



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

Project Title:	<i>Impact of the Philippines Conditional Cash Transfer Program on Empowerment and Gender Based Violence: Understanding Mechanisms and Measurement</i>
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Primary study site(s):	<p>Philippines (spread across 18 provinces) Names of provinces provided in research design document</p>
Participation of Human Subjects From – to dates	September 2019-January 2020
Funding Source:	<p>The World Bank Group, through Umbrella Facility for Gender Equality</p> <p>The Umbrella Facility for Gender Equality (UFGE) is a multi-donor trust fund dedicated to strengthening awareness, knowledge, and capacity for gender-informed policy-making. It invests in priority areas critical to closing gaps between what we know and what we do to advance gender equality. The UFGE is closely aligned with the World Bank Group's strategy for gender equality and regional priorities and currently supports more than 150 activities in more than 80 countries. The UFGE supports World Bank and IFC projects and is managed by the World Bank's Gender & Development Group. Since its launch in 2012, the UFGE has received generous contributions from Australia, Bill and Melinda Gates Foundation, Canada, Denmark, Finland, Germany, Iceland, Latvia, Netherlands, Norway, Spain, Sweden, Switzerland, United Kingdom, and the United States.</p>
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→ **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.

	Ethics Review Board Criteria of Interest	IRB OK	Reviewer Comments or Requests for More Information
Section 1	<i>Research Risk:</i> 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	
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	<p>In an email you asked: <i>"do you think asking questions on GBV from randomly selected subjects could qualify as 'minimal risk'. We have also mentioned that in case we come across any disclosure or suspect infliction of GBV, we will be required to report the same to the local authorities and will provide the subject referral services to seek help, if she desires so. Based on your thoughts, we will tweak section IV of the form."</i></p> <p>We see many surveys that deal with GBV, and while this population may be at greater risk than the general public, as long as their confidentiality is assured and they are given the</p>

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			chance to affirm informed consent, we feel that their contribution to knowledge justifies study. Okay, thank you
1.4	If there is potential for greater than minimal risk, are mitigating procedures described?	X	
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	
2.3	Does study involve an intervention or treatment group? Received Tx	X	Information provided in research design document
2.4	Does study involve a comparison or control group? Did not receive Tx	X	Information provided in research design document
2.5	Type of data collection: a. survey questionnaire.....X b. subject interview.....X c. key informant interview (KII)..... d. focus group discussion (FGD)..... e. document review..... f. on-site observation..... g. case study..... h. physical measurements i. biological specimen j. other.....	X	Please provide your survey(s). 4 survey instruments attached 1. Tracking questionnaire 2. Household questionnaire 3. Individual questionnaire 4. List randomization questionnaire
2.6	Number of Data Collections: a. one-time (no follow-up).....X b. two or more (follow-up)	X	
2.7	Sample size: Total <i>n</i> or approximate <i>n</i> =	X	Updated sample size: 2,700 individuals in 1,350 households

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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 recordedX d. no PII is recorded e. subjects are given a unique identifier.....X	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?		<p>In an email you asked: <i>"in our third research component (RC3), we cannot tell the subjects that we will ask them questions on GBV exposure as that may influence their response and defeat the purpose of this research component, i.e. to examine under-reporting of GBV. Please suggest if you think we can apply for a waiver or alteration of the informed consent (omitting the parts on GBV) only for RC3, based on federal regulations 46.116(f). We can provide adequate de-briefing on this after the survey is completed, if required."</i></p> <p>We will okay this as long as you provide the de-briefing.</p> <p>We changed the research design and are including list randomization questions in the women's questionnaire, before asking GBV questions. Thus, all the participants will complete informed consent forms.</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	

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3.6	If subjects are children, do materials adequately describe ages and why these ages are appropriate?	NA	
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	<p>Victims of GBV are clearly a group with potential vulnerabilities. Please explain a little further how they will be recruited in light of these vulnerabilities.</p> <p>The study does not specifically target GBV survivors. It will interview women respondents, some of who could be GBV survivors. In cases of GBV disclosure and if the respondent desires to seek help, adequate referral information for counseling or legal support (as the case may be) will be provided by the enumerator.</p> <p>Informed consent of all participants is essential to our project. We will follow the WHO guidelines, who advises subject during initial consent that “some of the topics discussed may be personal and difficult to talk about” but wait until the GBV module to specifically state that violence will be discussed (Ellsberg and Heise, 2005).</p>
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?	NA	
3.11	Comments, amendments, additions, or revisions	X	

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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 & signedX b. written not signed c. verbal & signed d. verbal not signed 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	
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	

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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	<p>There appears to be a typo on the IC here: 4. The I data shall be stored for a maximum of three years from the data of completion of data collection before being permanently deleted from the system. []</p> <p>Thank you! This has been corrected</p>
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	
5.3	If children or other vulnerable groups are subjects, do materials clearly describe special considerations or accommodations for their safety or protections?	X	
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>Will enumerators receive training to work with GBV victims?</p> <p>All surveyors will be carefully trained by Innovations for Poverty Action (IPA). This organization, apart from its long experience managing outstanding research projects in the social sciences, has taken an active role in the study of GBV and successfully managed studies on the topic. More recently, IPA conducted fieldwork on Intra-Partner Violence in Mexico,</p>

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			Côte d'Ivoire (Gupta et al., 2013) and Uganda (Green D., 2019), and Peru (Field et al., 2019).
5.5	Have personnel collecting data from subjects had ethical training specific to the target group?	X	Please describe All staff collecting or handling personally identifiable data will be trained in Human Subjects Protocol and required to sign confidentiality agreements. All topics covered during the interview will remain confidential.
5.6	Are personnel collecting data aware of ethical issues that may arise and their mitigation strategies?	X	Please describe Surveyors will be trained to be sensitive to respondents' experiences and recognize signs of distress and take appropriate steps to support and/or terminate the interview if needed.
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 relationship to expected gains?	X	
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	Please describe The strategies to protect human subjects to risks are in adherence to high standards recommended by WHO (2003), Jewkes et al. (2012), Ellsberg and Heise (2005), Ellsberg et al. (2001).

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			<p><u>Voluntary participation</u> Participation in the study is on a voluntary basis. No inducements will be made. Participants must be clear that refusal to participate will not result in any negative consequences.</p> <p><u>Reporting of violence:</u></p> <ul style="list-style-type: none"> - IPA has experience on request local legal advice for sensitive subjects. IPA will ensure all local laws governing reporting of violence of any type. For example, IPA successfully conducted field work of child labor related issues, including sexual exploitation. Moreover, IPA has already successfully conducted surveys modules explicitly aimed to address domestic violence in rural Peru. IPA follows a comprehensive protocol to reduce bias. <p><u>Data confidentiality and individual or household identifiers:</u></p> <ul style="list-style-type: none"> - Household's questionnaire will be administered in the presence of the couple, and Women's questionnaire will be administered to women in absence of their spouses and family members. - Data will be encrypted and kept in encrypted form for storage and transmission and only accessible from password-protected computers. - Personally Identifiable Information (PII) will be separated and encrypted from the rest of the survey as soon as the enumerators upload the survey to the cloud. Furthermore, to distinguish each individual for the analysis, research
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			<p>staff will substitute individual and household level with unique codes.</p> <p><u>Physical safety of informants and researchers</u></p> <ul style="list-style-type: none"> - To enable the respondent to explain the study to others safely, the survey will be framed with a safe name that does not include the word 'violence' and will be introduced at the community and household levels in this manner. We will phrase the interview as "A Study on Women/Men's Health and Life Experiences".
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	
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>Where will data collection take place?</p> <p>Household and women interviews will take place inside the respondent's house. Men interviews could take place either inside respondent's house or workplace</p> <ul style="list-style-type: none"> - Where necessary, locations outside the household where the interview can be conducted in private will be identified (such as in nearby fields or at a local clinic, church or temple).

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			<ul style="list-style-type: none"> - The participant will be free to reschedule (or relocate) the interview to a time (or place) that may be more convenient for him/her. - Interviewers will be trained to terminate or change the subject of discussion if an interview is interrupted by anyone.
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	<p>Please describe</p> <p>Raw data will be collected using tablets and stored in password-protected computers in an encrypted format. All surveyors will be trained in the Human Subjects Protection Protocol and will have active confidentiality agreements. PII will be encrypted throughout the entire data flow process. All data collection devices will be full disk encrypted. We will use AppLock to prevent enumerators from accessing other apps during data collection and enable remote wiping capabilities in case of loss or theft. We will encrypt files stored on laptops and the cloud, and during transmission to and from the cloud. Access to PII will be strictly limited to those members of the research team that are listed on the IRB application as having access to PII (all research staff with access to PII will complete a special IRB-approved training in order to receive the human subjects' certification).</p> <p>Since the study requires tracking individuals and households across the baseline surveys, it is necessary to maintain identifiers until the study is completed. To protect subjects' confidentiality, survey data will be uploaded to a cloud and personally identifiable information separated from the rest of</p>

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			<p>the survey and encrypted. Thus, all identifiers will be removed from the analysis data files and will be substituted with individual and household level unique codes.</p> <p>Once the follow-up surveys are completed in the future, individual identifiers will be deleted from the cloud.</p> <p>The data will not be used for purposes other than research.</p>
7.5	Is future contact with subjects, if any, planned in a way that ensures data security?	NA	
7.6	Comments, amendments, additions, or revisions	X	

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