



**IRB Review of Research Ethics Protocols for the Protection of Human Subjects
EXPEDITED REVIEW**

Project Title:	<i>Evaluating Impacts of Rural Road Maintenance Employment among Women in Laos -- Phase II</i>
Principal Investigator: Degree(s), address, email	Elizaveta Perova, Ph.D., World Bank 1818 H Street NW, Washington, DC, 20433, eperova@worldbank.org
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Primary study site(s):	Lao PDR
Participation of Human Subjects From – to dates	Please update
Funding Source:	East Asia and Pacific Gender Innovation Lab (World Bank Group) through Umbrella Facility for Gender Equality
PO Number or other billing info	Please provide

→ **PROCESS:** HML IRB will conduct a research ethics review of submitted materials and make comments below.
We will then return this template for responses from researchers.
Please reply in the right-side column, and we will issue a letter of approval or ask for further clarification.

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	Ethics Review Board Criteria of Interest	IRB OK	Reviewer Comments or Requests for More Information
Section 1	Research Risk: Do submitted materials address potential risks to subjects?		Researchers: Please respond to IRB's red comments in another color
1.1	<u>Minimal Risk Only:</u> The probability and magnitude of anticipated harm or discomfort is not greater than ordinarily encountered in daily life or during performance of routine physical or psychological exams or tests	X	
1.2	Research involves greater than minimal risk, but where risks are justified by anticipated benefits; where the relation of the anticipated benefits to risks is at least as favorable as available alternative approaches.	X	<p>Our primary concern is with the protection of subjects through what appears to be a subterfuge with their husbands. Please clarify if husbands know their wives are subjects, and if they know what the study their wives are involved in is about, or if they are purposefully being kept unaware.</p> <p>Also, please respond to our concerns in Item 6.3, below.</p> <p>Yes, we can confirm that husbands (if at home at the time of the interview) will be read the consent form and will be aware of what their wives are doing – they do not know that they are answering questions on GbV per-se but know that they are participating in a study assessing the full spectrum of impacts of PRF activities on the community.</p> <p>After field testing the 'husband separation' approach, we decided that this approach would not be successful in practice and have now switched over to doing the interviews with Audio Computer Assisted Self-Interviews (ACASI) for the sensitive sections. What this means is that for theses sections, the women we are interviewing will be given the tablet computer and a pair of earphones. They will be listed to the question via earphones and answer directly into the tablet</p>

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			<p>themselves. We have pilot tested this approach (with non-sensitive questions) and found that respondents are indeed able to successfully use the system (even when their literacy level is not high).</p> <p>While we will still try to ensure privacy for the women's section of the interview, we will rely on ACASI to guarantee privacy for the sections where the questions are highly sensitive.</p> <p>Note also that the strategy of separating husbands from their wives we had first proposed was only for half of the survey (the women's section). For the other half of the survey (the household section), we administer the survey to a knowledgeable member of the household: this may include the husband. So the husbands may even be respondents for the first part of the survey.</p>
1.3	Research involving greater than minimal risk and no prospect of direct benefit to subjects, but where the intervention or procedure is likely to yield generalizable knowledge	X	
1.4	If there is potential for greater than minimal risk, are mitigating procedures described?	X	<p>Please see Item 6.4, below.</p> <p>Yes, we plan to use Audio Computer Assisted Self-Interviews (ACASI) to ensure privacy of respondents while answering questions on GbV incidence, the main driver of risk on this study.</p>
1.5	Comments, amendments, additions, or revisions	X	
Section 2	Research Design: Do submitted materials describe the proposed research?		
2.1	Background and rationale	X	
2.2	Description of methodology	X	

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2.3	Does study involve an intervention or treatment group?	X	
2.4	Does study involve a comparison or control group?	X	
2.5	Type of data collection: a. survey questionnaire.....X b. subject interview..... c. key informant interview (KII).....X d. focus group discussion (FGD).....X e. document review..... f. on-site observation.....X g. case study..... h. physical measurements i. biological specimen j. other.....	X	
2.6	Number of Data Collections: a. one-time (no follow-up)..... b. two or more (follow-up)X baseline and endline	X	
2.7	Sample size: Total n or approximate n =	X	<p>You state:</p> <ul style="list-style-type: none"> - Primary study sample (treatment and control group, surveyed at both baseline and endline): Approximately 1146. - Representative sample of households (surveyed only at baseline): ~740 - Price Survey (carried out at both baseline and endline): 74 villages. <p>What is the estimated total sample size?</p> <p>There are different samples corresponding to the different questions we want to answer in this study. We can consider the primary study sample to consist of women in the treatment and control group (and the households these women come from). There are 1146 such women (and corresponding households). This is the sample upon which we will base study</p>

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			<p>estimates of the impact of the program and from whom we are collecting data on GbV at the endline.</p> <p>The complete answer on sample size is what you had pasted above. To provide a bit more information on the other two samples mentioned there,</p> <ul style="list-style-type: none"> The “representative sample of households” refers to a randomly selected households in each village who were interviewed at baseline in order to understand how the study sample compared to other women in their village (was the study sample richer or poorer than randomly selected households?). This is a secondary research question about how well the program is targeted at poor households. The “price survey” aims to understand whether the program (which offers wage-paying jobs to respondents for 18 months) led to any increase in prices in study villages ompared to villages not in the study. We collect data on prices of common goods is collected from sellers in the main market in each village. It is also an important part of the primary research question on the impacts of the program.
2.8	Comments, amendments, additions, or revisions	X	
Section 3	Recruitment: Do submitted materials describe subjects and the recruitment process?		
3.1	Subject identification: a. subjects’ names are recordedX b. no names are recorded c. other personally identifiable information (PII) is recorded d. no PII is recorded	X	

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	e. subjects are given a unique identifier.....X		
3.2	If name or any other PII is recorded, are procedures included for how this info will be kept separate from responses?	X	
3.3	Are sampling strategy & subject recruitment procedures adequately described?	X	<p>You describe who will be drawn, but presumably this is not the entire group of women in the program. Please describe how they will be selected.</p> <p>This is a small scale program that we are evaluating – it could be described as a second stage pilot. If successful, it will be scaled up.</p> <p>Therefore, our sample size does include ALL the women in the program (treatment group). In fact, it also includes women who were interested and eligible for the program but who in the lottery-based selection, did not get selected for the program (control group).</p> <p>Note: Since the number of interested and eligible women was higher than the number of available RMG jobs, a lottery was carried out to select which women would get the RMG jobs and which women would be placed on the waitlist for RMG jobs. The women in the RMG correspond to our treatment group and the women in the waitlist correspond to our control group.</p>
3.4	Do recruitment procedures show any indication of coercion, intimidation, compulsion, pressure, or force?	X	
3.5	Are any subjects children (<18 years old)? None	NA	
3.6	If subjects are children, do materials adequately describe ages and why these ages are appropriate?	NA	

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3.7	If subjects are children, are materials (e.g.: survey instruments, focus group topics, etc.) appropriate based upon age?	NA	
3.8	If subjects are children or other vulnerable groups, is recruitment done in a manner sensitive to potential vulnerabilities or weaknesses (real or perceived) subjects may have?	X	
3.9	If subjects are paid, compensated, or provided a gift for participation, is the incentive described and justified as being non-coercive?	X	
3.10	If future contact with subjects is planned, does it provide for subject safety and data security through the research period and beyond?	X	
3.11	Comments, amendments, additions, or revisions	X	
Section 4	Informed Consent: IC must be sought and documented from each subject or the subject's legally authorized representative.		
4.1	Type of Informed Consent: a. written & signed b. written not signed c. verbal & signed d. verbal not signedX e. other	X	
4.2	Are procedures for obtaining IC adequately described?	X	
4.3	Are written IC documents, using clear and simple wording, included?	X	
4.4	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?	X	
4.5	Does IC state that participation is voluntary, and subject may choose to not respond to any or all questions, or may withdraw without consequences?	X	

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4.6	Does IC include a description of any risks or benefits to subjects?	X	
4.7	Does IC include a statement describing how confidentiality (or anonymity) of subjects and data will be maintained, and any limitations to confidentiality?	X	
4.8	Does IC include the expected duration of the subject's participation (hours/minutes)?	X	
4.9	Does IC provide identity and contact info of investigators?	X	
4.10	Do IC materials advise subjects of their obligation to keep information confidential in focus group discussions?	NA	
4.11	Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type?	X	
4.12	Where data collection differs by method (e.g.: survey, FGD, interview), do IC materials cover each method?	X	
4.13	For child subjects, is there provision for including consent from parent, guardian, caregiver, or responsible person? If not, is this explained and justified ?	NA	
4.14	If IC is written, is a copy left with subjects or there is explanation for not doing so?	X	
4.15	Comments, amendments, additions, or revisions	X	Note typo on IC: We we are asking your permission to interview you today. Noted, with thanks!
Section 5	Subject Protections: Do submitted materials clearly identify protection against risk?		
5.1	Do materials describe the use of information collected?	X	
5.2	Are subjects given a clear indication of who will have access to their responses and in what form?	X	

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5.3	If children or other vulnerable groups are subjects, do materials clearly describe special considerations or accommodations for their safety or protections?	X	<p>Please clarify.</p> <p>We do not interview children. We interview women belonging to ethnic minorities – we should note that these are minorities at the national level but typically either dominant or not a minority locally.</p> <p>Since these minorities are a large portion of our sample, our survey protocol is designed keeping this in mind. Here are some relevant aspect of it,</p> <ul style="list-style-type: none"> • As far as possible, we carry out interviews using female enumerators who belong to the ethnic minority. Otherwise, we use female enumerators who can speak the minority language/dialect. • We ensure privacy and confidentiality during interviews. • We train enumerators to ask questions in a manner that is sensitive in each language/dialect. • If these women have been victims of gender-based violence, we also help them either report or seek support services.
5.4	If children or other vulnerable groups are subjects, have personnel had experience working with these groups? If not, what specialized instruction will they receive?	X	<p>Please describe</p> <p>The fieldwork supervisors and some enumerators will have experience collecting data from ethnic minorities. Moreover, we are also attempting to have our fieldwork team look like</p>

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			<p>our respondents – we are trying to recruit as many women who are part of the same ethnic minority groups as we can.</p> <p>All enumerators and supervisors will attend 3 weeks of in-depth training prior to the start of data collection which will cover in-depth the survey as well as the fieldwork procedures which will cover how to minimize risks and discomfort for respondents (so covering all of the steps described in 5.3).</p>
5.5	Have personnel collecting data from subjects had ethical training specific to the target group?	X	<p>Please describe</p> <p>Yes, the enumerators who will be collecting data from the study sample will go through a 3-week long training period which will cover all aspects of data collection including the ethical aspects of training collection.</p>
5.6	Are personnel collecting data aware of ethical issues that may arise and their mitigation strategies?	X	<p>Please describe</p> <p>Yes, as we note above, the enumerators who will be collecting data will be exposed to training which covers the ethics of data collection.</p> <p>The fieldwork supervisors are typically people with prior experience of this type of work who have worked with both the target population and with the types of sensitive questions that will be included in this survey.</p>
5.7	Comments, amendments, additions, or revisions	X	
Section 6	Subject Risks: Are risks reasonable in relation to any benefits to subjects and to the importance of knowledge that may be expected to result from the research?		
6.1	Do study objectives show that risk is reasonable in	X	

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	relationship to expected gains?		
6.2	Does study deliver potential benefits to subjects through provision of information or services?	X	
6.3	In event of physical, psychological, social, or legal risk, do protocols describe and outline clear strategies to mitigate against these risks?	X	<p><i>You state: "The main driver of the risk on this study is the fact that we are collecting data on exposure to gender- based violence in the endline. Answering these questions in the presence of their spouse or other family members can increase the risk that our research subjects face, including a risk of violence. Our protocol tries to guarantee that this is an outcome that does not materialize. It calls for interviewers to suspend the interview if they cannot guarantee complete privacy during this module. To increase the likelihood that interviews actually take place, we are designing activities to occupy the husbands of the women while the women are being interviewed."</i></p> <p>This is indeed the main driver of risk in this study.</p> <p>What are the activities designed to occupy the husbands?</p> <p>What if husbands say no?</p> <p>What if husbands find out what their wives were doing and this places the wives at risk?</p> <p>Since the original submission, we have changed our approach. We tested two approaches to separate husbands from their wives – to invite husbands to a group meeting with the village head and to interview women outside of their household in common areas like temples or schools. We found that neither approach worked as well as we would like in practice.</p>

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			<p>Therefore, we have now decided to switch approaches and use Audio Computer-Assisted Self-Interviews (ACASI) instead. For the sensitive questions on the incidence of gender-based violence, enumerators will turn over the tablets to the women to complete the survey on their own. They will have earphones and the questions will be played as audio recordings. The response options are displayed on the screen but are non-revealing – they are shapes and colors (corresponding to yes/no or often/sometime/never options that the respondent will be told via audio and tested on prior to the start of the section).</p> <p>The ACASI section will also start with a few test questions that are meant to make the respondent comfortable with the system. If any other household members try to also listen in or take the tablet, enumerators will tell them that it is important that the women answer these questions on their own (and if they are hard to turn away, can show them the test questions to satisfy their curiosity).</p> <p>If they are impossible to turn away, then we may need to avoid asking these questions but based on our experience in the pilot (asking non-sensitive questions) and of the data collection firm in the field, we believe that the number of such cases will be very low.</p> <p>Husbands may still find out about the GbV module – for instance, though the approach ensures privacy from other household members, women themselves may reveal that they were asked questions about GbV after the interview and this information may become public later on. We plan to tell the women about the domestic 1362 violence hotline provided by the Women's Union that is meant to help</p>
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			women who have experienced violence both report and receive counselling help in case of domestic violence.
6.4	If a subject discloses or is suspected to be at risk outside of the study, are procedures in place to address or report risk?	X	<p>You state this is “NA” in your request. However, this does seem like a concern to us. What will you do if a subject reports violence or some other risk? Will you report this to local authorities?</p> <p>This is a great point and we agree. We will to inform the women of how to (i) report these incidents and (ii) seek help for them.</p> <p>We looked into the different available options and for our study sample in rural Laos, we believe that the best option is the domestic violence hotline maintained by the Laos Women’s Union. This service helps women both report violence and get support including counselling services.</p> <p>This will apply to risks arising from the study and risks arising outside of the study. We have added this to our field plan.</p>
6.5	Comments, amendments, additions, or revisions	X	
Section 7	Data Protection: Do data collection and storage protocols adequately ensure subject & data safety?		
7.1	Are data collection tools appropriate and constructed to assure subject privacy, confidentiality, or anonymity?	X	
7.2	Do data collection procedures and environment ensure subject safety and data security?	X	<p>You state that data will be collected in view of others. What will happen if the others inform the husbands of subjects?</p> <p>As we note above, though the data will be collected in view of other members of the households, the sensitive sections of the interviews will now be administered using ACASI, which means that other members of the household will not be able</p>

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			<p>to hear the questions that the women are answering. Enumerators will be on hand to explain that it is important that women answer this section by themselves and with privacy (See section 6.3 for more).</p> <p>For the other questions (not related to gender-based violence), the risks associated with being overheard are lower and relate to the general risks of data collection. We take the usual steps of separating and securing storing and transferring any personally identifiable information and keeping this information strictly confidential to the research team.</p>
7.3	Do procedures cover all data types (e.g., written, audio, video, observation), & are protections described for each type?	X	
7.4	Is chain of custody of data, from collection, transfer, analysis, de-identification, storage, to destruction, clearly described?	X	
7.5	Is future contact with subjects, if any, planned in a way that ensures data security?	X	
7.6	Comments, amendments, additions, or revisions	X	

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