Annex 1. Recommended format for research proposal (checklist, proposal format and budget template) for financial and or technical support from WHO Regional Office for South-East Asia

I. SUMMARY SHEET AND CHECKLIST OF REQUIRED DOCUMENTS

1		Principal Investigator Professor/Dr/Mr/Ms FAMILY NAME (SURNAME): FIRST NAME: OTHER NAMES:
	1.1	Title of post, position or appointment presently held by principal investigator
	1.2	Complete postal address: Email:
2		Institution responsible for the research proposed Name and address (including website address, if any)
3		Title of health research proposed: (should be brief, precise and informative to workers outside your field)
	3.1	Objectives of research have been clearly listed. Yes ☐ No ☐
	3.2	Duration of research from preparations for field work till analysis and compilation of final research results From (date): To (date): Total (years):
	3.3	Total budget of research (US$)
	3.4	Any conflict of interest by research institute/PI/funding source declared Yes ☐ No ☐
4	4.1	Informed consent documentation included in the proposal

		Yes ☐ No ☐
	4.2	Questionnaires for collection of data included in the proposal Yes ☐ No ☐
	4.3	If the study design involves a clinical trial, proof of Registration in a database linked to Search Portal of International Clinical Trial Register Platform of WHO is attached Yes ☐ No ☐ Not a clinical tria☐
5	 5.1	<u>Institutional and national ethical clearance</u> Name and contact details of the local ERC/IRB/ERB in the country of research where the proposal has been reviewed/submitted: Name of local ERC/IRB: Contact details including email address:
	5.2	Institutional/national ethical clearance • Proposal reviewed & approved by institutional/national ERC ☐ proof of approval to local ERC enclosed) • Proposal has been submitted and is under review ☐ (proof of submission to local ERC enclosed) • Proposal has not yet been submitted and is in the process of submission ☐
6		<u>Approval of national Ministry of Health or national Medical Research Council (or equivalent body</u>) National approval document enclosed Yes ☐ No ☐ Not applicable ☐
7		<u>Institutional endorsement (can be attached as a separate document also)</u> Head of Institution Title:_________________________________ Name: ______________________________ Date: ________________ (print) Signature:
8		Curriculum Vitae of Principal Investigator attached Yes ☐ No ☐
9		Applicant's signature Date: Signature:

II. Recommended format for research protocol

The recommended format is aligned with what is recommended by WHO HQ at (as accessed on Feb 23, 2022). https://www.who.int/groups/research-ethics-review-committee/recommended-format-for-a-research-protocol

Research Protocol: Part 1

1. **Project Summary**: should be no more than 300 words
2. **General information** (protocol title, version, date, name & address of sponsor/funder, name and titles of investigators; address and telephone number of research sites; name and address of clinical laboratories and other institutions involved in research.
3. **Rationale for conducting the research** (or problem statement) **and background information** (literature review of what we already know about the issue at hand).
4. **Study goals and objectives or study hypothesis**.
5. **Study design and methodology:** Key research design (e.g. experimental study, cross-sectional survey, facility survey, etc.); Research setting (country, district, province, etc.) and study population (age groups, women, men, etc.); Sampling design, sample size and use of controls (if applicable); Study instruments

6. **Ethical and safety considerations**: safety considerations (for research participants, communities and researcher themselves), follow-up provided to research participants, if any. Documentation of issues that are likely to raise ethical concerns (risk assessment for different stakeholders), how informed consent will be obtained from research participants. Inclusion of informed consent forms and information sheet for research participants as part of the proposal.
7. **Data collection and analysis**: Plans for fieldwork for collecting data; Data analysis plan, including a description of key outcome indicators proposed to be measured in the research.

8. **Time line for research implementation**

Research Protocol: Part 2

1. Budget (please see the template at annex 3), please highlight any compensation/reimbursements made to research participants and the justification for that. Also highlight the salaries paid to PIs who are staff members of the contracting Institution.
2. Other support for the project funding received or anticipated for this project from other funding organization)
3. Collaboration with other scientists or research institutions
4. Links to other projects
5. Curriculum Vitae of Investigators (In general CVs should not be more than 1 page, unless a complete CV is specifically requested for).
6. Other research activities of the investigators (PI should list all ongoing research projects that they are involved in, the source of funding of those projects, the duration of those projects and the percentage of time spent on each.
7. Financing and insurance—where relevant.

III. Recommended format for presenting budget

	ITEM		Amount (local currency)	Amount (US $)
1	**PERSONNEL**[a] (allowances to be paid)			
	1.1	Professional scientific staff (name and functional title)		
	1.2	Technical staff (name and functional title)		
	1.3	Other staff (name and functional title)		
	Subtotal			
2.	**MAJOR EQUIPMENT**[a] (over US$ 500) (include specifications, shipment and freight insurance costs; comment on local provision for maintenance and service			
	Subtotal			
3	**SUPPLIES**			
	3.1	Chemicals		
	3.2	Glassware		
	3.3	Minor equipment (less than US$ 500 each)		
	3.4	Animals		
	3.5	Other supplies		
	3.6	Operating cost (specify maintenance of equipment, gasoline, etc)		
	Subtotal			
	TRAVEL[a] (specify domestic and international)			
	Subtotal			
5.	**DATA ANALYSIS COST**[a]			
	Subtotal			
6.	**COST OF DISSEMINATION OF RESULTS* (including that of publication in any peer reviewed journal for making it open access[b])**			
	Subtotal			
7.	**MISCELLANEOUS EXPENDITURES**[a]			
	Subtotal			
8.	**SUMMARY**			
	(1) Personnel			
	(2) Major equipment			
	(3) Supplies			
	(4) Travel			

	(5) Data analysis cost		
	(6) Cost of dissemination of results		
	(7) Miscellaneous expenses		
	TOTAL		

[a] please provide detailed budget providing sufficient break-up of costs included under each budget item to facilitate expedited approval.

[b] The condition 7.2 provides the publication will in accordance with WHO policy on open access (https://www.who.int/about/policies/publishing/open-access) and from Jan 1, 2021, all WHO authored and WHO funded articles that are submitted for publication in peer-review journals must be published in an open access journal or an open access platform. It further states that where applicable, reasonable article processing charges (APCs) will be covered by WHO for articles published in open-access journals or on open-access platforms that are compatible with the requirements mentioned in its open access policy.

Annex 2. Additional documents (or information) to be included in a research proposal (where applicable) for submission to the Committee for review

In addition to the items required in Section IV-B for all research proposals involving human participants, the responsible technical staff member shall submit additional information that may be helpful in the review process, such as:

(1) An explanation of how the research is relevant to the health needs of the population in which it will be conducted and how it is consistent with the research agenda of the country where it will be conducted, or, in the absence of such relevance or consistency, a justification for why it is appropriate to conduct the research in that country.

(2) A copy of any instruments being used to collect data, such as questionnaires that will be administered, including translations into the local language.

(3) Detailed information about how biological materials or other data from the research will be collected, preserved, transported and stored, and the conditions under which such items will be released in the future to people outside the present research project. A copy of the information that will be provided to participants about such future use and whether, and if so how, their consent will be sought before such use outside the present project would occur, and whether they will be provided with information derived from such future studies.

(4) A description of the plans that have been made and any formal agreements that have been negotiated with representatives of the participant population or officials of the country where the research will occur. The description should include plans to continue to provide any drug, device, vaccine or other product being tested, or any other service, to any participants who are benefiting from such intervention at the conclusion of their participation in the research or a justification for the absence of such plans.

(5) A description of the plans that have been made and any formal agreements that have been negotiated with officials of the country where the research will occur (or with any agency providing services to the members of the population from which participants will be drawn or to residents of that country) to make any drug, device, vaccine or other product being tested, or any other service, available at an affordable cost to the population or residents once such drug, device, vaccine or other product has been approved for use by the relevant authorities or a justification for the absence of such plans.

(6) Complete information on the regulatory status of any drug, vaccine or device being studied,

including an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the product and of the clinical experience to date.

(7) Where the research involves a risk of injury (such as research on an infectious agent or research involving venipuncture), a description of the means that will be used to avoid or minimize risks to the investigator and other persons conducting the research.

(8) Where the research involves an infectious agent or a vaccine, a description of any risk to people who are not directly involved in the research but who might be exposed to risk through contact with participants or otherwise.

(9) A description of the arrangements that have been put in place to address any needs that will arise should harm occur to the people conducting the research or to other people who might be harmed in the foreseeable future.

(10) Details concerning any Data Safety and Monitoring Board (DSMB) or comparable body that will be established to oversee the research, including information on who will appoint the DSMB, to whom it will report (including the circumstances for which it will provide specified information to the Committee), and the decision rules it will use in deciding or recommending that the research should be altered or halted.

Annex 3: Examples of guidelines and templates of informed consent forms

- World Health Organization. Informed consent form templates. Accessed on February 23, 2022 at https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms

- Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services (HHS), U.S. Government. Last visited on February 23, 2022 at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Other templates

- World Health Organization. WHO-ERC guide for principal investigators. Accessed on February 23, 2022. https://cdn.who.int/media/docs/default-source/documents/ethics/guide-for-practical-investigation.pdf?sfvrsn=826ad3be_0

Annex 4: Committee protocol review standards

[adapted from the National Institutes of Health, United States of America and WHO-ERC review standards]

Minimum regulatory requirements for Committee review, discussion, documentation in the meeting minutes

Regulatory Review Requirement	Suggested question for SEARO-ERC discussion
1. The proposed research design is scientifically sound and will not unnecessarily expose human research participants to risk	(a) Is the hypothesis or research question clear? Is it clearly stated? (b) Is the study design appropriate to prove the hypothesis or answer the research question? (c) Will the research contribute to generalizable knowledge, and is it worth exposing human research participants to risk?
2. Risks to the participants are reasonable in relation to anticipated benefits, if any, to the participants and the importance of the knowledge that may reasonably be expected to result.	(a) What does the Committee consider the level of risk to be? (See risk assessment guide on the back of form). (b) What does PI consider the level of risk/discomfort/inconvenience to be? (c) Is there a prospect of direct benefit to human research participants (see benefit assessment guide below)
3. Participant selection is equitable	(a) Who is to be enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously ill patients? Healthy volunteers? (b) Are these research participants appropriate for the protocol?
4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.	(a) Is appropriate protection in place for vulnerable participants, e.g. pregnant women, socially or economically disadvantaged, cognitively impaired, subjects in special situations, e.g. doctor-patient relationship making them more vulnerable?
5. Informed consent is obtained from research participants or their legally authorized representative (s).	(a) Does the informed consent document include all the required elements? (b) Is the consent document understandable to participants? (c)Who will obtain the consent (PI, nurse, other?) and in what setting? (d) Is the Committee asked to waive or alter any informed consent requirements?
6. Risks to the participants are minimised?	(a) Does the research design minimize risks to participants? (b) Would using data and safety monitoring board or other research oversight process enhance participant safety?

7. Subject privacy and confidentiality are maximized.	(a) Will personally identifiable research data be protected to the extent possible from access or use? (b) Are any special privacy and confidentiality issues properly addressed, e.g., use of genetic information?

Risk/benefit assessment

Risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Check appropriate risk category:

1. _______ The research involves no more than minimal risk to the participant**.**

2. _______ The research involves more than minimal risk to participants.

- o The risk(s) represents a minor increase over minimal risk, OR
- o The risk(s) represents more than a minor increase over minimal risk.

Benefit: A research benefit is considered to be something of health-related, psychosocial or other value to an individual research subject or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit but rather compensation for research-related inconveniences**.**

Check appropriate benefit category(ies):

1. ______ No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition.

2.______ No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge to further society's understanding of the disorder or condition under study.

3._____ The research involves the prospect of direct benefit to individual participants.