Please ensure that those items that correspond to the research conducted are included in the WHO/EMRO submission as they will be assessed by WHO/EMRO Ethics Review Committee reviewers.

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# SECTION 1

# PROTOCOL (SCIENTIFIC AND TECHNICAL ISSUES)

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

This section is not intended to provide a definitive guidance on how to design a study, but rather list key technical and scientific issues that need to be detailed and explained in study protocols. For guidance on how to design a research study, please consult the following link: <https://www.who.int/groups/research-ethics-review-committee/recommended-format-for-a-research-protocol>

The WHO website also has additional guidance documents on writing research protocols and informed consent forms, available at the following link: https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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?  |  |  |  |
| Does every participant have access to standard of care treatment - even in natural history studies? |  |  |  |
| ***Goals and objectives and expected outcomes*** |
| 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, 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 and admission fully described?  |  |  |  |
| Are the procedures for follow-up and completion fully described? |  |  |  |
| Are the laboratory tests and other diagnostic procedures fully described? (in particular for multinational research protocols) |  |  |  |
| 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, 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? |  |  |  |
| If the research involves study of existing samples/records, were the methods to authorize access to samples/records well described? |  |  |  |
| ***Participant safety*** |
| Have any risks to participating in the research been identified?  |  |  |  |
| Does the protocol state how risks in the research will be minimized? |  |  |  |
| If the research involves medicinal products (including vaccines), is clearance from the national drug regulatory authority attached? |  |  |  |
| If the research involves medicinal products (including vaccines), is the Investigator's Brochure (including safety information) attached? |  |  |  |
| Where appropriate, is the establishment of a Data Safety Monitoring Board (DSMB)[[1]](#footnote-1) envisaged? If yes, is information about the DSMB included ([see DSMB Charter](https://www.niehs.nih.gov/research/clinical/patientprotections/dsmb/charter/index.cfm))? |  |  |  |
| 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? |  |  |  |
| Does the protocol describe the main lines of the statistical analysis?  |  |  |  |
| ***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, websites, flyers, leaflets etc.)? |  |  |  |
| ***Gender equity and human rights*** |  |  |  |
| 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? |  |  |  |
| Does the protocol discuss how the research contributes to identifying and/or reducing inequities and inclusion of economic status and disability? |  |  |  |
| ***Demographic issues*** |
| Does the protocol ensure that no discrimination based on demographic characteristics (E.g., gender, age, ethnicity, religion, education, refugees), unless scientifically justified? |  |  |  |
| ***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 and easily understood? |  |  |  |
| If applicable, have case report forms, adverse event forms etc. been prepared and 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 - 17 years? Are these included?  |  |  |  |
| **Please provide comments as required:**  |

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# 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? |  |  |  |
| Is the research outcome sustainable or acting on long-term?  |  |  |  |
| ***Study population*** |
| Is a vulnerable population being studied (i.e., any of the following: pregnant women, children, adolescents, elderly people with mental or behavioural disorders, prisoners, refugees, those who cannot give consent (unconscious, others? |  |  |  |
| If a vulnerable population is being studied, is the justification adequate? |  |  |  |
| Is the inclusion or exclusion in the study of vulnerable populations (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) properly discussed and justified? |  |  |  |
| Have adequate provisions been made to ensure that inclusion of vulnerable population is ethically and scientifically justified and that all necessary measures to protect their rights have been envisaged?? |  |  |  |
| ***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 psychosocial 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 the communities to participate in randomized controlled trials. They can give permission to approach individuals in the communities and invite them to participate in the research.

# 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:

https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms

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** |
| ***Consent*** |
| Does the ICF state that the participant is free to not answer any question? |  |  |  |
| Does the potential participant agree to the research study? Has a provision been made for subjects incapable of reading and signing the written consent form (e.g. illiterate patients)? |  |  |  |
| Have the potential participants been informed, as fully as possible, of the scientific validity of the study? |  |  |  |
| 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 be embarrassing for the participant?  |  |  |  |
| Is the potential participant informed, as fully as possible, about the investigators/ investigational team's relationship with the sponsor of the study |  |  |  |
| Improved care and follow-up: Has an offer been made to the potential participants of more frequent consultations or no delay in consultation, or easier access to the health professionals, personal contacts…? |  |  |  |
| Do children, who cannot read or write, signal their willingness to participate using an affirmative act (for example, nodding their head).  |  |  |  |
| Is consent by minors referred to as “assent”?  |  |  |  |
| Are cultural factors; local social and cultural norms addressed? |  |  |  |
| ***Disclosure*** |
| Does the document of informed consent make it clear that the study is a research study, and not any clinical therapy? |  |  |  |
| Is the research study presented in the context of existing therapies? |  |  |  |
| Is the potential participant assured, as fully as possible, that regardless of their willingness to participate, they will still receive what is considered the best treatment for their condition? |  |  |  |
| Does the ICF outline how participants will be informed of the progress & outcome of the research? |  |  |  |
| Is the potential participant informed, as fully as possible, of the nature and purpose of the research? |  |  |  |
| Is the potential participant informed, as fully as possible, of the procedures to be used?  |  |  |  |
| Is the potential participant informed, as fully as possible, of alternatives to participating to 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?  |  |  |  |
| Is the potential participant informed, as fully as possible, of the expected benefits to the participant and/or society?  |  |  |  |
| Does the document make it clear whom to contact with questions about the research study, research subjects' rights, and in case of research-related injury? |  |  |  |
| Does it describe the nature of any compensation or reimbursement to be provided (in terms of time, travel, man-days lost from work, etc.)? |  |  |  |
| Is the potential participant informed as fully as possible of the potential of reasonably foreseeable risks, stresses, and discomforts? |  |  |  |
| Does the informed consent document disclose what compensation and medical treatment are available in the case of a research-related injury?  |  |  |  |
| Is there assurance that participants will be referred for treatment in a timely manner from injury that results from participating in the study and that the costs of this treatment will not be the responsibility of the participant? |  |  |  |
| Is there a statement that describes procedures in place to ensure the confidentiality of data and anonymity of the participant?  |  |  |  |
| ***Voluntariness*** |
| Is the participant's consent to participate in the research voluntary? |  |  |  |
| Is the participant's consent to participate in the research free of any coercion, inflated promise of benefits from participation ?  |  |  |  |
| Is the consent form administered by someone who does not hold authority over the participant ?  |  |  |  |
| Has the potential participant been given the opportunity to discuss their participation in the study with family, trusted friends, or their physician before reaching a decision ? |  |  |  |
| ***Understanding*** |
| Are you sure that the participant understands what has been explained ? |  |  |  |
| Has the participant have been given the opportunity to ask questions and have them answered by someone fully competent in the study? |  |  |  |
| Is the informed consent document written in lay language, avoiding any technical jargon ?  |  |  |  |
| Is the potential participant able to read and/or understand the language in which the consent form is written ?  |  |  |  |
| In case of multinational research, have the consent forms have been translated into the respective language for each participating country and back-translated to verify accuracy? |  |  |  |
| ***Competence*** |
| Is each the participant competent to give consent ?  |  |  |  |
| If the participant is not competent due to mental status, disease, or emergency, is the designated surrogate to provide consent of the participant's acting in his/her best of interest to participate?  |  |  |  |
| In cases, of lack of competence of the participant were there measures of an appropriate surrogate according to prevalent laws (as available)?  |  |  |  |
| ***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?For longer term study, a broad type of consent will be needed and will not be specific for given current protocol |  |  |  |
| 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/will 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? (Indicate if results/information provided to the patient on a systematic basis) |  |  |  |
| Is the potential participant informed as fully as possible for consent to be broad for future unspecified research? |  |  |  |
| For especially transnational studies where samples will be moved cross border and if a company needs to bank the samples: Has the potential participant been informed, as fully as possible, for a broad consent (Material Transfer Agreement)? |  |  |  |
| **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) |
| 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:**  |

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1. DSMB is an independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing. It is established to ensure that each research study has a system for appropriate oversight and monitoring of the conduct of the study to ensure the safety of participants and the validity and integrity of the data. [↑](#footnote-ref-1)