

# Review form for SEARO Research Ethics Review Committee

This is the form used by reviewers (SEARO-ERC members or other external reviewers) to review the research proposals received from different technical units within RO and WCOs. This will be available online within the system. The reviewers should submit his form to submit their feedback on the proposals assigned to them. In addition they can upload any other file (e.g. Word file etc.) to give their additional feedback.

\* This form will record your name, please fill your name.

1. The proposed research design is scientifically sound and will not unnecessarily expose human research participants to risk.

1 a) The research hypothesis or research questions or objectives are clearly stated.

- Yes
- No
- Can't say / not sure

2. 1b. The study design is appropriate to prove the hypothesis or answer the research questions.

- Yes
- No
- Can't say /Not sure

3. 1c Will the research contribute to the generalizable knowledge about the subject at hand, and is it worth exposing human research participants to risk, even if minimal?

- yes
- No
- Can't say /not sure

4. 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.

2a) What does the Reviewer consider the level of risk to be?

*(please note: '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.)*

- The research involves no more than minimal risk to the participants.
- The risk(s) represents a minor increase over minimal risk
- The risk(s) represents more than a minor increase over minimal risk.

5. 2(b) Is there a prospect of direct benefit to human research participants?

*(Please note: A research benefit is considered to be something of health-related, psychosocial or other value to an individual research participant 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.)*

- No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder
- No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge to further society's understanding of the disorder or the condition under study.
- The research involves the prospect of direct benefit to individual participants.

6. Is the participant selection equitable?

*(Note: please see who is to be enrolled? (men, women, ethnic minorities, children, seriously ill patients, healthy volunteers, is the sampling designed to enroll only certain socio-economic or ethnic groups).*

- Yes
- No
- Can't say /Not sure

7. Are these research participants appropriate for the protocol?

*(Note: see in relation to research objectives)*

- Yes
- No
- Can't say /Not sure

8. Any additional safeguards required for research participants likely to be vulnerable to coercion or undue influence?

- Yes
- No
- Can't say /Not sure

9. Informed consent is obtained from research participants or their legally authorized representatives in an appropriate manner

*(the consent document is understandable to participants, and the participants are fully informed about any risk or benefits and how research results will be used, including an option on withdrawing from research or not answering any questions they do not wish to).*

- Yes
- No
- Can't say /Not sure

10. Does research team making sufficient efforts to minimize or address the Risks to participants, even if there is minimal risk?

- Yes
- No
- Can't say /Not sure
- not applicable, as there is no risk at all.

11. Does the research design ensures subject privacy and confidentiality? Are any special privacy and confidentiality issues properly addressed?

- Yes
- No
- Can't say /Not sure

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