

**Form No. 2: SSERB Study Protocol Assessment Form**

# Reference no. (to be filled by SSERB) Date

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# Project Title

# INSTRUCTIONS

FOR THE RESEARCHER: Please summarize how you intend to address the ethical concerns cited below. If extensive discussion is included in the Study Protocol, please indicate the page and paragraph where this information can be found.

FOR THE REVIEWER: Please evaluate how well the researcher has addressed the indicated ethical considerations. Indicate your recommended action and sign the document.

# ETHICAL ASPECTS OF THE RESEARCH PROJECT

## A. RESPECT FOR PERSONS

In research, respect for persons is an acknowledgment that each human research subjects are "autonomous" and has the right to self-determination. The participants of the study must have adequate information regarding the research. This principle also requires that investigators protect subjects with diminished autonomy from exploitation and harm.

### Researcher's Summary

### Reviewer's Comment

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## B. INTEGRITY

Integrity or the commitment to accuracy, intellectual honesty and truthfulness must be upheld in the conduct and reporting of studies. It involves scholarly rigor in obtaining, recording and analyzing data, and in reporting and publishing results. It means taking into consideration the long and short-term effects of research projects on the people, places, natural and social environments under investigation.

### Researcher's Summary

### Reviewer's Comment

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## C. CONFIDENTIALITY, PRIVACY AND ANONYMITY

Confidentiality and anonymity of research participants should be maintained and their personal privacy protected. Unless data have been sourced from public documents, the identity of individuals in the study should not be revealed. Moreover, identities of individuals, groups or organizations who participated in a study can be revealed only when written permission is obtained from them by the researcher.

### Researcher's Summary

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## D. INFORMED CONSENT

Informed consent must be obtained by researchers from the research participants without coercion or undue influence after they have explained the purpose and objectives of the study, the methods to be used in collecting information, the nature of the research participant’s involvement, and potential risks in and benefits of their participation.

### Researcher's Summary

### Reviewer's Comment

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## E. BENEFICENCE

Beneficence (“do good; do no harm”) should be ensured in the conduct of a study. This means enhancing the well-being and improving the situation of the populations under study, rather than undermining or endangering them in any way. Participants must be protected from possible harm, including physical, medical, psychological and social damage (such as distress, embarrassment, social stigma), and financial, criminal or civil liability.

### Researcher's Summary

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## F. SOCIAL JUSTICE

Social justice should always be considered by researchers in the allocation of burdens and benefits to the research participants and their communities. The study or its results must not introduce nor exacerbate inequalities and inequities among the research participants and the community in the study area.

### Researcher's Summary

### Reviewer's Comment

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## G. CULTURAL AND GENDER SENSITIVITY

Cultural and gender sensitivity to traditions, cultural norms, and values, as well as gender related perspectives and practices, must always be observed by researchers in the conduct of the study. The esteem accorded by individuals and communities to their language and other forms of cultural knowledge and practices must be respected and acknowledged.

### Researcher's Summary

### Reviewer's Comment

## H. PROTECTION OF VULNERABLE GROUPS

The protection of vulnerable and at-risk individuals and groups should be foremost in the mind of researchers when undertaking a study. These sectors include those who are marginalized or disadvantaged by virtue of their age, gender, social class, disability, ethnicity, and physical or mental health. Additional measures must be placed to protect them.

### Researcher's Summary

### Reviewer's Comment

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# RECOMMENDATION (For Ethics Review Committee use only)

## Reviewer's recommendation

**\_\_\_ Approve (no need for modification)**

**\_\_\_ Conditional approval (minor modification)**

**\_\_\_ Major modification**

**\_\_\_ Partial approval (for multi-stage research; identify particular phase approved)**

**\_\_\_ No basis for review (incomplete protocol)**

**\_\_\_ Disapprove**

**\_\_\_ Clarificatory interview**

**Remarks**

## Name of reviewer

First Last

## Signature of reviewer

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## Date

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