# Operationalizing the Ethical Review of Global Health Policy and Systems Research: A Proposed Checklist

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**Abstract**: There has been growing consensus to develop relevant guidance to improve the ethical review of global health policy and systems research (HPSR) and address the current absence of formal ethics guidance.

Health policy and systems research (HPSR) is the investigation, evaluation, and/or implementation of healthcare strategies or issues at the institutional or systems-level. HPSR includes, but not limited to, questions of system strengthening, capacity building, policy or strategy implementation and evaluation — including operations, organizational structure, finance, governance, management, and improvement of health systems.[1] HPSR is characteristically different from clinical research in terms of methodology, analysis, approach, definition, and ethical issues.[2] Where clinical research is concerned with studying the efficacy or effectiveness of an intervention, HPSR may be concerned with studying how and why the intervention is delivered and accessed within a health system or at a regional level. HPSR often involves the study of collective effects on a group or sub-group of people — making consent challenging when compared to clinical research which prioritizes the individual. Thus, the uniqueness of HPSR stems from the type of question it aims to address as opposed to a particular methodology.

As a result, research ethics committees (RECs) (e.g., institutional review boards) and review mechanisms may therefore be inappropriate for evaluating HPSR. RECs may overlook important ethical issues or create delays in review processes altogether. These barriers to appropriate and timely review are often related to a lack of experience in appraising HPSR, misclassification of HPSR as clinical research, or the application of imprecise or variable criteria.[3]

Previous studies have highlighted the paucity of HPSR guidance with the apt concern that RECs globally are reviewing this type of research without appropriate considerations.[4] An international HPSR ethics working group of nearly two dozen experts noted that RECs may not be applying appropriate ethical frameworks in the evaluation of HPSR. A scoping survey of several dozen RECs at major public health institutions worldwide also corroborated that RECs are not equipped to appropriately review HPSR.[5] As HPSR grows, especially in low- and middle-income countries (LMICs), addressing the unique ethical concerns of this type of research becomes more of an immediate priority for researchers and RECs alike.[6]

Recently, there has been growing consensus to address the current absence of formal ethics guidelines by developing relevant guidance to improve the ethical review of HPSR.[7] However, guideline development is an iterative and deliberative process that will require involvement from a multitude of stakehold-

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ers internationally — especially from LMICs.[8] In the meantime, it is arguably worthwhile to collate the current guidance and lessons in the form of an initial protocol that takes into account usability and practicality for immediate implementation by RECs while also serving as a starting point from which the iterative process can germinate.

Our group has been engaged in concerted efforts to operationalize the ethical review of HPSR through (1) a series of international workshops and surveys eliciting expert opinion, (2) scoping and systematic reviews, (3) numerous publications, and more recently as (4) contributors to a benchmark report published by the World Health Organization (**Box 1**). We aim to summarize the knowledge on HPSR ethics to date (with a focus on the most salient ethical issues of HPSR in LMICs) in the form of a practical checklist for use by researchers and RECs. In addition, we provide a summary of each component of this inaugural checklist and review it alongside a case study to better elucidate its application.

We aim to summarize the knowledge on HPSR ethics to date (with a focus on the most salient ethical issues of HPSR in LMICs) in the form of a practical checklist for use by researchers and RECs. In addition, we provide a summary of each component of this inaugural checklist and review it alongside a case study to better elucidate its application.

## A Proposed Checklist

We employed a mixed-methodological approach by incorporating a scoping review of the literature, expert opinion in the form of an international REC survey, content analysis of the literature, WHO HPSR ethics report, and relevant workshops (**Box 1**). The checklist aims to address the challenges faced by review committees by incorporating the key features expected of an HPSR guidance tool as outlined by Pratt et al.[9] and Luyckx et al.[10] The proposed checklist is divided into ten categories (**Table 1**) and designed to facilitate discussions between investigators and RECs.[11] Therefore, we propose the checklist be completed by both the REC and investigator independently. Areas of disagreement between the REC and investigator should serve as an opportunity for clarification, revision, and establishment of strong ethical practice. The fixed items (Yes/No/Not Applicable (NA)) should be routinely audited and additional information should be requested at the discretion of reviewers. Each category and respective item is discussed below in brief detail.

### *HPSR Features and Ethical Principles*

In the design of HPSR studies, who will receive the intervention and who will be observed (Category I) should be established early as these units are often different in HPSR and can impact the validity of a study.[12] Next, who will be studied (individuals versus groups) (Category II) and whether they reflect a fair sample of the population — including vulnerable communities (Category III) — are additionally important HPSR features for consideration. The subsequent two features of HPSR — nature of the intervention and

Box 1

**Sources for Proposed Checklist**

1. Seminal scoping and systematic reviews of the literature aimed at capturing relevant references to ethical issues in HPSR.[67]
   a. Including Pratt et al.'s expansive review, which queried both indexed medical/scientific and gray literature databases until 2015.[68]
2. Our own search via PubMed/MEDLINE for HPSR literature published between January 1, 2015 and April 1, 2019. Articles were included if HPSR ethical issues were discussed in general or specific to methodology or study design, REC evaluation, challenges encountered by RECs or researchers, or application of legal or ethical frameworks.
3. Discussions at a two-day international workshop convened in Baltimore, Maryland (USA) in June 2013 to specifically discuss and analyze ethical issues pertinent to health systems research, especially in LMICs.[69]
   a. This was published in the December 2016 special issue of the journal *Developing World Bioethics*.[70]
4. An international survey sent to public health institutions and associated institutional ethics and scientific regulatory review boards.[71]
5. The World Health Organization's "Ethical Considerations for Health Policy and Systems Research" report published in 2019.[72]



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features of comparison groups — are combined into one category (Category IV) and should be considered alongside Category I to assess study validity. While community engagement is listed as Category V, it is an important aspect of HPSR and should also be established early in the study design process. Concerted community engagement efforts can help inform other checklist categories related to acceptability of benefits and risks, informed consent mechanisms, respect for persons/communities, responsiveness, and post-study features.[13] Where appropriate, community engagement can inform study validity concerns as well.

Benefits and risks (Categories VI and VII) can take on special forms in HPSR which are articulated in more detail under their respective sub-sections. The social value or responsiveness of a study is an important part of the global justice commitment of HPSR (Category VIII).[14] Appropriate responsiveness follows from transformative community engagement that aims to understand and respond to the needs of the community and provide meaningful social value.[15] Finally, what is owed to the host community both immediately and over time are important post-study considerations that should be outlined and discussed before the start of the study and after its completion. These items are respectively captured in Categories IX and X.[16]

We contextualize each checklist category below in terms of the larger ethical principles and HPSR features. Because of the nuances and complexity, some categories are informed by more than one principle which is then expounded upon in detail. In brief, each category can be traced back to the larger ethical principles of autonomy, beneficence, non-maleficence, and justice.[17] The ethical principle of autonomy, which is often understood as respect for the dignity and decision-making capacity of individual persons, is expanded to include a respect for groups, communities, and populations. This respect informs the checklist items on defining types of subjects, informed consent, fair subject selection, community engagement, and dissemination. The principle of beneficence in turn informs the checklist items pertaining to benefits assessment, responsiveness, dissemination, and research translation and sustainability. The concept of reducing harm or non-maleficence serves as the basis for the checklist items pertaining to informed consent, fair subject selection, standard of care, and risk assessment. Finally, justice as fairness is understood in terms of global justice — which demands that global health research promote health equity and improve the well-being of the worst-off.[18] All HPSR should aim to decolonize global health and alleviate existing health inequities. Global justice informs the basis of the checklist categories on defining types of subjects, fair subject selection, standard of care, community engagement, responsiveness, dissemination, research translation and sustainability.

## Checklist Categories

*I. Types of Subjects*

In contrast to clinical research where the target of an intervention is often an individual person, HPSR oftentimes involve groups or clusters of individuals. The unit of intervention may also be different from the unit(s) of observation or data collection — a departure from clinical research where the unit of intervention and observation are identical.[19] As such, defining who is the subject has proven to be challenging.[20] For example, in attempting to study student outcomes following a workshop for instructors, the unit of intervention may be teachers while the unit of data collection is student performance. Defining the appropriate unit is not only an important consideration for study validity and analysis, but it determines the consent process and associated downstream ethical requirements for each unit.

Apart from the consent issues the differences in units pose (e.g. who should be consented?), further consideration is required in differentiating direct and indirect research subjects. Direct subjects are defined as those either receiving the intervention or those from whom data is to be collected. These units are directly impacted by the research and follow from the objective of the study. The Ottawa Statement offers guidance in helping researchers identify who constitutes as an individual human subject in research:

> A research participant can be identified as an individual whose interests may be affected as a result of study interventions or data collection procedures, that is, an individual (1) who is the intended recipient of an experimental (or control) intervention; or (2) who is the direct target of an experimental (or control) manipulation of his/her environment; or (3) with whom an investigator interacts for the purpose of collecting data about that individual; or (4) about whom an investigator obtains identifiable private information for the purpose of collecting data about that individual. Unless one or more of these criteria is met, an individual is not a research participant.[21]

If the final point of delivery is a single subject, investigators are required to follow human subjects protections guidelines as outlined by the Ottawa Statement.

Indirect subjects, on the other hand, are those affected as consequence of the research. These are subjects who may exist on the periphery of the study.



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They can include a vast diversity of entities and as a result are more challenging to identify. It is important for researchers to consider the ways in which their study may extend beyond direct subjects and may have implications or render consequences beyond those who are immediately identifiable.

*II. Informed Consent*

Issues related to informed consent and respect for persons are quintessential to all ethical considerations. In HPSR study designs, consenting individuals may not be feasible. For example, in a program designed to study a new trauma triaging system involving patients, first responders, hospital staff, etc. — consent requirements are less clear. As such, individual representatives of a community may serve as a proxy for consent. The principles of respecting the dignity and autonomy of human beings must still be upheld even if it is extended to a respect for groups. To this end, our checklist asks researchers to further define the unit of intervention being tested — individual versus group/population. By "tested," we specifically mean both the units of intervention and data collection. It is possible for the unit of intervention to be individuals while the unit of data collection to be population-level or vice versa. In such scenarios where the units differ in terms of individual and group, the researcher should aim to answer questions 2 and 3 in this section respectively.

The second series of questions take established clinical research ethics principles and extend their application to groups/populations. In studies where individual consent is to be waived, all the outlined conditions in Item 2a must be met. However, consent may be meaningless in situations where it is difficult to avoid exposure to a study arm. In these circumstances a waiver of consent may still necessitate that the research population be informed of research being conducted along with details about the protocol and waiver of consent justification must also be provided in relevant situations.[22] As we discuss below, respect for persons must extend to those most vulnerable and marginalized; study information must penetrate to these groups as well. Given literacy or education concerns, mechanisms to inform and opportunities to opt-out must be thoughtfully considered.

In consent situations where gatekeepers are to serve as a proxy for individual community members, one should also be aware of the nature of the gatekeeper in relationship to their authenticity, legitimacy, conflicts of interest, and their degree of connectedness or separation to the study population(s) (e.g., government official, community leader, head of household, hospital administrator). An awareness of power dynamics, dependency, undue influence, or coercion at various gatekeeping levels are necessary for cultivating protections to individual community members. The role of the gatekeeper is also important in community engagement efforts as briefly discussed in Category V.

Given the recent literature on solidarity and global justice in HPSR, it is incumbent on researchers to (1) be aware of sensitive or controversial interventions where great potential for harm is possible and (2) take extra measures to mitigate and minimize this potential.[23] Researchers and review committees should have protocols in place for potential issues of misunderstanding or mistranslations in the consent process.

Assuming the criteria to waive consent is not met, individual consent is often required for anyone directly participating in research and may also be required for indirect participants who may be affected by the outcomes of the study. Acknowledging the potential for complexity in HPSR study designs, consent may need to be tailored for each component where relevant. Finally, as stressed above and in sections below, the voluntariness of the consent process needs to be ensured for vulnerable and marginalized populations given their increased risk for exclusion, exploitation, coercion, or undue influence.

Beyond the scope of this checklist are standard research ethics requirements which must be adhered to for what consent covers and for how long consent is applicable.

*III. Fair Subject Selection*

Implicit in the title of this category is ensuring fairness in who is recruited because this reflects a commitment to the global justice framework of HPSR.[24] HPSR in LMICs present special considerations when defining vulnerable, disadvantaged, and marginalized populations. Poverty and illiteracy often compound vulnerability, especially when it involves previously defined vulnerable communities (e.g., disabled, prisoners, children, etc.).[25] Through community engagement efforts (Category V), researchers can gain a better understanding of who are worst-off and how best to surmount challenges to inclusion and recruitment with guidance form community leaders.[26] In defining how these barriers to recruitment are to be addressed, special precautions to limit harm and risk should also be included.

*IV. Standard of Care*

Standard of care considerations are born out of a commitment to avoiding or reducing harm, especially in LMICs where great variability of care may exist within various levels of a health system. Standard of care concerns are primarily salient in interventional studies



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wherein populations may be subjected to receive care outside the status quo.

The nature of an intervention can be examined as two non-exclusive conditions: (1) deploying a novel intervention, and (2) creating demand for existing services. Novel interventions pose challenges in constrained-resource settings where a greater responsibility is placed on researchers to justify the intervention's need in an already resource-constrained setting due to the possibility of further burdening the current health system. A novel intervention can also consist of increasing demand for existing services which in turn can exacerbate pre-existing fault lines within a health system. In developing new intervention methods, some have raised the issue of limited human resources and whether it is ethical to employ community health workers when this may further weaken existing healthcare systems.[27] Therefore, Item 1 of the checklist asks researchers to define comparators and corresponding interventions to identify what care looks like at various levels of data collection. Depending on the standard of care participants are subjected to, RECs may modify the extent of justification required from researchers to explain the rationale behind the care being received.

Attention should be given to comparison groups affected by a restructuring of the local health system. Groups may be impacted differently based on varying levels of care at various health system levels or locations (e.g., urban versus rural). Thus, a referral mechanism that directs participants to appropriate levels of care must be articulated by researchers. If the intervention arm proves efficacious, what is owed to the control group by researchers versus local ministries of health must also be considered. In more complex study designs, it is possible that one group may be set to receive less than the local de facto standard of care. Clearly, these types of situations place a greater requirement for ethical deliberation to justify providing less then the standard while remaining committed to the larger goals of global justice to improve the health welfare of the worst-off.[28]

Equipoise, as defined here, is true uncertainty between the efficacy or benefit of competing interventions — justifying randomization of groups to either a control (current standard of care) and an experimental group. Defining equipoise can be difficult in situations where standards of care may differ between the national and local level or between two neighboring local communities. Establishing equipoise may be more evident in certain parts of a health system and ambiguous in others.[29] For example, if equipoise exists in terms of delivery method, but not in the quality of health services being offered — to what extent can the nature of the intervention and corresponding conditions of equipoise be evaluated?[30]

When considering new interventions and the conditions for equipoise, researchers should aim to contextualize their proposed study with a concerted effort to identify similar studies and their outcomes. By doing so, this will help elucidate whether clear uncertainty is apparent in achieving equipoise and whether exacerbations to existing health systems are justified.

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*V. Community Engagement*

Community engagement in HPSR is based on an important commitment to relationship-building with host communities and nations that stems from a concerted effort to understand and respond to their health needs.[31] Through thoughtful community engagement efforts, researchers can begin the process of identifying the religious, cultural, socioeconomic, environmental, and political factors at various and phases of research that may be at stake during a systems-wide undertaking. Traditional figures of wisdom, traditional healers, community gatekeepers (see Category II), and authority figures should be respected and appropriately engaged with when HPSR is conducted. Sensitivity and deference should be shown to populations where HPSR may be relatively new or unfamiliar. Given the litany of cultural considerations, the onus of responsibility is placed on researchers to highlight that they have fully considered and offered solutions to potential problems.[32]



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Partnerships can occur at multiple-levels (national, district, local) depending on the nature and design of the study with varying health needs and concerns requiring response. Moreover, different phases of research may require involvement from different communities, gatekeepers, or stakeholders. Researchers must be aware of what may be lost by only engaging partners at a national versus local level or at the stage of study topic selection versus data collection or dissemination, for example.

Equality in the distribution of power to make decisions, object, or modify various aspects of the study must be established between researchers and communities. An absolute requirement of ethical HPSR is the empowering of local researchers and the facilitation of capacity building or strengthening. One suggestion is requiring a local researcher of the host nation to serve as the first or last author of any published work. This suggestion is meant to go beyond a gesture or formality, but to establish the role of the local research in a given project. Researchers should outline expectations and engagement processes toward the development of an agreeable set of principles that empowers host communities and ensures their participation (i.e., memoranda of understanding).

In addition to who is involved in community engagement and who is being represented by stakeholders — especially in efforts to include the voices of vulnerable and marginalized populations — it is important for researchers to outline processes by which dissent or alternative/competing community leaders are incorporated.[33] Moreover, channels of communication must remain transparent and accessible even after the study has been concluded so host countries can raise issues and obtain relevant management assistance.[34]

*VI. Benefits Assessment*

Given the nature of HPSR, benefit assessments (like risks) should include immediate benefits to be seen during the study, as well as post-study benefits as part of global justice goals of what is owed to host communities and nations. This also stems from the larger transformative goal of HPSR—i.e., to improve the health situation of those worst-off.[35] Therefore, our checklist requires researchers to articulate the benefits to the individual (if applicable), group, and system both during and after the study period.[36] Our checklist also provides a list of study benefits that represent the key aspirations of HPSR to actively contribute and ensure the future healthcare and scientific success in LMICs.[37]

*VII. Risk Assessment*

Risk assessment stems from the principle of non maleficence with the primary objective being harm reduction. The protection of vulnerable and marginalized populations is especially prioritized in this category. Researchers need to be aware of how the risks of their study are compounded across domains (i.e., medical, social, economic, psychological, and political) and levels (i.e., individuals, groups, and systems). The compounding of risks is especially increased among vulnerable populations. Researchers are required to ensure their safety, wellbeing, and livelihood by interfacing with communities to identify all possible consequences or implications of their study. For example, one foreseeable unintended consequence that researchers should be aware of is the double role of providers or medical assistants as researchers, which may result in confusion among participants between research and health care. This is particularly salient in LMIC contexts where the research enterprise is not as established or widely familiar as an integrated component of a health system.

In addition to an awareness or understanding of risks, researchers must be prepared to provide clear, and preferably validated, strategies to mitigate and address those risks as they emerge.[38] Longitudinal monitoring mechanisms are equally important in capturing and terminating risks as they emerge in a study's cycle. Monitoring harms should be an important component of HPSR and RECs are best positioned to request regular reports on how risks are monitored, measured, and minimized.

Researchers should further aim to adhere to the principle of proportionality wherein the intended benefits and study goals are commensurate with the anticipated risks.[39] The anticipated risks should be directly associated with the benefits that stand to be gained and not as a by-product or peripheral aspect of the study. The clinical research ethics concept of maximizing benefits and minimizing harms serves as a reminder to researchers that they must concretely assess risk and actively design practical strategies toward risk reduction.[40]

HPSR often involves the use of incentives to promote behaviors of interest. However, the use of incentives creates a unique risk for harm especially in LMICs where the socioeconomic effects of poverty may inappropriately influence participation.[41] Removing incentives may also lead to negative consequences if participant behaviors are reliant on these incentives.[42] Some have also argued whether incentives are autonomy-promoting versus autonomy-reducing, the former refers to incentives that expand a participant's range of opportunities and the latter refers to incen-


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tives that entice participants to undergo risks they would not otherwise.[43] Concern arises when participants are unclear or indifferent towards an incentivized activity. Thus, the nature of incentives should be considered in parallel with their appropriateness in the study design. Our checklist includes points for consideration around incentive use, and where applicable, researchers should provide clear examples and strategies to minimize these risks.

*VIII. Responsiveness*

A central principle of global justice in HPSR is for studies to improve the lives of the worst-off/most vulnerable, which is arguably achieved by understanding and responding to the needs of the host population.[44] Our checklist incorporates this principle by asking researchers at what levels of society does their study respond to: the national, regional, district, and/or local health system(s). It is important for researchers to recognize that local needs, for example, can differ or even contradict national needs. In cases where local or district needs are forgone in favor of national priorities, researchers should provide justification for why both needs could not be addressed, why higher level needs were pursued, and at what cost to the local community. If a study is designed to create demand for existing services, it is important for interventions to address barriers to accessing services and whether supply is adequate to meet the new demand.[45]

*IX. Dissemination*

In the same line of reasoning of defining what is owed to host nations, dissemination of findings to improve systems remains an important post-study consideration.[46] While dissemination is a post-study consideration, it should be anticipated and planned for in advance as part of the study protocol. Researchers must consider a dissemination strategy at various levels to ensure results are communicated to all LMIC stakeholders, gatekeepers, and policymakers in a timely manner. This is important in continuing the commitment to "knowledge translation and exchange" in regions where HPSR takes place.[47] Dissemination represents questions around data ownership, application of research findings, engagement with policymakers and stakeholders toward implementing these findings, and the responsiveness to the research needs of LMICs.[48]

*X. Research Translation and Sustainability*

Considerations for application, translation, and sustainability are important goals of HPSR and is a deliberative process that should begin at the study development stage. To ensure the long-term benefits to host nation health systems, timely engagement with partners, stakeholders, and policymakers is necessary.[49] Outlining such strategies early in the research process is important to ensuring post-study success and implementation of sustainability efforts. These four items are necessary in ensuring that HPSR is implementable if proven efficacious. However, we recognize the variability in HPSR studies and have included an opportunity for researchers to explain why their post-study implementation plan may not meet these requirements.

## Case Study

To better contextualize the application of the checklist, an HPSR case study on conditional cash transfers has been adapted for this purpose (**Box 2** and **Appendix 1**).[50] The case study highlights the value of the checklist in identifying important ethical considerations. A sample checklist to this study (**Appendix 2**) is included as a reference aid for researchers and RECs. The briefness of the example checklist is for deliberative purposes and used herein to represent initiated answers that invites further detail upon interrogation by RECs (as represented either by "etc." or ellipses).

Briefly, the case study represents a cash transfer in the form of vouchers that is awarded once certain conditions are met. The study exhibits one of the classic features of HPSR, i.e., the unit of intervention differing form the unit of observation (Category I). Namely, pregnant women, nursing mothers, and children in beneficiary households are the units receiving the intervention, but data is being collected from local health services. Those receiving the intervention clearly meet the conditions of the Ottawa Statement and thus are consent appropriate. However, the unit of data collection, i.e., the use of health and educational services, represents a larger entity of comparison. The ambiguity around "who" or "what" is the unit of data collection may also hint at the difficulties in identifying the indirect subjects that may be impacted by the study. These indirect subjects may include, but not limited to, those providing the health services or those standing to benefit from the allotment of resources to health teams.

While the units of intervention may be required to give consent, it is likely that the unit of data collection may qualify for a waiver. In which case, Category II will need to be completed for both the unit of intervention and the unit of data collection. As is noted in item 3d, each of the four study arms will require a detailed consent process and assurance that the units of intervention and data collection either meet waiver criteria or require consent. This study also focused on municipalities with the highest prevalence of malnu-


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trition and substantial illiteracy, and thus it is assumed the researchers were cognizant about including vulnerable and marginalized populations (Category III). As such, RECs may request more information about the barriers to recruitment and an explanation for addressing these barriers in addition to what was provided as an example in the sample checklist. Additional questions about risk and harms related to the inclusion of pregnant women and children from multiple municipalities should be detailed in Category VII along with the ways in which minimal administrative autonomy, inferior infrastructure, and high illiteracy rates may compound risk.

This design is similar to a case-control study, but with several comparison groups and one control representing the local de facto standard of care (Category IV). It is assumed that the cash transfers are to incentivize the use of the Honduran de jure health services. RECs may require further justification if less than de jure services are to be rendered. Moreover, the study must have social value and be responsive to local priorities (as will be further explored in Category VIII). In responding to the needs of a community, researchers must highlight how their current study is based on precedent and/or expands upon previous work. In this example, RECs will need to further interrogate the uncertainty in this study to establish clear grounds for equipoise for this study to proceed. Given that this case study is an expansion of a previously conducted study, the details of the first study may need to be provided at the discretion of the REC.

In this case study we have assumed that the researchers employed rigorous community engagement efforts rooted in solidarity (Category V).[51] At a minimum, researchers must have engaged with Honduran health officials both at the municipality and national level to execute this study. The interests of the funders or international partners must not supersede that of the host community. RECs must also ensure that the women heads of household are engaged in the process — with gatekeepers possessing the power to interrogate each phase of research as appropriate. RECs may wish to request more information for any of the items to learn how researchers plan to execute each fixed item (Yes/No/NA). The absence of secondary questions soliciting explanation does not preclude RECs from further requesting additional explanation.

Box 2

**Brief Summary of an HPSR Case Study on Conditional Transfers** (see Appendix 1 for additional detail)

**Background**

- Direct payments have been used in some poor households in LMICs to promote demand for maternal and child health interventions or services.
- In one such case, the Honduran government created a program requiring pregnant women, nursing mothers, and children in beneficiary households to make regular visits to health centers in exchange for freely exchangeable monetary vouchers for cash or health care services.
- The program expanded to increase the household incentive by making its receipt contingent upon beneficiary mothers using more health services.
- Several entities from high-income countries decided to formally compare which form of resource transfer resulted in higher use of health services: maternal-child vouchers or allotting service resources to local health teams.

**Methods & Study Design**

- Municipalities with the highest prevalence of malnutrition (1/3 of whom were illiterate) were enrolled and randomly assigned to one of four groups: (1) household-level package alone, (2) service-level package alone, (3) both packages, and (4) standard services (control group).
- Beneficiaries of the household-level vouchers were informed that their payments would be suspended if they did not keep updated with routine antenatal and well-child preventive health care, or if children did not attend school regularly. Adherence to these requirements was not strongly enforced.
- The service-level package was aimed at strengthening peripheral health services.
- Evaluation surveys asking about use of health services (primary outcome) and convergence of interventions (secondary outcome) were undertaken at baseline and 2 years later in a representative sample of all households in each municipality.
- Reports were supplemented with data from children's health cards and government service utilization data.
- Analysis: mixed effects regression accounting for municipality-level randomization.



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This point is applicable across all items within the checklist.

Given the uniqueness of this case study, benefits to both individuals and groups should be accounted for as the example matrix highlights (Category VI). The aim of this study is to increase the use of important services, and thus it is reasonable that this study does not improve research capacity for individuals or strengthen the health system. The latter benefit is arguable, but in our review of this case, it appears that the study is primarily focused on health services and may not be positioned to improve the health system in its entirety. Regardless, RECs may decide to question researchers on their decision-making for determining what is owed to the population as part of the actualized benefits.

A few examples of possible risks across multiple domains and levels have been provided in the sample risk assessment matrix. Items 2 through 6 in Category VII are assumed to be true as they would be important requirements for ethical research. The unique feature of this study that RECs may be interested in auditing further is the use of incentives in a low resource setting, where the potential for harms is increased if these incentives are not autonomy-promoting as aforementioned. The use of vouchers as incentive for utilizing services carries the potential for serious harms on an already vulnerable population. However, the potential for harm does not preclude the study from being conducted. Rather, it requires researchers to be honest in their risk assessment and forthright about minimizing these risks. Similarly, the risks outlined in the matrix may require further explanation by RECs if harm minimization strategies are unclear. We recommend engaging with communities and stakeholders at every level to solicit additional risks and discuss ways to respond to these anticipated risks in total.

It appears that the researchers aimed to respond to the need of improving health and educational services among this population (Category VIII). The important global justice principle behind responsiveness is to improve the health situation of the worst-off and the generation of new knowledge should be directly responsive to this goal. The objectives of this study arguably incorporate these important global justice principles by focusing on a specific vulnerable population. Continuing with the goals of HPSR, dissemination of knowledge at various levels are thus vital for the collective improvement of communities (Category IX). The types of dissemination strategies are assumed here and not articulated in the study itself, and will need to be articulated before the commencement of the study. Finally, the partnership between researcher and host country need to continue beyond the study to ensure appropriate translation of findings, policy guidance, and sustainability long after the study has concluded (Category X). The dissemination, translation, and sustainability efforts are expectations of ethical HPSR and are assumed in this study.

While this case study is an example of one type of HPSR, we have reviewed it in the context of the proposed checklist as a means of informing researchers and reviewers alike of the checklist's application. We have only provided sample answers as a means of initiating additional conversation on how the proposed checklist would have helped had this study been reviewed against HPSR ethics principles.

## Discussion

In this paper we respond to calls for the creation of a checklist for the ethical review of health policy and systems research.[52] This work represents an initial proposal for a practical, "living" checklist aimed to reflect and incorporate important HPSR ethics scholarship to date and serve as a tool to facilitate conversation between researchers and RECs. Given the depth of HPSR scholarship and lack of standardization in the REC review processes of non-clinical studies,[53] this checklist can offer supplement guidance to the review process. We want to reiterate that RECs should frequently solicit additional information from researchers for any checklist item as appropriate. We subsequently agree with other scholars on establishing a deliberative feedback process.[54] We call on HPSR researchers and review bodies to implement and test the checklist and develop a volume of experience to further refine and improve the review of HPSR.

RECs should consider this checklist in the broader context of the challenges for RECs outlined by our group,[55] the WHO,[56] and Luyckx et al.[57] in improving the sophistication by which HPSR is reviewed. Given the complexity and uniqueness of HPSR, the onus of responsibility to design ethically mindful studies should not only fall on researchers alone. The nature of HPSR requires RECs to engage with these issues internally and help educate researchers who may be struggling with the more ethically ambiguous aspects of their study.[58] By having both the investigator and REC compare completed checklists, areas of disagreement become points of ethical discussion. RECs should frequently interrogate and modify the fixed items (Yes/No/NA) as appropriate to obtain additional clarity from investigators.

As noted, this checklist represents a "living document" requiring subsequent iterations as HPSR ethics continues to grow and develop as a field and as committees and researchers alike encounter their respective challenges.[59] For example, the importance of


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gender analysis and intersectionality is an important consideration in HPSR review given disparities in literacy and representation in LMICs.[60] Other debated issues include whether generalizability is possible — or even a necessary component — given the unique context in which some HPSR may be conducted.[61] As the study of the ethics of HPSR evolves, we anticipate that this checklist will be updated accordingly.

We hope to also encourage a more reflexive and deliberative process at the level of both researchers and stakeholders with the goal of fostering a more thoughtful approach to study design prior to REC submission.[62] RECs may find it beneficial to explore these topics at greater length by reviewing the WHO's recent report on the ethics of HPSR,[63] which was largely inspired by important work on which our checklist is based.[64] Furthermore, we recognize that ethical issues can also emerge while studies are in progress.[65] The secondary utility of a checklist is to solicit strategies or reasoning behind certain processes and better prepare researchers to address ethical issues as they arise.

It is important to reduce the variability in the review of HPSR across ethics committees and move toward a more standardized process. In addition to encouraging the presence of health systems researchers on RECs committees,[66] this checklist should be seen as part of the effort to establish a guidance tool for meaningful review.

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## Note

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Table 1

**Proposed Checklist for Ethical Review of Health Policy and Systems Research**

| Ethical Categories | Checklist Items | Yes | No | N/A |
|---|---|---|---|---|
| **I. Types of Subjects** | **1.** Who or what comprises the unit of intervention and who comprises the unit of data collection in the study?<br>Unit(s) of intervention:<br>Unit(s) of data collection: | | | |
| | **2** Where relevant, does each direct subject meet the definition of human subject proposed in the Ottawa Charter? | ☐ | ☐ | ☐ |
| | **3** Identify any indirect subjects that may be impacted by the study and describe how they may be impacted. | | | |
| **II. Informed Consent** | **1a** Does the study test a group-level intervention? (If yes, proceed to Question 2) | ☐ | ☐ | ☐ |
| | **1b** Does the study test an individual-level intervention? (If yes, proceed to Question 3) | ☐ | ☐ | ☐ |
| | **2a** Can individual consent be waived? If consent is to be waived it must fulfill all of the following conditions:<br>○ No more than minimal risk<br>○ Rights/welfare of subjects should not be adversely affected<br>○ Research cannot be carried out in other ways<br>○ Mechanism for debriefing subjects (when appropriate) is in place<br>○ Process for educating community on study goals, risks, benefits, opt-out process, etc.<br>○ Justification for including or excluding vulnerable populations | ☐ | ☐ | ☐ |

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Table 1 (Continued)

**Proposed Checklist for Ethical Review of Health Policy and Systems Research**

| | | | | |
|---|---|---|---|---|
| | **2b** Where consent is waived, has the research population been informed that the study is taking place and has information been made available to them about the study? | ☐ | ☐ | ☐ |
| | **2c** If not, why not? If yes, how has this been done? | | | |
| | **2d** What has been done to ensure the information reaches vulnerable and marginalized groups? | | | |
| | **2e** Where consent is waived, have steps been taken to ensure that individuals, especially members of vulnerable and marginalized groups, have an available means of opting-out? | ☐ | ☐ | ☐ |
| | **2f** Where consent *cannot* be waived, what person or persons constitute as a gatekeeper(s)? | | | |
| | **2g** Do the gatekeepers have legitimate authority that is recognized by the study population? | ☐ | ☐ | ☐ |
| | **2h** Do the gatekeepers have relevant conflicts of interest? | ☐ | ☐ | ☐ |
| | **2i** Have the choices of gatekeepers and the reasons behind them been documented? | ☐ | ☐ | ☐ |
| | **2j** If the study intervention is sensitive or controversial, community consultation may be required in addition to gatekeeper consent. Has community consultation occurred? | ☐ | ☐ | ☐ |



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| | | |
|---|---|---|
| | **3a** Can individual consent be waived? If yes, please fill out 2b and 2c above.<br><br>**3b** Where consent cannot be waived, has individual consent been sought from both direct and indirect research participants (i.e. the unit of intervention and unit of data collection)?<br><br>**3c** Has the consent process been tailored for the different study arms?<br><br>**3d** Does the study have a mechanism for ensuring the voluntariness of participation of members of vulnerable and marginalized groups? | ☐ ☐ ☐<br><br>☐ ☐ ☐<br><br>☐ ☐ ☐<br><br>☐ ☐ ☐ |
| **III. Fair Subject Selection** | **1** Does the intended research population include members of disadvantaged and marginalized groups in the host population?<br><br>**2a** What barriers may prevent these groups from being recruited into the study (e.g. illiteracy, poor health, fear of authorities, cost of travel)?<br><br>**2b** How will study recruitment procedures address these barriers? | ☐ ☐ ☐ |
| **IV. Standard of Care** ***(Intervention studies only)*** | **1** Who is the comparison group and what comparator intervention will they receive?<br><br>**2a** What standard of care will the comparison group receive?<br>• Less than the local de facto standard of care<br>• Local de facto standard (normally accessible care)<br>• Local de jure standard (highest standard of care in the host country)<br>• Other:_____ | ☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐ |

*Continued on page 106*



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Table 1 (Continued)

**Proposed Checklist for Ethical Review of Health Policy and Systems Research**

| | | | | |
|---|---|---|---|---|
| | **2b** What is the justification for offering this standard of care to the comparison group? | | | |
| | **3a** Where else have similar interventions been tested and what was their efficacy? | | | |
| | **3b** Does equipoise exist for the study intervention? | ☐ | ☐ | ☐ |
| | **3c** Why is it unclear whether the intervention will work in the proposed research setting? | | | |
| **V. Community Engagement** | **1a** Has the research team partnered with non-research stakeholders within the host country? If yes, how? | ☐ | ☐ | ☐ |
| | **1b** Identify these stakeholders in the context of the community: | | | |
| | **1c** At what level(s) has community engagement with stakeholders occurred? | | | |
| | • National | ☐ | ☐ | ☐ |
| | • District | ☐ | ☐ | ☐ |
| | • Local | ☐ | ☐ | ☐ |
| | **1d** Has a formal partnership agreement (e.g. Memorandum of Understanding) been developed and signed that is freely agreed upon by all partners? | ☐ | ☐ | ☐ |



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| | | |
|---|---|---|
| | **2a** Will community engagement occur during the following phases of the study?<br>• Selection of research topic and questions<br>• Research design (intervention design, selection of comparators and outcomes)<br>• Data collection<br>• Data analysis<br>• Dissemination and translation<br><br>**2b** If not, what is the justification? | ☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐ |
| | **2c** Will the most disadvantaged and vulnerable within the community be engaged in all these study phases? | ☐ ☐ ☐ |
| | **3a** Did local researchers and other stakeholders share decision-making power over the research topic and questions?<br><br>**3b** Describe the ways local researchers were empowered and capacity was built or strengthened: | ☐ ☐ ☐ |
| | **4** Did members of the research population participate in selecting the research topic and questions?<br><br>**5** What mechanism is in place to reconcile dissenting or alternative opinions?<br><br>**6** How do study members plan on remaining in communication with community leaders after the study? | ☐ ☐ ☐ |

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Table 1 (Continued)

**Proposed Checklist for Ethical Review of Health Policy and Systems Research**

| | | |
|---|---|---|
| **VI. Benefits Assessment** | **1** What benefits will accrue to individual participants, group participants, and health systems during and after the study?<br><br>During the study / After the Study<br>Individual participants<br>Group participants<br>Health system<br><br>**2** Do study benefits include:<br>• Research capacity development for individuals<br>• Research capacity development for institutions<br>• Health system strengthening<br>• Health care and services provision<br>• Health care and services provision that reduces inequalities in access<br>• Infrastructure<br>• Education<br>• Other: _____ | ☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐<br>☐ ☐ ☐ |
| **VII. Risk Assessment** | **1** What are the risks associated with the proposed study for individual participants (unit of intervention and unit of data collection), group participants, and the health systems involved? Consider the risk of harm(s) in the following matrix:<br><br>Medical / Social / Economic / Psychological / Political<br>Individual participants<br>Group participants<br>Health system | |



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| | | | | |
|---|---|---|---|---|
| | **2** Will the risk of these harms be higher for the various marginalized or vulnerable groups within the research population? Which harms and for which groups? | ☐ | ☐ | ☐ |
| | **3** Have possible unintended harmful consequences of the study been identified? | ☐ | ☐ | ☐ |
| | **4** Will strategies be in place to minimize identified risks (including for marginalized or vulnerable groups)? What are the strategies? (RECs may require regular communication about the mitigation of these risks) | ☐ | ☐ | ☐ |
| | **5** Will a monitoring system be in place during the study to capture harms across individual and group participants and the health system during the study? | ☐ | ☐ | ☐ |
| | **6** Do the identified risks stand in reasonable relation to the knowledge to be gained or benefits of the study? If no, explain why. | ☐ | ☐ | ☐ |
| | **7a** If incentives are being offered to study participants as part of the intervention, is there risk of: | | | |
| | a. Compromise to autonomous decision-making in relation to the behavior the incentive addresses | ☐ | ☐ | ☐ |
| | b. Compromise to voluntariness of participation | ☐ | ☐ | ☐ |
| | c. Harms associated with withdrawing behavior-influencing incentives if intervention cannot be sustained after the study? | ☐ | ☐ | ☐ |
| | d. Drain of scarce health resources by implementing the incentive | ☐ | ☐ | ☐ |

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Table 1 (Continued)

**Proposed Checklist for Ethical Review of Health Policy and Systems Research**

| | | | | |
|---|---|---|---|---|
| | e. Creation of patient demand that overburdens the supply side of the health system | ☐ | ☐ | ☐ |
| | **7b** Are strategies in place to minimize the aforementioned risks? | ☐ | ☐ | ☐ |
| **VIII. Responsiveness** | **1a** Are the research topic and questions responsive to identified health system needs? If so, how? | ☐ | ☐ | ☐ |
| | **1b** At what level: | | | |
| | • National | ☐ | ☐ | ☐ |
| | • Regional | ☐ | ☐ | ☐ |
| | • District | ☐ | ☐ | ☐ |
| | • Local | ☐ | ☐ | ☐ |
| | **2** If the research topic and questions are not responsive to district and/or local health system priorities, what is the justification? | | | |
| | **3** Will the study generate new knowledge that will improve the health system for disadvantaged and vulnerable groups? If Yes, how? If No, why? | ☐ | ☐ | ☐ |
| **IX. Dissemination** | **1** Will the research findings be disseminated at the following levels: | | | |
| | • Local | ☐ | ☐ | ☐ |
| | • District | ☐ | ☐ | ☐ |
| | • National | ☐ | ☐ | ☐ |
| | • International | ☐ | ☐ | ☐ |



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| | | |
|---|---|---|
| | **2** List the forms of dissemination<br><br>**3** If dissemination will not occur at local or district levels, what is the justification? | |
| **X. Research Translation and Sustainability** | **1** Have researchers and non-research partners developed a plan for research translation together during the development of the study protocol (e.g. objectives, audiences, and strategies)?<br><br>**2** Does this plan entail engaging with relevant policymakers and other stakeholders with the power to change policy and practice?<br><br>**3** Does the plan entail communicating research findings to policymakers and other stakeholders in a timely manner?<br><br>**4** If the study tests an intervention, does the research translation plan include objectives and strategies for sustaining effective interventions after the study?<br><br>If **No** or **N/A** was answered for any of the above, please provide an explanation below: | ☐ ☐ ☐<br><br>☐ ☐ ☐<br><br>☐ ☐ ☐<br><br>☐ ☐ ☐ |


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Appendix 1

## Detailed Summary of an HPSR Case Study on Conditional Transfers

Although effective maternal and child health interventions exist, they do not reach all those who need them. Scaling-up effective preventive interventions in child and maternal health is hindered in many developing countries by various constraints including a lack of demand. In Latin America, some governments have been trying to increase demand for maternal and child health interventions by making direct payments to poor households contingent on them keeping up-to-date with such health services.

The Honduran government's programa de asignación familiar (family allowance programme), for example, was created in 1990 to mitigate the social effects of structural adjustment on the poor in Honduras. Its principal mode of action consists of the periodic distribution of monetary vouchers that are freely exchangeable for cash or certain goods to a variety of vulnerable groups. As part of the initial stage of this program, maternal and child vouchers were distributed to poor households with the requirement that pregnant women, nursing mothers, and children in beneficiary households make regular visits to health centers. Households could either use the vouchers to directly pay for health care at health centers or take the vouchers to a bank to exchange them for cash. The aim of introducing this household-level package (i.e. maternal and child voucher) was to increase use of antenatal and postnatal services by pregnant women and new mothers and to increase the numbers of children accessing health services.

At the end of 1998, the Inter-American Development Bank approved a $45 million USD loan to the family allowance program to implement a second-phase. The design of the second phase increased the value of the household-level package and made receiving it contingent upon mothers in beneficiary households making five pre-natal visits during their pregnancy and attending a post-partum check-up. Children were required to attend nutritional and health check-ups. The Inter-American Development Bank loan also set aside a substantial budget for evaluation of the family allowance program, which, it was specified, would include both a baseline assessment and subsequent evaluation after two years.

To perform the evaluation of the maternal and child voucher component, a research team from the London School of Hygiene and Tropical Medicine, Emory University (USA), and the Food Consumption and Nutrition Division, International Food Policy Research Institute (USA) undertook a program effectiveness trial (randomized at the municipality level) in Honduras to assess this approach (i.e. the household-level package), contrasting it with a direct transfer of resources to local health teams (i.e. a service-level package). The researchers hypothesized that the conditional payments to households would increase use of maternal and child health-care services by these groups by wholly compensating any cost to the user (since the value of the health vouchers was, by design, equal to the market rate for a day's agricultural labor during the coffee harvest).

The second phase of the maternal and child voucher program was implemented and evaluated in 70 municipalities in the west of Honduras, with a total population of 660,000. These municipalities were selected because they had the highest prevalence of malnutrition in the country. They are mountainous and rural, with limited road and health infrastructure, minimal administrative autonomy, and an average land area of about 166 km.$^2$ In mid-2000, there were just 159 health centers in the area, most of them staffed by a sole auxiliary nurse. Nearly a third of the population aged older than 12 years was unable to read and write. The 70 program municipalities were randomly assigned to one of four groups: (1) household-level package alone, (2) service-level package alone, (3) both packages, and (4) standard services (the control group).

The household-level package consisted of monetary vouchers paid to women in households. Each beneficiary household received vouchers worth 55 Lempiras ($3.71 USD according to currency conversion rate in late 2001) per month for each pregnant woman or child younger than 3 years of age in the household, up to a maximum of two. In addition, all households with children between 6 and 12 years of age enrolled in primary school in grades 1–4 received, for each child up to a maximum of three, vouchers worth 80 Lempiras ($5.40 USD) per month, for 10 months of the year. Thus, the total monthly entitlement for a household with at least one young child or pregnant woman could vary from 55 to 350 Lempiras. By way of reference, the monthly value of staple foods (maize and beans) consumed by an average household in the region was 301 Lempiras in the second half of 2000. The vouchers were distributed on three occasions between the baseline and post-intervention surveys. A fourth round of voucher distribution partly coincided with the post-intervention survey. Beneficiaries of the 55 Lempira vouchers were informed that their payments would be suspended if they did not keep up-to-date with routine antenatal and well-child preventive health care, or if children did not attend school regularly. From late 2001, beneficiaries had to deposit a certified, bar-coded attendance slip in an urn on every visit to their local health center to demonstrate they were meeting the requirements for receiving the household package. However, adherence to the requirements was not strongly enforced. No beneficiary was actually suspended for non-compliance.

The service-level package was aimed at strengthening peripheral health services. Quality improvement teams set up at each health center in municipalities allocated to this in-

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Appendix 1 (Continued)

## Detailed Summary of an HPSR Case Study on Conditional Transfers

tervention, and with a wide representation from the local community, were given basic training in quality assurance methods. They produced an annual work plan with a budget ceiling dictated by the program. The median value was 70,733 Lempiras ($4,773 USD) per year. Work plans could include minor structural repairs, as well as the purchase of equipment, materials, and essential drugs, and money to pay lay assistants. The package also included the introduction of a community-based nutrition program for children younger than 2 years in two villages per health center. This intervention, previously implemented and documented in other parts of Honduras, involved the training of lay nutrition promoters. The promoters held monthly meetings in their community at which all young children (younger than 2 years) were weighed and their mothers were individually counselled.

Evaluation surveys of about 5,600 households were undertaken at baseline and roughly 2 years later in a representative sample of all households in each municipality. In each household, pregnant women and mothers of children younger than 3 years old were asked about their use of health services (primary outcome) and coverage of interventions such as immunization and growth monitoring (secondary outcome). Interviews were done in respondents' homes by specially trained fieldworkers employed by an independent data collection company. The same team undertook both surveys. Reports were supplemented with data from children's health cards and government service utilization data. Analysis was by mixed effects regression, accounting for the municipality-level randomization.

**Adapted from:** S.S. Morris, R. Flores, P. Olinto, J. M. Medina, "Monetary Incentives in Primary Health Care and Effects on Use and Coverage of Preventive Health Care Interventions in Rural Honduras: Cluster Randomised Trial," *Lancet* 364 (2004): 2030-2037.



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Appendix 2

## Sample Checklist for Case Study on Conditional Transfers

| Ethical Categories | Checklist Items | Yes | No | N/A |
|---|---|---|---|---|
| **I. Types of Subjects** | **1.** Who or what comprises the unit of intervention and who comprises the unit of data collection in the study?<br>Unit(s) of intervention:<br>pregnant women, nursing mothers, and children in beneficiary households<br><br>Unit(s) of data collection:<br>Use of health services: maternal-child vouchers versus allotting service resources to local health teams; convergence of interventions | | | |
| | **2** Where relevant, does each direct subject meet the definition of human subject proposed in the Ottawa Charter? | X | ☐ | ☐ |
| | **3** Identify any indirect subjects that may be impacted by the study and describe how they may be impacted.<br>Pregnant women, nursing mothers, and children may be impacted if vouchers are suspended. Local health service, teachers, healthcare workers, etc. | | | |
| **II. Informed Consent** | **1a** Does the study test a group-level intervention? (If yes, proceed to Question 2) | ☐ | ☐ | X |
| | **1b** Does the study test an individual-level intervention? (If yes, proceed to Question 3) | X | ☐ | ☐ |
| | **2a** Can individual consent be waived? If consent is to be waived it must fulfill all of the following conditions:<br>○ No more than minimal risk<br>○ Rights/welfare of subjects should not be adversely affected<br>○ Research cannot be carried out in other ways<br>○ Mechanism for debriefing subjects (when appropriate) is in place<br>○ Process for educating community on study goals, risks, benefits, opt-out process, etc.<br>○ Justification for including or excluding vulnerable populations | ☐ | ☐ | X |



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| | | | | |
|---|---|---|---|---|
| | **2b** Where consent is waived, has the research population been informed that the study is taking place and has information been made available to them about the study?<br><br>**2c** If not, why not? If yes, how has this been done?<br>N/A<br><br>**2d** What has been done to ensure the information reaches vulnerable and marginalized groups?<br>Same strategies used in the initial study to distribute information will be employed (will attach appendix) | ☐ | ☐ | ☒ |
| | **2e** Where consent is waived, have steps been taken to ensure that individuals, especially members of vulnerable and marginalized groups, have an available means of opting-out?<br><br>**2f** Where consent *cannot* be waived, what person or persons constitute as a gatekeeper(s)?<br>N/A | ☐ | ☐ | ☒ |
| | **2g** Do the gatekeepers have legitimate authority that is recognized by the study population? | ☐ | ☐ | ☒ |
| | **2h** Do the gatekeepers have relevant conflicts of interest? | ☐ | ☐ | ☒ |
| | **2i** Have the choices of gatekeepers and the reasons behind them been documented? | ☐ | ☐ | ☒ |
| | **2j** If the study intervention is sensitive or controversial, community consultation may be required in addition to gatekeeper consent. Has community consultation occurred? | ☐ | ☐ | ☒ |
| | **3a** Can individual consent be waived? If yes, please fill out 2b and 2c above. | ☐ | ☒ | ☐ |
| | **3b** Where consent cannot be waived, has individual consent been sought from both direct and indirect research participants (i.e. the unit of intervention and unit of data collection)? | ☒ | ☐ | ☐ |

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Appendix 2 (Continued)

**Sample Checklist for Case Study on Conditional Transfers**

| | | |
|---|---|---|
| | **3c** Has the consent process been tailored for the different study arms? | ☒ ☐ ☐ |
| | **3d** Does the study have a mechanism for ensuring the voluntariness of participation of members of vulnerable and marginalized groups? | ☒ ☐ ☐ |
| **III. Fair Subject Selection** | **1** Does the intended research population include members of disadvantaged and marginalized groups in the host population? | ☒ ☐ ☐ |
| | **2a** What barriers may prevent these groups from being recruited into the study<br>Illiteracy, poor health, fear of authorities, fear of losing access to health or school services, cost of travel, etc. | |
| | **2b** How will study recruitment procedures address these barriers?<br>Not strictly enforcing penalties, liaisons and community volunteers to aid participants, travel reimbursements, etc. | |
| **IV. Standard of Care** ***(Intervention studies only)*** | **1** Who is the comparison group and what comparator intervention will they receive?<br>(1) household-level package alone, (2) service-level package alone, (3) both packages, and (4) standard services (the control group) | |
| | **2a** What standard of care will the comparison group receive?<br>• Less than the local de facto standard of care<br>• Local de facto standard (normally accessible care)<br>• Local de jure standard (highest standard of care in the host country)<br>• Other:_____ | ☐ ☐ ☒<br>☐ ☐ ☒<br>☒ ☐ ☐ |
| | **2b** What is the justification for offering this standard of care to the comparison group?<br>To incentivize use of de jure health services in Honduras… | |



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| | | | | |
|---|---|---|---|---|
| | **3a** Where else have similar interventions been tested and what was their efficacy?<br>Honduran government has previously conducted similar study in other municipalities… | | | |
| | **3b** Does equipoise exist for the study intervention? | X | ☐ | ☐ |
| | **3c** Why is it unclear whether the intervention will work in the proposed research setting?<br>Highest prevalence of malnutrition in these particular municipalities and thus may not be receptive to vouchers alone… | | | |
| **V. Community Engagement** | **1a** Has the research team partnered with non-research stakeholders within the host country? If yes, how? | X | ☐ | ☐ |
| | **1b** Identify these stakeholders in the context of the community:<br>Honduran government representative, head of municipality, heads of household, liaison of local health team, local healthcare workers, school administrators, etc. | | | |
| | **1c** At what level(s) has community engagement with stakeholders occurred? | | | |
| | • National | X | ☐ | ☐ |
| | • District | X | ☐ | ☐ |
| | • Local | X | ☐ | ☐ |
| | **1d** Has a formal partnership agreement (e.g. Memorandum of Understanding) been developed and signed that is freely agreed upon by all partners? | X | ☐ | ☐ |
| | **2a** Will community engagement occur during the following phases of the study? | | | |
| | • Selection of research topic and questions | X | ☐ | ☐ |
| | • Research design (intervention design, selection of comparators and outcomes) | X | ☐ | ☐ |
| | • Data collection | X | ☐ | ☐ |
| | • Data analysis | X | ☐ | ☐ |

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Appendix 2 (Continued)

**Sample Checklist for Case Study on Conditional Transfers**

| | | | | |
|---|---|---|---|---|
| | • Dissemination and translation | X | ☐ | ☐ |
| | **2b** If not, what is the justification? N/A | | | |
| | **2c** Will the most disadvantaged and vulnerable within the community be engaged in all these phases? | X | ☐ | ☐ |
| | **3a** Did local researchers and other stakeholders share decision-making power over the research topic and questions? | X | ☐ | ☐ |
| | **3b** Describe the ways local researchers were empowered and capacity was built or strengthened: | | | |
| | **4** Did members of the research population participate in selecting the research topic and questions? | X | ☐ | ☐ |
| | **5** What mechanism is in place to reconcile dissenting or alternative opinions? Regular community meetings, with individual study coordinators available for private meetings. All comments are reviewed and incorporated into study as appropriate… | | | |
| | **6** How do study members plan on remaining in communication with community leaders after the study? Regular meetings, study coordinators/liaisons will be available… | | | |



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**VI. Benefits Assessment**

**1** What benefits will accrue to individual participants, group participants, and health systems during and after the study?

| | During the study | After the Study |
|---|---|---|
| Individual participants | Access to needed services, etc. | Education about outcomes, etc. |
| Group participants | More access points: services, education, infrastructure, etc. | Expansion of efficacious option to all municipalities, etc. |
| Health system | Increased use of health services, etc. | Strengthening of local health services, etc. |

**2** Do study benefits include:

| | | | |
|---|---|---|---|
| • Research capacity development for individuals | ☐ | ☐ | ☒ |
| • Research capacity development for institutions | ☒ | ☐ | ☐ |
| • Health system strengthening | ☐ | ☒ | ☐ |
| • Health care and services provision | ☒ | ☐ | ☐ |
| • Health care and services provision that reduces inequalities in access | ☒ | ☐ | ☐ |
| • Infrastructure | ☒ | ☐ | ☐ |
| • Education | ☒ | ☐ | ☐ |
| • Other: _____ | | | |

**VII. Risk Assessment**

**1** What are the risks associated with the proposed study for individual participants (unit of intervention and unit of data collection), group participants, and the health systems involved? Consider the risk of harm(s) in the following matrix:

| | Medical | Social | Economic | Psychological | Political |
|---|---|---|---|---|---|
| Individual participants | Substandard care depending on comparison group, poor-quality of services, etc. | Relationships between individual households in different comparison groups, etc. | Dependence on vouchers, burden to use services to retain vouchers amidst other priorities, trading of vouchers for currency, etc. | Concerns around child's (or expecting child) education, impact on decision-making, etc. | Use of data by government, etc. |
| Group participants | Excluded municipalities may demand particular services, etc. | Relationships between municipalities, etc. | Need for more teachers or healthcare providers, etc. | Concern for participating in "inferior" study arm, etc. | Exclusion of other municipalities, etc. |
| Health system | Possible diminished need for local health services, overburdening of healthcare providers, etc. | Relationship between government and municipalities, etc. | Increased demand for use of health and educational services, funding expectations overtime by government, etc. | Concerns between outside funders and government, etc. | Data interpretation for policy design, etc. |

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Appendix 2 (Continued)

**Sample Checklist for Case Study on Conditional Transfers**

| | | | | |
|---|---|---|---|---|
| | **2** Will the risk of these harms be higher for the various marginalized or vulnerable groups within the research population? Which harms and for which groups?<br>Neighboring communities might enter the municipality under study and burden health system… | X | ☐ | ☐ |
| | **3** Have possible unintended harmful consequences of the study been identified? | X | ☐ | ☐ |
| | **4** Will strategies be in place to minimize identified risks (including for marginalized or vulnerable groups)? What are the strategies? (RECs may require regular communication about the mitigation of these risks)<br>Adherence not strictly enforced, randomization to avoid perception of favoritism, anonymization of data given to government officials, staffing support provided to healthcare providers, schools, local health teams, etc. | X | ☐ | ☐ |
| | **5** Will a monitoring system be in place during the study to capture harms across individual and group participants and the health system during the study? | X | ☐ | ☐ |
| | **6** Do the identified risks stand in reasonable relation to the knowledge to be gained or benefits of the study? If no, explain why.<br>N/A | X | ☐ | ☐ |
| | **7a** If incentives are being offered to study participants as part of the intervention, is there risk of: | | | |
| | a. Compromise to autonomous decision-making in relation to the behavior the incentive addresses | X | ☐ | ☐ |
| | b. Compromise to voluntariness of participation | X | ☐ | ☐ |
| | c. Harms associated with withdrawing behavior-influencing incentives if intervention cannot be sustained after the study | X | ☐ | ☐ |
| | d. Drain of scarce health resources by implementing the incentive | ☐ | X | ☐ |
| | e. Creation of patient demand that overburdens the supply side of the health system | X | ☐ | ☐ |
| | **7b** Are strategies in place to minimize the aforementioned risks? | X | ☐ | ☐ |



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| | | | | |
|---|---|---|---|---|
| **VIII. Responsiveness** | **1a** Are the research topic and questions responsive to identified health system needs? If so, how?<br>Maternal and child health interventions exist but are underutilized and often don't reach those who would benefit most from these services. This study aims to responds to the problem of access. | | X | ☐ ☐ |
| | **1b** At what level:<br>• National<br>• Regional<br>• District<br>• Local | | X<br>X<br>X<br>X | ☐ ☐<br>☐ ☐<br>☐ ☐<br>☐ ☐ |
| | **2** If the research topic and questions are not responsive to district and/or local health system priorities, what is the justification?<br>N/A | | | |
| | **3** Will the study generate new knowledge that will improve the health system for disadvantaged and vulnerable groups? If Yes, how? If No, why?<br>Study focused on municipalities with highest incidence of malnutrition among pregnant women, nursing women, and children. Understanding how vouchers versus providing resources to center versus both will help shape larger policy… | | X | ☐ ☐ |
| **IX. Dissemination** | **1** Will the research findings be disseminated at the following levels:<br>• Local<br>• District<br>• National<br>• International | | X<br>X<br>X<br>X | ☐ ☐<br>☐ ☐<br>☐ ☐<br>☐ ☐ |
| | **2** List the forms of dissemination<br>Local: community meetings, leaflets for literate populations, etc.<br>District: meeting with district leaders, reports, workshops, etc.<br>National: meeting with national leaders, reports, health policy design, implementation strategies, etc.<br>International: publications, online resources, seminars, funding partners, etc. | | | |

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Appendix 2 (Continued)

**Sample Checklist for Case Study on Conditional Transfers**

| | | | | |
|---|---|---|---|---|
| | **3** If dissemination will not occur at local or district levels, what is the justification?<br>N/A | | | |
| **X. Research Translation and Sustainability** | **1** Have researchers and non-research partners developed a plan for research translation together during the development of the study protocol (e.g. objectives, audiences, and strategies)? | X | ☐ | ☐ |
| | **2** Does this plan entail engaging with relevant policymakers and other stakeholders with the power to change policy and practice? | X | ☐ | ☐ |
| | **3** Does the plan entail communicating research findings to policymakers and other stakeholders in a timely manner? | X | ☐ | ☐ |
| | **4** If the study tests an intervention, does the research translation plan include objectives and strategies for sustaining effective interventions after the study? | | | |
| | If **No** or **N/A** was answered for any of the above, please provide an explanation below:<br>N/A | X | ☐ | ☐ |



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