What do you mean by 'informed consent'?
Household survey ethics in development research

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The ethical conduct of research depends on the informed consent of research participants. Across North America, Institutional Review Boards (IRBs) attempt to guarantee that ethical standards are met and that researchers are familiar with the process of obtaining informed consent. However, incongruities exist across regions, particularly in the developing world. In this paper, we consider informed consent, as practiced by agricultural and applied economists. We examine informed consent material on IRB websites of land grant universities in the United States, as well as at the centers of the CGIAR. We also undertake a survey of researchers at universities to evaluate actual practice of informed consent practices. IRB regulations are clear but heterogeneous, with some universities and CGIAR centers without any ethical review process. Standards often emphasize process, rather than outcome. The lack of IRBs in some contexts and the particulars of the principles employed may fail to protect research participants.

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1. *Introduction*

The ethical conduct of research relies on the informed consent of research participants. As such, much effort goes to ensure informed consent is practiced in survey work. Across North America, Institutional Review Boards (IRB)[1] guarantee that relevant expectations are followed and that researchers are familiar with the process of obtaining informed consent. However, though ethical principles are clearly defined at most institutions in North America, discrepancies exist across countries. These divergences are exacerbated in the developing world. In the field of agricultural and applied economics, Josephson and Michler (2018) identify two limitations to the ethical review of study design and implementation. First is the discrepancy between requirements and practice, meaning that there may be differences in the *de facto* reality of ethical standards practiced and *de jure* stipulations from IRBs. Second is the use of institutional review primarily within Western universities, meaning that a significant number of economists engaged in research have no requirement to obtain ethical approval of new studies. We use these two limitations to frame our investigation. We are interested in the process of informed consent, rather than other procedures which may be required in order to obtain IRB approval.[2] Most economic studies are "exempt[3]" and approval simply requires that research participants are informed of all of their rights as a research subject and consent to participation.

We examine informed consent as required by IRBs and practiced by researchers in North America. We review informed consent material on IRB websites of land grant universities in the United States as well as at the centers of the CGIAR. We find heterogeneity in requirements. Further, not all public universities and few CGIAR centers have IRBs. Because of this finding, we undertake a survey of researchers at universities to evaluate informed consent practices and perspectives of researchers. We find that though regulations are clear, modifications are needed to adapt standard practices to be context appropriate. The lack of IRBs in some contexts and the

[1] Such boards are also known as Research Ethics Boards (REB), Independent Ethics Committees (IEC), or other similar names. We refer to them in this paper as IRBs.

[2] Our purpose is not to review all ethical standards that researchers face in the process of obtaining IRB approval, but instead we seek to highlight recent issues germane to informed consent.

[3] "Exempt" studies may still require IRB review and registration, but these are generally less rigorous than full committee reviews. To qualify, research falls into six federally defined categories (see 45 CFR 46.101(b)), but in all cases exempt research presents low to no risk to subjects.

emphasis on process for those that exist raise questions about whether research participants are adequately protected and if the regulations imposed by IRBs achieve their stated goals.

Informed consent advises research participants of their rights as a research subject. Of these rights, perhaps the most important is that participation is voluntary and that they can withdraw at any time. While the typical standards for obtaining consent are clear, the considerations for researchers are more complicated in contexts outside North America. Populations may be non-written language based, non-literate, or have conceptions of the self that extend beyond an individual making the typical wet signature[4], written consent form inappropriate. Further, enumerators may be in charge of data collection. These individuals may not have training relevant for obtaining informed consent and thus they may not see its value and role in the research process, ultimately limiting or prohibiting its use in practice.

Moreover, there are longstanding issues with different application of IRB standards to vulnerable groups. Women, children, those not in power, and other marginalized research participants have historically faced abuse, mistreatment, and violation of their rights. The most infamous case of this is the Tuskegee Syphilis Study (for more information, see: Brandt, 1978; Corbie-Smith, 1999; Freimuth et al., 2001). Native American populations in the United States historically experienced mistreatment, including the case of the Havasupai Tribe (for more information see: Adolf and Tuttle, 2008; Garrison, 2013). These marginalized peoples are often referred to as "vulnerable populations", indicating some disadvantage of the group, in comparison with the broader population (Caballero, 2002). The freedom and capability of vulnerable individuals to protect themselves from intended or inherent risks may be abbreviated (Shivayogi, 2013). Research participants outside North America have comparable limits on their ability to secure their rights in accordance with regulations from IRBs a continent or more away. Due to these vulnerabilities, diligent attention is needed to ensure that individuals are made aware of their rights and that individuals are secure in their rights.

Following the evolution of thought on this topic, ethical research must not only be the process of meeting codified standards, but also includes consideration potential harms and benefits, equity, and autonomy. Ethical research and informed consent is not just a set of forms, but an ongoing process. The practice must be culturally appropriate and recognize the context, intelligence, and rights of the individuals and groups involved. We attempt to provide a thorough

[4] A wet signature is created when a personally physically marks a document.

discuss on informed consent, but our coverage and the associated ethical considerations is far from exhaustive. We address several sensitive issues and make recommendations for adapting informed consent procedures based on these complications, we do not claim to hold all the answers to the problems discussed, nor do we claim to be the ethical arbiters of the profession or in survey work broadly. The goal of this paper is to engage agricultural and applied economists in a discussion about the ethical considerations, best practices, and procedures of our work.

2. *Background and Status of IRB*

The protection of individuals has long been inherent to scientific, particularly medical, practice. In a training module for graduate preparation on human subject research, the University of Idaho notes several precursors to modern research ethics. The first, the Hippocratic Oath ("first, do no harm" or "*primum, non nocere*") is well known. DeMartino and McCloskey recommend economists adopt a similar philosophy (DeMartino and McCloskey, 2016). Another, perhaps, less well known is a concept expressed by philosopher Immanuel Kant: "act in such a way that you treat humanity, whether in your own person or in the person of any other, always at the same time as an end and never merely as a means to an end" (Kant, 1785).

Following World War II internationally recognized declarations formalized regulations on the conduct of research with human participants. The Nuremberg Code states that "the voluntary consent of the human subject is absolutely essential" in any experiment involving humans. According to the Code, voluntary consent means that "the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements involved as to enable him to make an understanding and enlightened decision" (USGPO 1946-1949: 181-182). The key elements of this definition are both "free choice" and "sufficient knowledge and comprehension." Though the Nuremberg Code is not legally binding it influenced formation of national guidelines, rules and regulations on the conduct of research.

In 1974, the United States Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research following revelations of abuse of humans by the U.S. Public Health Service at Tuskegee University. The Commission

issued the Belmont Report in 1978, which defined the basic principles of the U.S. system of ethical research (Josephson and Michler, 2018). Three core principles were identified: respect for persons, beneficence, and justice (Belmont, 1978). Further, three areas of application of these principles were also given: informed consent, assessment of risks and benefits, and selection of participants (Belmont, 1978).

The Belmont Report does not specify rules for application in economics research, though the profession has adopted many of the rules and regulations, including those related to informed consent. The presence of IRBs at universities ensures the *du jure* application of the ethical principles of the Belmont Report in economics research (Josephson and Michler, 2018). Field guides written to assist economists and social scientists in designing research projects in accordance with review board standards also serve to dictate norms in the profession (e.g. Burgess, 1984; Comstock, 2013; Alderman et al., 2016; Duflo and Banerjee, 2017). Applied economists at universities across Europe and North America typically obtain approval of study design and survey instruments prior to fieldwork.[5] Through the Belmont Report the United States government plays an important role in regulating the treatment of research participants. If an organization receives federal funding of any kind, the Common Rule (Federal Policy for the Protection of Human Subjects, Title 45 of the Code of Federal Regulations, Part 46) stipulates that an IRB approval be obtained before undertaking research.

These Common Rule also stipulates informed consent procedures. This requires that researchers explain any risks of harm associated with participation in a study to those involved. The researcher must also obtain consent from the study participants, after informing them of the risks associated, but before proceeding with research activities. The requirement of a signed consent form may be waived if 1) the only record linking the subject and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality; and/or if 2) the research presents no more than minimal risk of harm to the participants and involves no procedures for which written consent is normally required outside the research context. However, even if the IRB approves a waiver of written documentation,

[5] Research outside North America is not always regulated as it is in the United States.The International Compendium of Human Research Standards (2018) and the Office of Human Protections of the Department of Health and Human Services compile a tabular analysis of 27 social-behavioral research standards from around the world (HHS, n.d.). Internationally, legal status is most often in the form of guidelines rather than regulations, though also appears as law in the cases of the Kyrgyz Republic (for traditional knowledge) and Botswana (for anthropological research).

other accommodations may be required such as an oral statement made at the outset of each interview or a cover letter that includes the essential elements of informed consent, when introducing a web or mail survey.

Informed consent is complicated when a service is provided to an entire community, in the interest of research, thus an individual is not able to opt-out of participation (Hutton, 2001; Glennerster, 2017).[6] This may cause unintended harm and confound the meaning and practice of informed consent. An example of this is demonstrated in a case of medical research undertaken on the Kenyan Coast: Molyneux et al. (2004) reported that parents signed consent for over 4,000 children to be involved in ongoing research each year, ranging from observational studies to testing of new drugs. Additionally, thousands more community members were consented to interviews and sometimes invasive procedures. Despite the review of study design and consent forms by national and international committees, Molyneux et al. (2004) found that the study participants were not appropriately treated. Both conceptual and linguistic barriers were found to exist when communicating about the research. Additionally, fieldworkers and nurses played a complex and critical role during the consent procedure. This is a case of compliance with IRB regulations but a failure to adequately protect subjects.

The problems associated with informed consent and research ethics generally are well documented in the medical profession (see Kegley, 2004; Wicher and Michalek, 2005; Ilfeld, 2006; Rady et al., 2011; Milner and Mangus, 2013, among others), but less is said in the field of applied and agricultural economics. Some of this is due to the nature of the questions at hand: for applied economists, the research questions of interest are generally low risk to participants. Whatever the reason: the conversation in economics and applied economics is nearly silent. We hope that this paper sparks discussion of this important topic in our profession.

3. Method

To gain an understanding of the current status of informed consent practice and policies with agricultural and applied economics profession, we conduct a layered search. We follow the

[6] Examples iterated by Glennerster (2017) include "adding chlorine to the community well, erecting streetlights, modifying the rules under which the mayor is elected, or changing how teachers teach." While typically the community may give assent before proceeding with this type of intervention, it is still possible that individual members of the community do not, or do not feel, they have consented.

issues raised by Josephson and Michler (2018): 1) the discrepancy between regulations and practice and 2) the use of IRBs primarily within Western universities.

To address this first issue of discrepancies between practice and regulation, we conduct a university search. We created a list of universities from the National Institute of Food and Agriculture's list of land grant universities or LGUs (NIFA, n.d.). NIFA has lists of 1862, 1890, and 1994 LGUs. Of these, there are 19 1890 LGUs, 31 1994 LGUs[7], and 50 1862 LGUs, excluding the District of Columbia and the territories of the United States. We exclude our home universities, leaving us with 48 1862 LGUs. From this list of 108 universities, we collect details on their ethical review policies. We screened universities according to whether a search of their main website with the letters "IRB" led to information about the Institutional Review Board and/or research protocols. If an IRB was found, we then searched for informed consent language in the policy documents or on-line tools provided for researchers. Finally, we searched for language about the waiver of informed consent. The information from this search gives us a picture of the expectations for ethical review across universities.

Based on the findings of this search and to investigate how researchers at universities actually practice research ethics in agricultural and applied economics, we distributed a survey. Our target respondent currently has work in the field, somewhere outside of North America. On 9 October 2018, a survey and short message[8] were sent to 283 researchers across the United States.[9] On 18 October 2018, the survey was distributed again, through the listserv of the International Section of AAEA, with the objective of reaching additional researchers who were missed in the initial search process. Ultimately 55 researchers responded to the survey.

The objective of the survey was to learn about the practices of obtaining informed consent, for researchers based in the United States and conducting surveys outside of North America. Methods of research, location of project, and questions of interest were recorded, as well as whether or not a consent form or waiver was used, whether consent was given orally, signed, witnessed, etc., and at what level consent as provided. Additionally, the survey inquired about informed consent value, from the perspective of researchers, and the extent to which

[7] Of these 31, 2 were added in 2014. The original list from 1994 included only 29. We include all 31 universities for completeness.
[8] The survey instrument and email request are included in the Appendix.
[9] Thanks to Leah Palm-Forester who shared a list of researchers at many land grant universities, which provided a starting point for the list we ultimately developed.

researchers perceive that research participants understand their rights, as iterated in informed consent procedures. The information from this survey informs us of the actual practice of ethical research practices within universities.

To consider the second issue, the use of IRB primarily only within Western universities, the next component of our search focused on non-university research institutions, specifically within the 15 CGIAR centers. We collect details on their ethical review policies, per their website. As before, we screened each Center with search of their main website to see if using the terms "IRB", "Research Ethics," or "Protection of Human Subjects" lead to information about the Institutional Review Board or research protocols. We also searched for informed consent language in the policy documents or on-line tools provided for researchers. If possible we searched for language about the informed consent process. The information from this part of our search gives us a picture of the expectations for ethical review outside of universities, within the CGIAR system.

4. Status of Ethical Review Across Academic Institutions in the United States

Results of screening the websites of 1862 LGUs are presented in Table 1. In each of these, with the exceptions of the University of California System, the University of Massachusetts and the University of Nebraska, a search for "IRB" on the homepage yields links or the main page of the university's review process for research involving human participants.[10] IRB offices are named differently across LGUs, and there is a range of electronic systems for researchers to use when submitting proposals. These typically reference the Common Rule in the Code of Federal Regulations, in varying level of detail, and offer examples of informed consent documents. Most refer to federal regulations permitting oral informed consent in specific situations and with prior consent, obviating the use of a signature of the subject or legally-authorized representative. In a number of cases, written policy documents are provided on the websites with varying dates (or undated, as with the University of Connecticut policy of 126 pages) and regularity of updates.

Most IRBs do not provide explicit standards for international work, though the University of Georgia and the University of Illinois at Urbana-Champaign are two exceptions.[11] The

[10] Searching individual universities within the system (e.g. University of California Berkeley) leads to extensive web information.

[11] While other IRBs may also provide similar information, these two were found using our search process described above.

University of Georgia website has a stated policy for research conducted internationally, noting that the UGA IRB has "the responsibility to ensure that research performed in other countries meets equivalent levels of protections that would be required in the University's principal locations (UGA, 2017)." Further, "the research conducted in a foreign country is expected to comply with local laws and have considerations for the cultural context of the potential human subjects research participant. Some local laws may include but are not limited to privacy, genetic testing, and reporting child, elder, or spousal abuse (UGA, 2017)." International research is discussed under the tab of "vulnerable populations" on the University of Illinois website: "procedures normally followed outside the United States for research engaging human subjects may differ. … [as a result of] differences in language, culture, social history, and societal norms (UIUC, n.d.)."

Some IRBs draw attention to the power dynamics inherent with research. Iowa State University indicates researchers need to be aware of any process that includes "power imbalances" between investigators and potential participants, or "undue influence or coercion (Iowa State, 2018)." This is essential to consider, if one pauses to visualize power dynamics of a team of PhD researchers from the United States or Europe, along with national PhD counterparts and local language interpreters or enumerators, in a remote rural village, where literacy rates may remain low. Today, in most geographical areas where social science research has been conducted for many years, local decision-makers are familiar with the research process. However, they may be unfamiliar with the rights of research participants. They may consider their approval sufficient for implementation of an observational survey. Individual consent may be waived informally.

An example of the discrepancy between practice and regulation which may arise in the 1862 LBUs occurred in a recent survey conducted by Michigan State University and the Institut d'Economie Rurale (IER) in Mali. In this survey, enumerators forgot to use the written statement of informed consent. They instead introduced the survey orally to the head of household for approval after obtaining clearance from village officials, including both traditional and government representatives. This is the usual modus operandi for the IER as literacy rates remain low in rural Mali, particularly among older heads of household. However, during the last round of interviews researchers requested that informed consent be obtained with written statements. At this time, women household members were given the opportunity to refuse questions about dietary intake. When given this chance, 27 of them (out of almost 6,000) did not consent.

Though small, this is a deviation from what the team had assumed by not asking for consent within households.

To their credit, most IRBs emphasize requirements very clearly. However, waiver options are not always found quickly on LGU websites. When found, they generally refer to the specific conditions as cited in the Code of Federal Regulations. The IRB websites and procedures of the 1862 LGUs are designed to adhere to and emphasize the regulations from the federal government, in line with ensuring funding compliance. The systems are *pro forma*, intended to adhere to federal guidelines.

Table 2 presents the same type of summary for the 1890 LGUs. In the Historic Black Colleges and Universities (HBCUs), a search of "IRB" on the homepage leads in most cases to a webpage with supporting materials. This was not the case for Kentucky State University, the Southern University System, and West Virginia State University (as of November 24, 2018). Overall, it is more difficult to find detailed information about informed consent and waiver options on these websites. This probably reflects resources available and funding levels from the United States government. However, this is disturbing given the history of ethics violations at some HBCUs.

Available information is often limited. Consider several cases: Tuskegee University has a 22-page manual on the LGU website, dated 2005; South Carolina State University's is seven pages, dated 2008 and their website has an IRB checklist, updated in 2016; Langston University in Oklahoma has a 40-page Policy and Procedures Handbook updated in 2007, and recognizes that waiver for informed consent may be valid in some cases; finally, North Carolina A&T has a 49-page document of Standard Operating Procedures for the LGU's IRB, dated 2013-14, but a search of the document does not reveal language about informed consent or waiver options. Within the 1890 LGUs there is a troubling, though perhaps unsurprising, lack of detailed information about procedures, regulations, and waiver opportunities, within their IRB systems.

The summary for 1994 LGUs is presented in Table 3. There were 29 1994 LGUs, with two added in 2014 (College of Muskogee Nation and Keweenaw Bay Ojibwa Community College). A number of the home pages are not searchable. Even when they are, most when searched with "IRB" do not lead to further review boards. Informed consent may appear when the home page is searched, but not with respect to human participant research. Again, this result undoubtedly reflects resource constraints. However, it does not necessarily reflect the fact that

many of these LGUs offer only two-year programs. Detailed, well-developed IRB websites are found for Fort Peck Community College, Haskell Indian Nations University, Navajo Technical University, Northwest Indian College, and United Tribes Technical College. Aaniiih Nakoda College has a 30-page manual, dated 2013. Additionally, the IRB webpage for Navajo Technical University is easy-to-read and oriented to students, providing a checklist and noting the need for faculty supervision. The United Tribes IRB webpage explains why an IRB is needed and what it does, including links for further information, exempt, expedited, and full-review checklists.

Tribal colleges give particular attention to treatment of the populations which they serve. For example, the Fort Peck website states that, in addition to the three guiding principles of the Belmont Report that "Lead Researchers will respect the culture of the residents of the Fort Peck Reservation when designing and carrying out proposed research (Fort Peck, n.d.)." Stipulations require that all research results be shared with the College, Tribal Council and the Tribal Archives. In addition, "the research project must make available support services for participants, including ceremony and counseling, that may be needed (Fort Peck, n.d.)." Attention is drawn to the special care required if ceremonial protocols are involved. Photographic records are specifically mentioned as requiring IRB approval and consent of participants. Similarly, Northwest Indian College has a specific policy for indigenous research stipulating that research should be grounded in the culture of the Coast Salish. They acknowledge that Tribal College missions are different than mainstream public institutions—founded in order to save lives and to revitalize cultures and languages through tribal education. Thus, research should be to the benefit and enhancement of the community. Since the Tribal Family owns any cultural knowledge, they must control and consent to the way it is shared and also have access to all research results. Informed consent in this case includes sharing all mediums in which the research may be utilized. The Haskell Indian Nations University also has further regulations to ensure that individuals' rights are protected. The IRB page states that "when research is conducted on the Haskell campus, the researcher or principle investigator will need to have a Haskell faculty member involved (Haskell, n.d.)." The information presented on IRBs within the 1994 LGUs reflect the history of these universities and the populations they serve, designed to draw attention to the importance of individual and tribal rights.

Across the LGUs, existence and requirements of IRBs are heterogeneous. The 1862 LGUs largely have easily found IRBs, with clear language about informed consent and waivers.

The 1890 LGUs still have straightforwardly found IRBs for the most part, but lack details about informed consent and waivers. The 1994 LGUs often lack IRBs, but for those that have IRBs, details are clear and easily found. While this heterogeneity likely reflects receipt of funding from the government, it is still surprising and alarming that not all public institutions in the United States have an IRB to support research done at the school and to protect potential research participants associated with the university.

4.1 Practice and Perceptions Within Academic Institutions

Based on these findings, we wanted to better understand how researchers within a university environment perceive and practice ethical research. We asked 283 researchers in agricultural and applied economics to respond to a brief survey. Response rate was about one-fifth, for a total of 55 responses.

4.1.1 Practice

As the sample was of university faculty, the majority of respondents were professors at various ranks. Responses were also received from research directors, emeritus professors, adjunct professors, and postdocs. Respondents were mostly male (two-thirds), with a range of PhD completion dates from 1953 through 2018. Respondents provided specific details as to location and nature of projects, including sampling methods and questions of interest. Of the 48 respondents with projects outside of North America doing primary data collection, just over four-fifths received IRB approval for their project. Of these same 48 researchers, most (37) used a consent form or waiver before initiating data collection; 7 did not. The remaining 4 researchers were waiting for final IRB approval, intending to obtain consent waivers.

Of the researchers who used a consent form, there was a wide variety in type, including oral, signed, witnessed, shared in an information packet distributed to participants, and community consent.[12] Figure 1 shows details on the breakdown of consent type used. The two most reported forms of obtaining informed consent are signed and oral. Signed consent and witnessed consent are the standard method for research with human participants, as they provide a written record and a clear indication of who specifically consented. With these methods,

[12] The signed consent form is perhaps the most familiar, in which details about the participant rights are given on a form which is then signed by the participant. Similarly, with oral consent the same information required in a written consent document is given, but the signing of the consent form has been waived by the IRB. In witnessed consent, details are given, as in an oral consent, but the consent of the research participant is witnessed and recorded by a neutral third party or enumerator.

consent by omission is not possible. But, this fails to acknowledge the challenges associated with informed consent in a developing country. In areas with lower literacy rates or average years of formal education, written consent forms may not be comprehensible and may be daunting. Often, the emphasis on obtaining informed consent is on written documentation, rather than ensuring that research participants understand the research process and their rights within that process.

Other forms of consent observed have their own drawbacks. In our sample, oral consent represents the greater, in number, type of informed consent reported to be in use by researchers. Typically, oral consent is used when it is not feasible to provide participants with an information sheet, with a place for a wet signature. For example, this may be when interviews are contacted via telephone, rather than in person. Giving informed consent orally is relatively commonplace in developing countries, likely to reduce the lengthy process of adhering to signed informed consent and other IRB procedures in these contexts. Similarly, one researcher reports sharing informed consent materials in a packet of information on participation. The form includes all information similar to an informed consent form, but lacks a space for a signature.

Most methods used by researchers in our sample are approved by IRB, but may still fail to fully appraise research participants of their rights. There is likely a middle ground between obtaining only oral consent, which could easily result in type 1 errors, and the complex distribution and translation of informed consent documents. Bhutta (2004) suggests that methods including audio recording of individually provided informed consent or witnessed consent may be appropriate. Such methods of informed consent may be more contextually suitable.

Level of consent is also an essential consideration in the informed consent process. The standard level is for the individual. But, attaining individual consent may be complicated in developing country contexts. The majority, over three-quarters, of consents among our survey respondents were obtained at the individual-level. Consent was also obtained from spouses, parents, small groups, and villages. Breakdowns are shown in Figure 2. Parents gave consent in appropriate circumstances, in surveys involving minors. In these cases, although the research participant is not individually consenting, the person providing authorization is presumed to have the best interests of the research participant in mind (Nicolussi, 2015).

Researchers report in a few cases that consent was either obtained at a higher level of aggregation (group or village) or from a partner, rather than from the individual survey respondent themselves. The former is undertaken in contexts where local chiefs or leaders (both

traditional leaders and government representatives) may provide day to day guidance, research "clearance" and protection of villagers, and where the understanding of the individual may differ from Western or American conceptions. To this latter point, Tindana et al. (2006) observe that individual-based models of consent may be challenging where decision-making does not give emphasis to individual autonomy.[13] In a study by Burton (2002) problems were documented that arose in collecting samples from the population of the South Pacific island of Tonga because of opposition to individual informed consent, which ignored the traditional role of the extended family in decision-making. By contrast, in the Human Genome Diversity Project, the concept of group consent was criticized by indigenous populations because it failed to address social issues within group identity and community rights. While these dynamics pose concerns to which researchers must be attentive, cultural traditions – group based or otherwise – do not preclude the ability to make individual decisions. Rather than leaving decision-making on informed consent to a community level instead individual consent could take a collective process. In this, after sharing the informed consent script, participants would discuss and convene, before returning to individually sign or provide witnessed consent. Such accommodations allow for a collective aspect to what is, characteristically, an individual decision.

The problem with consent given by a local leader is that the ability to consent is taken away from the individual. This persists in another case we observe: when a spouse gives consent for their partner. Generally, having any individual consent on behalf of another adult is not permitted, as the expectation is that individuals will consent on their own behalf.[14] The observance of a partner consenting on behalf of another is common in studies in developing countries, at least anecdotally. Husbands will provide consent for wives who are busy doing household farming or caring for children. In some cultural contexts, a husband may not permit his wife or daughters to be interviewed individually in the absence of a male relative. Cultural norms like this complicate the meaning of informed consent and confidentiality, as the practice removes the ability to consent from the actual research participant.

[13] Tindana et al. (2006) also indicate that non-literate populations may benefit from group consent. However, acknowledging that, in these cases, individually written and signed forms may not be appropriate, witnessed and other forms of individualized informed consent are appropriate. Even if a researcher participant cannot read or lives in a culture that does not include a written language, there are accommodations that can be made.

[14] A notable exception exists when the individual in question is incapacitated.

It is essential to acknowledge the difference in cultural standards between where researchers often come from and the settings in which research is conducted. We do not suggest that researchers obligate the participants in their studies to hold the same views as themselves. But, individual-based must remain at the center of informed consent. Tindana et al. (2006) find that all female respondents in their survey consulted their husband before participating, with differing degrees to which their husband's desires affected their own decisions on participation. The responses ranged from: "…if he says I should go then I will go, but if he refuses, I won't go" to "I make that decision…If I don't want to participate, my husband cannot force me to participate." However, this consultation of a partner is much more appropriate than simply obtaining consent from one partner on behalf of the other. It allows for research participants to provide individual consent, while encouraging discussion between parties. These consultations can allow for both perspectives of individual and group consideration.

To be clear, obtaining communal consent is not inherently a bad idea. Cultural importance in many developing countries lies with a local chief or headman. However, the need for a community manager's approval must be balanced with obtaining consent from other levels of aggregation, including families and individuals. Often, this balance remains uncertain (Bhutta, 2004). Culture is never fixed – it continues to evolve. Increasingly we see more individualism tolerated and encouraged in "traditional" societies. Thus, there must be a place ensuring that for individuals within groups, opting out is feasible.

4.1.2 Perceptions

Recent weight within the IRB process emphasizes the process itself, not the value to researchers. So, to differentiate between practice and perception, at the conclusion of the survey we asked two opinion questions. First, we asked about each researcher's opinion on the value of informed consent. Next, we asked their perception of the extent to which their research participants understood their rights shared via informed consent. In both questions, respondents were asked to rate their perceptions on a scale from 1 (low) to 5 (high). In the case of value generally, the results for this question had a mode of 5, mean of 3.8, and median of 4. The perceived value of informed consent to research participants, by researchers, is slightly different, with a mode of 4, mean of 3.60, and median of 3. While this seems to suggests that researchers place slightly more value on informed consent for themselves, a Wilcox matched-pair signed-rank test reveals that

the two are not significantly different (Prob > |z| = 0.1851). In both cases, value to researchers and understanding of participants is perceived to be high.

5. Status of Ethical Review Within the CGIAR System

In agricultural and applied economics, a great deal of research is done outside the university system, in particular within the CGIAR system. For this reason, it is vital to consider the regulations within the CGIAR to fully understand the practice of informed consent in research. The lack of review boards is particularly acute within the CGIAR system. At this time, only eight of the 15 CGIAR centers require research involving human participants to be cleared by an ethical review board. These institutions include the International Center for Tropical Agriculture (CIAT), the Center for International Forestry Research (CIFOR), the International Maize and Wheat Improvement Center (CIMMYT), the International Food Policy Research Institute (IFPRI), the International Institute for Tropical Agriculture (IITA), the International Livestock Research Institute (ILRI), the International Water Management Institute (IWMI), and WorldFish.

In an examination of the websites for these eight institutions only IFPRI's 2003 document "Principles, Policies and Procedures for the Protection of Human Research Subjects" and CIFOR's 2015 document "Research Ethics Review (RER) Policy and Toolkit" are easily obtained. We did find that ILRI has a research compliance website, with information about the research process with animal and human participants. Table 4 presents relevant information about IRB requirements and status of development.

This is not the first time that IRB status within the CGIAR system has been surveyed. The Stripe Review of the Social Sciences in the CGIAR (Barrett et al. 2009) undertook a review for the Science Council of the CGIAR. The review team found that CGIAR social scientists are often unaware of IRBs and routinely fail to adhere to current international practices for the ethical protection of human participants in data collection. In response to a survey distributed by the review team, only IFPRI and WorldFish had a form of Institutional Review Board to "clear ethical issues as a routine part of project approval." Several Centers reported "alternative procedures" for ethical review in their social science research. Barrett et al. (2009) note that several Centers stated that "this is not an issue," or that they "are not really 'using' human participants in research," or that "researchers are responsible enough to know the level of confidentiality of the data that they are collecting" (Barrett et al. 2009). The Science Council had

commissioned earlier studies that made clear recommendations for the use of IRBS by Centers, but the team found "the ethical review of CGIAR research processes is deficient in many instances" (Barrett et al. 2009).

The Science Council of the CGIAR has continued to push for use of IRBs within the CGIAR in general. Doug Gollin of Oxford University, long-term research partner and advisor to the CGIAR, observes that though individuals working in the CGIARs are not quite in the same role as individuals working in the medical profession, but there are still "…genuine ethical issues associated with introducing new agricultural technologies to people when you don't know how/whether they will work" (Gollin, 2018). He further observes that, within these complex technologies, interventions do not all have decidedly positive impacts: "Indeed, it is rare for a technology to have unambiguous effects; most technologies create losers as well as winners. So the potential for doing harm is real" (Gollin, 2018).

Much of the impetus for IRBs within universities is motivated by regulations and the CGIAR must take similar protections. An IRB process could provide both legal and moral protection so that if a CGIAR developed technology or distributed project causes harm, the institution is able to show that it is not through a failure of oversight or a lack of attempts to minimize risk.

6. Conclusion and Recommendations

In this paper we investigate the process and practice of informed consent. We consider informed consent material on IRB websites of land grant universities in the United States, as well as at the centers of the CGIAR. We also use a survey of researchers at universities to evaluate informed consent practices and perspectives. We find heterogeneity in the presence of IRBs within LGUs in the United States and within the CGIAR centers. Even within the United States, IRBs within HBCUs and Tribal Colleges are lacking. In these areas, where historic mistreatment has taken place, IRBs are weakest. In the sample of researchers we consider, good practices are undertaken. But, this good behavior has limits, as IRB systems often do not exist in CGIAR centers. The lack of IRBs raises questions about whether IRBs are working and whether they are set up to sufficiently protect research participants.

Currently, innovations to IRB are focused on reducing burdens or requirements on researchers, with the objective of decreasing the administrative weight on universities and

decreasing the time between submission of projects and their final approval. However, such innovations fail to address a basic query: is the IRB process working?[15] IRBs and informed consent procedures are largely motivated by the protection of university interests, rather than the protection of participants themselves. This is an acceptable incentive: good can come from impure motives. But, it underscores existing concern for research participants.

IRBs take a deontological approach to ethics requirements: the rules exist prior and we must undertake them for our research to be ethical. This system simply provides a checklist for researchers to go through, rather than a goal of rights and protection to work to ensure. More attention should be given to research participants: how to they perceive the current regulations, how do they perceive the researchers, how do they perceive the outcomes of the research? Though we hope the motives of most researchers are likely ethical, we should turn our attention more closely to the participants. This will give us a better understanding of what is meant, what is understood, and how we can improve in the process of informed consent.

[15] Some debate still remains about the value of IRB regulations themselves. A natural question is whether ex-ante approvals are preferred to ex-post punishment when violations occur. This is beyond the scope of the current paper, however.

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Table 1. IRB, informed consent and waiver options, 1862 Land Grant Universities

Land Grant University	State	Type	Ag Econ Dept	IRB in homepage search	Informed Consent language	Waiver Option
Auburn University	Alabama	1862	1	yes	yes	yes
University of Alaska	Alaska	1862	0	yes	yes	yes
University of Arkansas	Arkansas	1862	1	yes	yes	yes
University of California System	California	1862	1	no		
Colorado State University	Colorado	1862	1	yes	yes	yes
University of Connecticut	Connecticut	1862	1	yes	yes	yes
University of Delaware	Delaware	1862	1	yes	yes	yes
University of Florida	Florida	1862	1	yes	yes	not easily found
University of Georgia	Georgia	1862	1	yes	yes	yes
University of Hawaii	Hawaii	1862	0	yes	yes	yes
University of Idaho	Idaho	1862	1	yes	yes	yes
University of Illinois	Illinois	1862	1	yes	yes	yes
Iowa State University	Iowa	1862	0	yes	yes	yes
Purdue University	Indiana	1862	1	yes	yes	not easily found
Kansas State University	Kansas	1862	1	yes	yes	yes
University of Kentucky	Kentucky	1862	1	yes	yes	yes
Louisiana State University	Louisiana	1862	1	yes	yes	not easily found
University of Maine	Maine	1862	1	yes	yes	yes
University of Maryland	Maryland	1862	1	yes	yes	yes
University of Massachusetts	Massachusetts	1862	1	no		
University of Minnesota	Minnesota	1862	1	yes	yes	yes
Mississippi State University	Mississippi	1862	1	yes	yes	yes
University of Missouri	Missouri	1862	1	yes	yes	yes
Montana State University	Montana	1862	1	yes	yes	yes
University of Nebraska	Nebraska	1862	0	no		
University of Nevada	Nevada	1862	1	yes	yes	yes
University of New Hampshire	New Hampshire	1862	1	yes	yes	not easily found
Rutgers University	New Jersey	1862	1	yes	yes	yes
New Mexico State University	New Mexico	1862	1	yes	yes	yes
Cornell University	New York	1862	1	yes	yes	yes
North Carolina State University	North Carolina	1862	1	yes	yes	yes
North Dakota State University	North Dakota	1862	1	yes	yes	yes
Ohio State University	Ohio	1862	1	yes	yes	yes
Oklahoma State University	Oklahoma	1862	1	yes	yes	yes
Oregon State University	Oregon	1862	1	yes	yes	yes
Pennsylvania State University	Pennsylvania	1862	1	yes	yes	yes
University of Rhode Island	Rhode Island	1862	1	yes	yes	yes
Clemson University	South Carolina	1862	0	yes	yes	not easily found

South Dakota State University	South Dakota	1862	1	yes	inside training materials	
University of Tennessee	Tennessee	1862	1	yes	yes	yes
Texas A&M University	Texas	1862	1	yes	yes	yes
Utah State University	Utah	1862	1	yes	yes	yes
University of Vermont	Vermont	1862	1	yes	yes	yes
Virginia Polytechnic Institute	Virginia	1862	1	yes	yes	yes
Washington State University	Washington	1862	1	yes	yes	yes
West Virginia University	West Virginia	1862	1	yes	yes	yes
University of Wyoming	Wyoming	1862	1	yes	inside training materials	

Source: https://nifa.usda.gov/land-grant-colleges-and-universities-partner-website-directory (accessed September 1, 2018)
Notes: 48 excluding District of Columbia, University of Arizona, Michigan State University, and 14 territories.

Table 2. IRB, informed consent and waiver options, 1890 Land Grant Universities

Land Grant University	State	Type	Ag Econ Dept	IRB in homepage search	Informed Consent language	Waiver Option
Alabama A&M University	Alabama	1890	0	Yes	did not find	did not find
Alcorn State University	Mississippi	1890	1	yes	did not find	
Central State University	Ohio	1890	0	Yes	yes	did not find
Delaware State University	Delaware	1890	0	Yes	yes	did not find
Florida A&M University	Florida	1890	1	Yes	did not find	
Fort Valley State University	Georgia	1890	0	yes	did not find	
Kentucky State University	Kentucky	1890		No		
Langston University	Oklahoma	1890	0	yes	yes	yes
Lincoln University	Missouri	1890	0	Yes	yes	did not find
North Carolina A&T State University	North Carolina	1890	1	Yes	did not find	did not find
Prairie View A&M University	Texas	1890	0	Yes	yes	yes
South Carolina State University	South Carolina	1890	0	Yes	yes	did not find
Southern University System	Louisiana	1890	0	No		
Tennessee State University	Tennessee	1890	1	yes	yes	yes
Tuskegee University	Alabama	1890	1	Yes	yes	yes
University of Arkansas Pine Bluff	Arkansas	1890	0	Yes	did not find	
University of Maryland Eastern Shore	Maryland	1890	0	Yes	yes	yes
Virginia State University	Virginia	1890	1	Yes	yes	did not find
West Virginia State University	West Virginia	1890	0	incomplete	no	no

Source: https://nifa.usda.gov/land-grant-colleges-and-universities-partner-website-directory; http://www.1890universities.org/node/ (accessed September 18, 2018)
Notes: There are 19 1890 land grant universities today out of over 100 Historic Black Colleges and Universities.

Table 3. IRB, informed consent and waiver options, 1994 Land Grant Universities

Land Grant University	State	Type	Ag Econ Dept	IRB in homepage search	Informed Consent language	Waiver Option
Aaniiih Nakoda College	Montana	1994	0	yes	Yes	yes
Bay Mills Community College	Michigan	1994	0	No		
Blackfeet Community College	Montana	1994	0	not searchable		
Chief Dull Knife Community College	Montana	1994	0	No		
College of the Menominee Nation	Wisconsin	1994	0	No		
College of the Muscogee Nation	Oklahoma	1994	0	not searchable		
Dine College	Arizona	1994	0	no		
Fond Du Lac Tribal & Community College	Minnesota	1994	0	no		
Fort Peck Community College	Montana	1994	0	yes	Yes	yes
Haskell Indian Nations University	Kansas	1994	0	yes	Yes	yes
Ilisagvik College	Alaska	1994	0	no		
Institute of American Indian Arts	New Mexico	1994	0	no		
Keweenaw Bay Ojibwa Community College	Michigan	1994	0	not searchable		
Lac Courte Oreilles Ojibwa Community College	Wisconsin	1994	0	no		
Leech Lake Tribal College	Minnesota	1994	0	not searchable		
Little Big Horn College	Montana	1994	0	not searchable		
Little Priest Tribal College	Nebraska	1994	0	no		
Navajo Technical University	New Mexico	1994	0	yes	Yes	yes
Nebraska Indian Community College	Nebraska	1994	0	no		
Northwest Indian College	Washington	1994	0	yes	Yes	yes
Oglala Lakota College	South Dakota	1994	0	not searchable		
Saginaw Chippewa Tribal College	Michigan	1994	0	not searchable		
Salish Kootenai College	Montana	1994	0	no		
Sinte Gleska University	South Dakota	1994	0	no		
Sisseton Wahpeton Community College	South Dakota	1994	0	no		
Sitting Bull College	North Dakota	1994	0	not searchable		
Stone Child College	Montana	1994	0	no		
Tohono O'Odham Community	Arizona	1994	0	no		
Turtle Mountain Community College	North Dakota	1994	0	no		
United Tribes Technical College	North Dakota	1994	0	yes	Yes	yes
White Earth Tribal and Community College	Minnesota	1994	0	no		

Source: https://nifa.usda.gov/land-grant-colleges-and-universities-partner-website-directory (accessed September 1, 2018).
Notes: 29 1994 land-grant colleges, originally, with two added in 2014 (College of Muskogee Nation and Keweenaw Bay Ojibwa Community College).

Table 4. IRB, status of IRB and relevant documentation, CGIAR Centers

Center	Status of IRB	Documentation provided
BIOVERSITY	Rely on partners' or external (e.g. Western Institutional Review Board) IRB processes.	No.
CIAT	Yes.	No.
CIFOR	Yes: Research Ethics Review Committee.	Yes.
CIMMYT	Yes.	No.
CIP	In the process of defining IRB procedures.	No.
ICARDA	No.	No.
ICRAF	No IRB, instead use: Research Ethics Policy.	No.
ICRISAT	No IRB. "All MIP (mostly VDSA staffs) including Field investigators, Scientific Officers and Scientists have taken the test and obtained certification before they conduct HH surveys."	No.
IFPRI	Yes.	Yes.
IITA	Yes.	No.
ILRI	Yes: Institutional Research Ethics Committee.	No.
IRRI	No.	No.
IWMI	Yes.	No.
WORLDFISH	Code of Ethics for Research Involving People updated late 2016 - beginning 2017.	No.

Thanks to Frank Place for sharing information relevant to this table. Status of IRB information as of August 2017. Documentation provided, following search in December 2018.

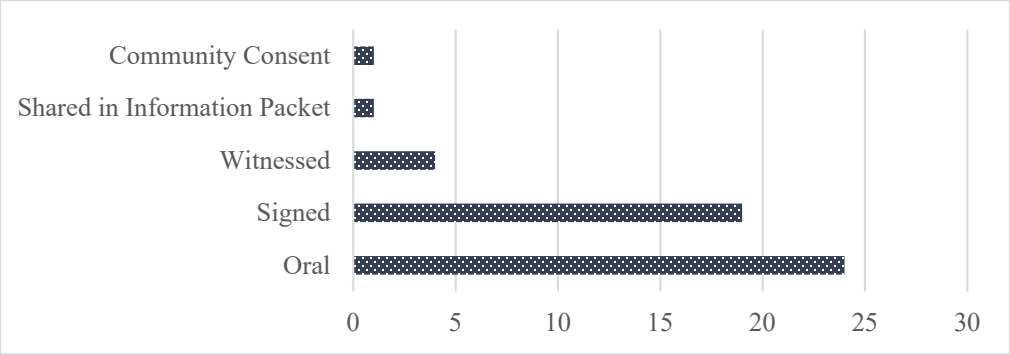


Figure 1: Types of Consent Forms Used

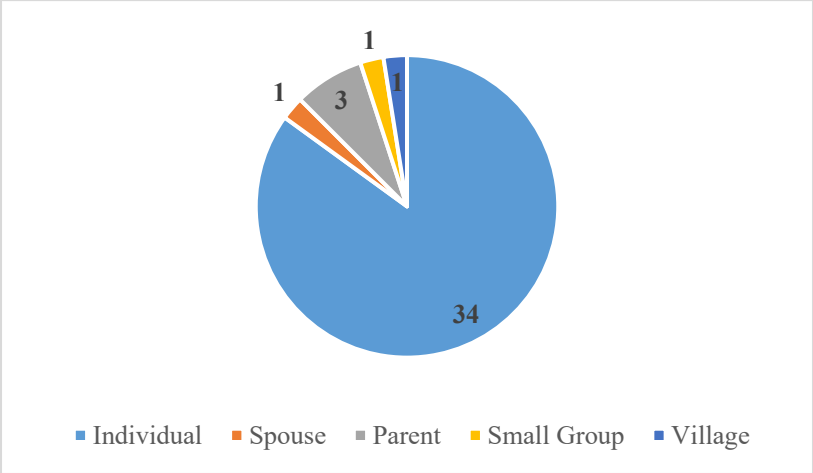
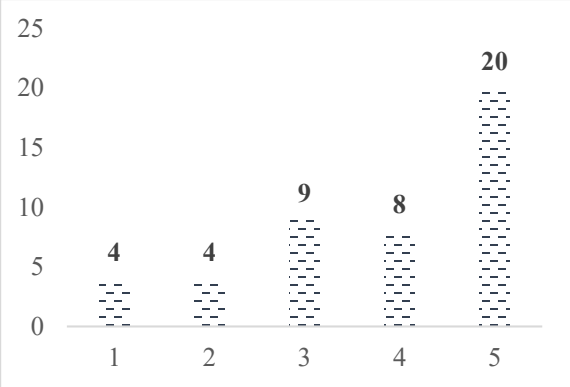


Figure 2: Level of Consent



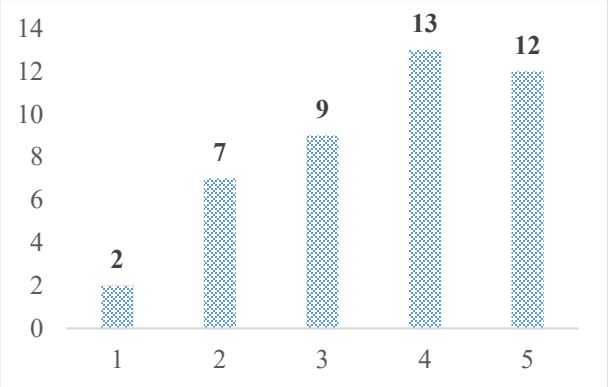


Figure 3: Informed Consent – Value and Understanding
L: Perceived Value of Informed Consent to the Researcher, R: Understanding of Rights by Research Participants

Appendix

A1. Invitation to Survey Email

Dear Researchers,

I am writing to request your participation in a research study on the Status and Role of IRB in Applied Development Economics of faculty at land grant universities, who participate in applied economics research internationally.

The survey is being conducted by Dr. Anna Josephson of the University of Arizona and Dr. Melinda Smale of Michigan State University. The objective is to learn more about the process of IRB in international research, in particular the use of informed consent.

The survey will take no more than five minutes to complete. Some respondents may be asked to participate in a follow-up survey, which, if the respondent is willing to participate, will be no longer than one hour. To participate, please click on the following link:

<LINK TO SURVEY>

Your participation in this survey is completely voluntary and you may opt out of any question in the survey. All of your responses will be kept confidential. They will only be used for statistical purposes and will be reported only in aggregated form. An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

If you have any questions about this survey, or difficulty in accessing the site or completing the survey, please contact Anna Josephson (<EMAIL> or <PHONE>).

Thank you in advance for providing this important feedback.

Sincerely,

A2. Survey Instrument

This research is investigating the use of informed consent in research outside of North America. The purpose of this study is to gain an understanding of the status of the practices of informed consent within the agricultural and applied economics profession. The results of this survey will be presented at the Annual Meeting of the Allied Social Sciences Association in January of 2019. This survey should take you no more than five minutes.

The project has been approved on ethical grounds by the University of Arizona Institutional Review Board, which has indicated that there are no foreseeable risks. Any questions regarding your rights as a participant may be addressed to that committee through the Institutional Review Board <EMAIL> or <PHONE>.

Confidentiality of records will be maintained. Records will be kept on encrypted drives and on Box at U of A, to ensure confidentiality and security. Data will be shared between researchers and thus will be transmitted between Dr. Smale (Michigan State University) and Dr. Josephson (University of Arizona).

In order to complete this survey, you may be required to answer certain questions; however, you are never obligated to respond and you may withdraw from the survey at any time by closing your internet browser. Participation is strictly voluntary.

By selecting to complete this questionnaire, your free and informed consent is implied and indicates that you understand the above conditions to participate in this study.

For more information, please contact: <EMAIL> or <PHONE>.

1. **Email:** (short answer)
2. **What is your organization / university and department?** (short answer)
3. **What is your title?** (mark one)
    a. Assistant Professor
    b. Associate Professor
    c. Professor
    d. Other (short answer)
4. **In what year did you complete your PhD?** (short answer)
5. **With what gender do you identify?** (mark one)
    a. Female
    b. Male
    c. Prefer not to say
    d. Other
6. **Are you currently working on a research project outside of North America? (By current, we mean about to collect data, collecting data, or complete data collection within the last 12 months.)** (short answer)
7. **What is your research question?** (short answer)
8. **In what way are you collecting data (RCT, survey, etc.)?** (short answer)
9. **In what country or countries are you working?** (short answer)
10. **Did you receive IRB/ERB approval for this project?**
    a. Yes
    b. No
11. **Did you use a consent form or waiver before initiating data collection?**
    a. Yes
    b. No
    c. Other (short answer)
12. **If you used a consent form, was it:** (check all that apply)
    a. Oral
    b. Signed
    c. Witnessed
    d. Other (short answer)
13. **Was consent obtained from the:** (mark one)

a. Individual
b. Spouse
c. Parent(s)
d. Small Group
e. Village
f. Other (short answer)

14. How do you perceive the value of informed consent, in the context of your current project? (mark one)

a. 1 (low)
b. 2
c. 3
d. 4
e. 5 (high)

15. When you provide information about informed consent, to what extent do you perceive that respondents understand their rights, as stated? (mark one)

a. 1 (low)
b. 2
c. 3
d. 4
e. 5 (high)