I. INTRODUCTION

Following good practice guidelines, the REB approves a research protocol when the following criteria are satisfactorily addressed (see § 46.111 of U.S. Revised Common Rule 2018):

1. The risks to persons and/or communities involved are minimized.
2. The risks to participants are reasonable in relation to anticipated benefits, if any, to participants/communities, and the importance of knowledge that may reasonably be expected to result.
3. There is fair and equitable selection of participants.
4. Informed consent will be obtained and documented (unless waived) appropriately.
5. There are adequate provisions for data monitoring to ensure safety of participants/communities if appropriate
6. There are adequate provisions to protect the privacy of participants and to maintain confidentiality of the data if appropriate
7. There are additional safeguards to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence

The approval criteria underscore the central importance of minimizing risks that impinge upon participants' autonomy, dignity, and welfare. However, before potential harm to persons/communities involved in research can be reduced or managed, these risks must be identified and understood first. Therefore, research ethics applications should include a thorough evaluation of research risks assessment and crafting a defensible risk mitigation plan.

This document serves as a guide in answering Section 2 (Risk Assessment) of UPLB REB FORM 2 (B): Registration and Application Form.

II. THE OBLIGATION OF RISK ASSESSMENT AND MITIGATION

1. Researchers – students, faculty, and staff – whose proposed study involves human participants are required to assess and mitigate research risks. REBs need to examine whether the researcher's risk assessment and mitigation plan are accurate and sufficient. Research risk assessment involves:
    a. Identifying foreseeable risks and those who may be potentially affected
    b. Gauging the likelihood and severity of risks
    c. Classifying research risks
    d. Developing risk mitigation/management plan

2. As a community of responsible scientists, we want to avoid two common pitfalls (World Health Organization, 2009) :
    a. Expose research participants to avoidable and unjustified harm because risks were underestimated, and potential benefits were overestimated
    b. Prevent beneficial research because risks were overestimated, and potential benefits were underestimated.

3. The REB evaluates the ethical acceptability of research protocols based on available evidence, including the researcher's risk assessment and mitigation plan. It is expected that the researcher provides adequate information so that the REB can make a proper evaluation or recommendation on the application.

III. UNDERSTANDING RISK

1. The UPLB REB approves non-biomedical/non-clinical research protocols that involve minimal risk. Research has minimal risk when:

> *the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests* (Philippine Health Research Ethics Board, 2021, p. 16) *See also 45 C.F.R. §46.102 (j) U.S. Revised Common Rule 2018.*

The definition raises some questions when considering minimal risk:

- What types of risks may be considered harmful?
- How do you calculate the probability and magnitude of harm without overestimation or underestimation?
- Whose daily life – a healthy person in a general population or the research population?

2. Risks in research involving human participants include convenience, discomfort, or harm (see Risk Assessment Matrix for definition). Studies initially assessed as minimal risk undergo expedited review – reviewed by two primary reviewers. Those that initially indicate "more than minimal" risk undergo a full board review.

3. Research projects classified according to a level of risk have the following characteristics (Note: The table and its contents are adapted from the University of Cape Town/Horn & Saner, 2021, pp. 7–8. Some statements were modified to suit the Philippine context):

NO/LOW/MINIMAL RISK

The following types of research are generally considered low risk and are suitable for **expedited review and approval processes**:

- Research in which the investigation of **largely uncontroversial topics** is undertaken through interviews, surveys, and participant observation. For example, anonymous market research surveys may be considered to be 'no risk' if an anonymous survey was paper-based and participants deposited surveys into a box, or an online platform was used with no risk of identification of individuals.
- **The participants are adults and not considered to be a vulnerable research population**. Children are generally considered to be a vulnerable research population.
- **Information will be collected that would generally not be regarded as sensitive**, such as opinions rather than personal information.
- **There is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than an inconvenience to participants.** Examples of inconvenience in human research may include filling in a form, participating in a de-identified survey or giving up time to participate in a research activity (playing a video game, completing a puzzle, reviewing pictures).
- **The only foreseeable risk is one of discomfort.** Discomforts include, for example, discomforts related to measuring blood pressure and limited anxiety induced by an interview.
- **No specifically identifiable community is involved** in the research or no specific community will be identified when the study is reported; there is no anticipated need for any form of community or stakeholder engagement activities in relation to the study and study results will not need to be fed back to a community.

MEDIUM RISK

The following types of research may be considered medium risk and **may not be suitable for expedited review** i.e. judgement required based on the context of each proposed project:

- **The research topic is considered 'sensitive'**.
- **Information gathered is personal,** rather than opinion or attitudes, or is a combination of these.
- **The information needs to be collected with personal identifiers** (name, student number, etc.).
- **The research participants may come from a vulnerable or marginalized group**, such as those with disabilities, people living with H.I.V. or other chronic diseases, pregnant women, the economically or educationally disadvantaged, indigenous peoples etc.
- **The research participants may come from an identifiable community** which could potentially be at risk of stigmatization; it is possible that the community will be identified in project outputs. This could either be a geographic community or participants from a particular institution or identity group; it is anticipated that some kind of community or stakeholder engagement activity may be required prior to the initiation of the research project and results will need to be given back to the community in an appropriate manner.
- **Researchers may be placed at some risk while conducting the research** (e.g. a spiral community mapping walk in an area that is not considered safe or recruiting participants in potentially unsafe public spaces such as taxi ranks).

HIGH RISK

Research falling into a high-risk category should be reviewed at a convened REB. meeting.

- Research involving **highly sensitive topics and/or very vulnerable and marginalized communities**.
- Research involving the **deception of the participants**.
- Research investigating **illegal activities** – for example, involving participants who are illegal immigrants or engaged in illegal activities (drug use, sex work, poaching, or illicit wildlife trade) – by agreeing to participate in the research participants will be placed at real risk of harm.
- The **researcher may be placed at risk of breaking the law** by carrying out certain activities, e.g. research investigating gang activities and possession of illegal drugs, wildlife trafficking and/or poaching.
- The **research may reveal information that requires action on the part of the researcher that could place the participant or others at risk** e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc.
- **Communities may well be stigmatized by the outcomes of the research** e.g. research reporting on incidence of gender-based violence in multiple relatively small identified neighborhoods; reporting of various illegal activities etc.
- **Communities may be subject to unwanted attention.** e.g. from the police because the research has drawn attention to activities (e.g. perlemoen poaching etc)
- Researchers place themselves at definite risk by conducting risk activities in **unsafe environments.**
- The **University is placed at risk** by having particular research projects and activities associated with it. Particularly relevant within the context of covert/undercover research. Funding of research by 'dubious' sources may also contribute to institutional risk. Potential for legal action against the university by aggrieved parties.

Among inter/national guidelines, the Australian Government has the clearest specification on what constitutes minimal risk (i.e. low/negligible risk research). The National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) (p.123) explains:

> The expression 'low risk research' describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.
>
> The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

IV. RISK ASSESSMENT MATRIX

For researchers and REB members to thoroughly assess risks in every research project, a risk assessment matrix (adopted from Southern Cross University/Baker, 2019) is included in the research ethics application form/research protocol.

Step 1: Carefully reflect and identify foreseeable risks in your research project.

Step 2: Specify **WHO** may be affected by that risk:

- Participant
- Researcher
- Other Stakeholders (please specify: relatives, other community members, the community-as-a-whole, organizations, the University, etc.)

Step 3: For each type of risk identified, specify the **LIKELIHOOD** of that risk occurring:

- *Unlikely*: extremely rare risks with almost no probability of occurring.
- *Seldom*: relatively uncommon risks but have a small chance of manifesting.

- *Occasional*: more typical risks, with about a 50/50 chance of taking place.
- *Likely*: risks that are highly likely to occur.
- *Definite*: risks that are almost certain to manifest.

Step 4: Describe the **SEVERITY** of the risk should it occur:

- *Insignificant*: Risks that bring no real negative consequences or pose no significant threat;
- *Minor*: Risks that have a small potential for negative consequences but will not have a significantly negative impact;
- *Moderate*: Risks that could potentially bring negative consequences, posing a moderate threat;
- *Critical*: Risks with substantial negative consequences that will seriously affect the participants or researchers.
- *Catastrophic*: Risks with extreme negative consequences for participants or researchers.

Step 5: **CLASSIFY** the level of risk associated with your study based on your assessment of the likelihood and severity of risks.

- *Low*: The consequences of the risk are minor, and it is unlikely to occur. These types of risks are generally considered 'everyday' and acceptable.
- *Medium*: Somewhat likely to occur, these risks come with slightly more serious consequences. As far as reasonably possible, the researcher should take steps to prevent medium risks from occurring in the first place. Generally considered 'tolerable' as long as minimization and mitigation measures are outlined.
- *High*: These are serious risks that have significant consequences and are likely to occur. These risks would generally be considered unacceptable for human research proposals

unless risk management measures are clearly defined, and the benefits of the research justify it. Active measures need to be in place to minimize/mitigate these risks.

- *Extreme*: Catastrophic risks with severe consequences are highly likely to occur. These risks are generally considered unacceptable for human research proposals.

If identified risks have consistently low likelihood and low severity, the research protocol will undergo an expedited review by two UPLB REB members.

The table below (Baker, 2019) shows a cross-tabulation of severity and likelihood of risk and its classification.

LIKELIHOOD / PROBABILITY OF RISK	**SEVERITY/MAGNITUDE OF RISK**				
	Catastrophic	**Critical**	**Moderate**	**Minor**	**Insignificant**
Definite	**Extreme**	**Extreme**	**Extreme**	High	High
Likely	**Extreme**	**Extreme**	High	Medium	Medium
Occasional	**Extreme**	High	High	Medium	Low
Seldom	High	High	Medium	Low	Low
Unlikely	Medium	Medium	Low	Low	Low

Step 6: Outline risk mitigation and management plan.

Completing a Risk Assessment Matrix for your research project allows you to map the risks and circumstances of vulnerability and positions you to think of a plan on how to address them. The table below shows a set of considerations and possible measures for managing and mitigating risks.

Note: The mitigation measures listed below are only indicative. In order for the REB to evaluate your plan, you should be able to provide full details about how you are going to address the risks identified.

Risk Example	What to consider	Possible mitigation and management measures
Inconvenience during individual interviews and focus groups	• Identity factors: sex assigned at birth, age, intellectual ability • Travel time • Access to and ambiance of the setting • Length of interview	• Inclusion of breaks within an interview/focus group session • Splitting of interview sessions (e.g., different days) • Possibility of using other platforms (e.g., email interview for follow-up, use of Zoom from synchronous focus groups to increase/extend participation)
Discussing sensitive/distressing topics with participants	• The age and ability of the participant • Consider optional support person • Provision of contact information for support agencies • Depending on the targeted participant group, topics could be considered more distressing/sensitive to some individuals	• Sequencing of questions, topics discussed • Adherence to a distress protocol during interviews (Haigh & Witman, 2015) • Adherence to good-practice guidelines when researching with children and at-risk populations • Consider whether it is appropriate to have someone on the research team that can provide specialist advice and support to the participant. i.e., has had previous experience or is experienced and counselor availability • Ensure relevant support services are in place and that the participants have access to these services. Ensure the support service is relevant to the participant and age group.

Risk Example	What to consider	Possible mitigation and management measures
		• Ensure it is clear to participants they can withdraw at any point from the study • In addition, ensure it is also clear to participants whether they can withdraw their data (how and at what point).
Emotional distress among researchers (Nguyen et al., 2021)	• Sex assigned at birth, gender, age of the researcher • Schedule • Access to a qualified mental health professional	• Writing of debriefing field notes/journal to unload emotions • Bi-monthly debriefing sessions with peers and adviser
Risk of accidents/harassment at fieldwork site	• Sex assigned at birth, gender of the researcher • Whether the researcher will be working alone • Assessment of risks in the research site (e.g., travel restrictions during public health emergencies, political turmoil, reported terror attacks) • Land, air, and sea travel arrangements	• Be thoroughly familiar with good practice guidelines on the safety of social researchers (e.g., Social Research Association) • Buy accident/life/medical insurance before fieldwork • Deliberately include safety considerations in research design
Collection of identifying information	• Data Privacy Act • Who will have access • Safeguarding and management of data	• Ensure that researchers and the team are aware of current privacy legislation • Only those on the research team and authorized individuals have access to records. • Ensure the data custodian has provided approval for access to data for research purposes • Protocols are in place to ensure only the applicable records are accessed

Risk Example	What to consider	Possible mitigation and management measures
		• De-identification/Anonymization of data (Clark, 2006) • Ensuring good data management is in place to safeguard collected data.

V. HISTORY OF SOP/GUIDELINE

Version number	Date	Authors	Main change
1	12/08/2022	Mark Oliver S. Llangco	-

VI. REFERENCES

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Nguyen, M., Goldsamt, L., Mazibuko, N., Zondo, S., & Fielding-Miller, R. (2021). Emotional distress among frontline research staff. *Social Science & Medicine*, *281*, 1–8. https://doi.org/10.1016/j.socscimed.2021.114101

Philippine Health Research Ethics Board. (2021). *2020 PHREB Standard Operating Procedures*.

Racine, E., & Bracken-Roche, D. (2019). Enriching the concept of vulnerability in research ethics: An integrative and functional account. *Bioethics*, *33*(1), 19–34. https://doi.org/10.1111/bioe.12471

World Health Organization. (2009). *Research ethics committees: basic concepts for capacity-building.* WHO.

RISK ASSESSMENT MATRIX

INSTRUCTION: Add rows as needed. For each relevant type of risk, please provide a brief explanation. Put an "**X**" mark inside the relevant cell. Write "**Not Applicable**" when the type of risk does not apply in your research. Write "Not applicable" if the risk category does not apply to your study. Outline your plan for mitigating these risks using the Risk Mitigation Plan.

TYPE OF RISK	AFFECTS WHO			LIKELIHOOD					SEVERITY					CATEGORY			
	Participant	Researcher	OTHER	Unlikely	Seldom	Occasional	Likely	Definite	Insignificant	Minor	Moderate	Critical	Catastrophic	Low	Medium	High	Extreme
1. **INCONVENIENCE**: including any less serious risks such as those associated with filling in a form, participating in a street survey, or giving up time to participate in research.																	
Example: conduct a 45-minute interview	X						X		X						X		
2. **DISCOMFORT**: which can involve the body and/or mind: e.g., minor side-effects of medication, discomfort related to measuring blood pressure,																	

TYPE OF RISK	AFFECTS WHO			LIKELIHOOD					SEVERITY					CATEGORY			
	Participant	Researcher	OTHER	Unlikely	Seldom	Occasional	Likely	Definite	Insignificant	Minor	Moderate	Critical	Catastrophic	Low	Medium	High	Extreme
and mild anxiety induced by an interview.																	
Mild anxiety	X				X					X				X			
3. **PHYSICAL HARMS**: including potential for injury, illness, pain, chemical exposure, and infection.																	
4. **PSYCHOLOGICAL HARMS**: including feelings of worthlessness, distress, guilt, anger, or fear related, for example, to the disclosure of sensitive or embarrassing information.																	
Repeated exposure to distressing narratives of participants		X				X				X					X		
5. **DEVALUATION OF PERSONAL WORTH**: including being humiliated, manipulated, or in other ways treated disrespectfully or unjustly.																	

TYPE OF RISK	AFFECTS WHO			LIKELIHOOD					SEVERITY					CATEGORY			
	Participant	Researcher	OTHER	Unlikely	Seldom	Occasional	Likely	Definite	Insignificant	Minor	Moderate	Critical	Catastrophic	Low	Medium	High	Extreme
Not applicable																	
6. **SOCIAL HARMS**: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment, or insurance; social stigmatization.																	
Not applicable																	
7. **ECONOMIC HARMS**: including the imposition of direct or indirect costs on participants.																	
Not applicable																	
8. **LEGAL HARMS**: including discovery and prosecution of criminal conduct; mandatory reporting requirements.																	
Not applicable																	

TYPE OF RISK	AFFECTS WHO			LIKELIHOOD					SEVERITY					CATEGORY			
	Participant	Researcher	OTHER	Unlikely	Seldom	Occasional	Likely	Definite	Insignificant	Minor	Moderate	Critical	Catastrophic	Low	Medium	High	Extreme
9. **REPUTATIONAL HARMS** include loss of reputation and credibility to any and all parties and the research findings.																	
Not applicable																	
10. **CIRCUMSTANCES OF VULNERABILITY:** including all dynamic circumstances of relational asymmetry in the research context (i.e., cognitive, juridic, deferential, medical, allocation, infrastructural, social) that make a person(s) more susceptible to harm (Kipnis, 2001; Luna, 2019; Racine & Bracken-Roche, 2019)																	
Not applicable																	
OTHER RISKS																	

TYPE OF RISK	AFFECTS WHO			LIKELIHOOD					SEVERITY					CATEGORY			
	Participant	Researcher	OTHER	Unlikely	Seldom	Occasional	Likely	Definite	Insignificant	Minor	Moderate	Critical	Catastrophic	Low	Medium	High	Extreme