WHO Ethics Review Committee

Checklist: Submission of new research protocols

Documents to be submitted by WHO Responsible Officers

This is a draft / interim document.

The WHO ERC secretariat is currently updating and revising its tools and guidance to better support users. We would very much appreciate your feedback on this document, including its usefulness, clarity, and any suggestions for further improvement.

Please send your feedback to ercsec@who.int

How to submit your documents:

Please submit research protocols through ProEthos at **https://extranet.who.int/ercweb/**

- Documents must be submitted in PDF format

For research protocols related to COVID-19 : Please submit research protocols to the COVID-19 branch of the ERC (CERC) via email to ercsec@who.int

- Documents may be submitted in PDF, Word, or Excel formats

Documents to submit:

1 ☐	***Submission form / Cover page information*** *For protocols submitted through ProEthos*: • Complete all fields online in ProEthos. This will create a "submission form" document within the system *For protocols submitted by email for CERC:* • Complete all sections of the cover page document available at CERC documents WHO staff public
2 ☐	***Research protocol*** *If needed, guidance on research protocol format is available at: https://www.who.int/ethics/review-committee/format-research-protocol/en/* • Submit the protocol version approved by the independent scientific/technical reviewers (see 5, below). Any changes to the protocol recommended by the reviewers should be either indicated in tracked changes or highlighted • Before submission, resolve formatting changes and margin comments and check that no boxes are visible in the margins • Specify the version number and date on each page of the document. There is no standard version numbering system, but numbering should reflect previous actions (e.g. changes made in response to independent scientific / technical review, or review by local IRBs)

3 ☐	***Informed consent / assent documents*** *Consent/assent documents comprise participant information pages and signature page(s)* • Specify version number and date on each page of each document • Submit initially in English. Local language documents are to be provided once they are available (NB: It may be most efficient to only prepare and submit in English first, to reduce revision time in case of modifications requested by the ERC) • There is no mandatory format. If needed, templates for informed consent documents are available here: https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms
4 ☐	***Study instruments/data collection tools*** *Surveys, questionnaires, interview schedules, case report forms, patient diaries, data dictionaries, etc.* • Specify version number and date on each page of each document • Submit initially in English. Local language versions of these documents are to be provided once available (NB: It may be most efficient to only prepare and submit in English first, to reduce revision time in case of modifications requested by the ERC)
5 ☐	***Results of the independent technical / scientific review*** *Independent reviews can be conducted by a Scientific Review Board, or alternatively, two technical reviewers demonstrably independent from the research.* • Provide: – Reviewer comments in a separate document (i.e. separate from the protocol). Please do not submit a protocol version with reviewers' comments in the margin. – Protocol and other document(s) with changes made in response to the review highlighted or tracked, ensuring there are no boxes visible in the margins (formatting or comment boxes) – The research team's point-by-point responses to the reviews, clearly indicating any changes made to study documents in response to the reviews, and including the page numbers where the changes have been made – Confirmation of final approval by the Board or each of the reviewers (email is acceptable) – Names and affiliations of individual reviewers (not necessary for Boards)
6 ☐	***Local Institutional Review Board (IRB) or local ERC ethics approval*** *Proof of local submission (e.g. acknowledgement of receipt) is required prior to ERC review, and proof of local approval is required prior to WHO ERC approval* • Provide documentation of submission/approval from: – At least one national ethics committee as appropriate based on the national requirements of each of the countries where the research will be conducted. The institutions responsible for reviewing depend on national requirements – The PI(s) institution(s) • Advise the ERC secretariat of all relevant committees that need to approve the proposal to comply with national, local and institutional requirements

7 ☐	***CVs of the Principal Investigator(s) and co-investigators*** *There is no mandatory format for CVs. Summary CVs are preferred provided that they contain key recent information.*
8 ☐	***Declaration of Interest (DoI) memorandum*** • Provide a memo – confirming that (1) all investigators have completed standard WHO Declaration/Conflict of Interest forms, (2) these have been reviewed by the WHO responsible unit, and (3) no conflicts of interest exist (or describing any potential conflicts of interest that were identified) – describing how any conflicts will be managed – including names of all investigators for which DoIs were reviewed – signed by Director or Coordinator of the responsible WHO technical unit • Do not submit individual signed DoI forms as these will not be reviewed
9 ☐	***Detailed Budget*** *There is no mandatory format for budgets. They can be submitted separately or within the protocol*

The following documents may need to be submitted depending on the research being proposed:

*Please submit available documents and note that the ERC may request additional document**s** where applicable.*

☐	Recruitment materials: advertisements, flyers, posters
☐	Investigator brochure and/or package inserts
☐	Clinical Trials registration details (WHO primary register ID, name of register, date of registration, and URL). Required for all interventional/clinical trials (details to be provided prior to approval)
☐	ToRs/Roles and responsibilities for Data Safety Monitoring Board/Committee (DSMB/C) or other statistical analysis groups, steering groups, etc
☐	Description of study insurance arrangements or insurance procured for interventional/clinical trials