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Featured Article

What Do you Mean by "Informed Consent"? Ethics in Economic Development Research[†]

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Abstract *The ethical conduct of research requires the informed consent and voluntary participation of research participants. Institutional Review Boards (IRBs) work to ensure that these ethical standards are met. However, incongruities in perspective and practice exist across regions. In this article, we focus on informed consent as practiced by agricultural and applied economists, with emphasis on research conducted in low income and/or developing countries. IRB regulations are clear but heterogeneous, emphasizing process rather than outcome. The lack of IRBs and institutional reviews in some contexts and the particulars of the principles employed in others may fail to adequately protect research participants.*

Key words: Development economics, Ethics, Informed consent, Institutional review board.

JEL codes: A11, B41, C83.

Introduction

The ethical conduct of research requires the informed consent and voluntary participation of research participants. As such, much effort goes into ensuring that informed consent is practiced in research, particularly in survey and experimental work (Barrett and Carter 2020). Institutional Review Boards (IRB)[1] guarantee that relevant regulations are followed and that researchers are familiar with the process of obtaining informed consent. However, though ethical principles are clearly defined at most Western institutions, including those in the United States, Canada, Australia, New Zealand, 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 article as IRBs.*

United Kingdom, and across the European Union, discrepancies still exist across countries and regions (Israel 2015). 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: 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, which results in a significant number of economists engaged in human subject research who have no requirement to obtain ethical approval of new studies.

We use these two limitations to motivate and frame this article. We specifically focus on the process of informed consent, as most economic studies are "exempt"[2] and approval requires only that research participants are informed of all of their rights as research subjects and they consent to participation voluntarily. Our purpose is not to review all ethical standards that researchers face in the process of obtaining IRB approval; we instead seek to highlight recent issues germane to informed consent. Specifically, we focus on these topics in an international context, for research in the field in low-income or developing countries. A large amount of applied economics work is conducted in these contexts and there are associated complexities of ensuring ethical treatment of subjects in these environments.

In this article, we explore informed consent as required by IRBs and practiced by researchers in the United States. Although (of course) not all agricultural and applied economics researchers are located in the United States, as Schrag (2010) observes, the standards of research ethics are by and large set in the United States. To this end, we focus on the standards as set by institutions and the government in the United States. We review informed consent material on IRB websites of land grant universities in the United States. To extend this analysis for international development economics work, we also review material at the centers of the CGIAR and other development research organizations. We find heterogeneity in requirements: most, though not all, public universities (though few CGIAR centers) have IRBs. The lack of IRBs in some contexts and, for those that exist, the emphasis on process, raises questions about whether research participants are adequately protected and if the regulations imposed by IRBs achieve their stated goals. To further study this finding, we survey researchers at universities to evaluate informed consent practices of researchers. We find that though regulations are clear, modifications may be needed to adapt standard practices to be appropriate for the context of the work.

The specific regulation and practice of interest in this article is that of informed consent. Informed consent advises research participants of their rights as research participants. Of these rights, perhaps the most important are that participation is voluntary and that the research participant can withdraw at any time. In the United States, the standards for conducting ethical research and obtaining consent are rooted in longstanding issues with different application of IRB standards to vulnerable groups. Historically, women,

[2] *"Exempt" studies still require IRB review and registration, but the process is generally less rigorous than a full committee review. Research falls into six federally defined categories (see 45 CFR 46.101(b)) and in all cases "exempt" research presents low to no risk to subjects. An "exempt" study per these classifications differentiates from studies which are completely outside of the process of IRB review, for example, those which use secondary data. In this article, we are referring only to studies which would go to the IRB for review.*

children, those not in power, and other marginalized research participants have faced abuse, mistreatment, and violation of their rights. A number of specific cases have shaped the relevant regulations and practices. Perhaps the most infamous case is that of the Tuskegee Syphilis Study, in which researchers deliberately did not treat African American men for syphilis, so that they could study the disease's progression. More cases of mistreatment of research participants occur in Native American populations, including the specific case of the Havasupai Tribe.[3] While these cases are largely within the medical discipline, social scientists have also perpetrated mistreatment, including on LGBTQ populations (Humphreys 1970). In all cases, the mistreatment is focused on marginalized groups or individuals. 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). By extension, research participants outside the US have comparable limits on their ability to secure their rights in accordance with regulations from IRBs located a continent or more away. Due to these vulnerabilities, diligent attention is needed to ensure that individuals are made aware of and are secure in their rights.

In addition, there may be further considerations for researchers that may complicate working in contexts in low-income or developing countries. Populations may not be literate, their language may not be written, or they may have conceptions of the self that extend beyond an individual making the typical wet signature.[4] Additionally, the consent process may not be viable if enumerators in charge of data collection do not have training relevant for obtaining informed consent and thus not see its value and role in the research process. Further, it may be the case that researchers are able to "get away with" research in developing countries that would be impermissible in high-income countries in the modern era.[5]

Following the evolution of thought on this topic, ethical research must not only meet codified standards, but should also consider potential harms and benefits, equity, and autonomy. Ethical research is not satisfied by completing forms that can be read and distributed, but is an ongoing process, extending from the genesis of an idea, through data collection and analysis, and through publication itself (Lybbert and Buccola 2020; Michler, Masters, and Josephson 2020). These practices must be culturally appropriate and recognize the rights of the individuals and groups involved.

In this article, we attempt to provide a thorough discussion on informed consent, though our coverage and the associated ethical considerations are far from exhaustive. We address several sensitive issues and make recommendations for adapting informed consent procedures based on these complications, but 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 of survey work broadly. The goal of this article is to engage agricultural and applied

[3]*For more information on the Tuskegee Syphilis Study, see: Brandt (1978), Corbie-Smith (1999), Freimuth et al. (2001). For more information on the case of the Havasupai Tribe, see: Adolf and Tuttle (2008) and Garrison (2013).*

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

[5]*Examples in the medical science literature abound, including Nie (2002), Kelly (2015), Schiebinger (2017). This does not mean to suggest that such experimentation has not occurred in the United States and other high-income countries; see Washington (2006) for more.*

economists in a discussion about the current structure of the IRB system, specifically our use of informed consent and the ethical considerations, best practices, and procedures of our economic development work.

Background and Status of IRB

The protection of individuals has long been inherent to scientific, in particular biomedical, practice. However, such standards were only codified following World War II. At that time, internationally recognized declarations formalized regulations on the conduct of research with human participants. Chief among these is the Nuremberg Code, which 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 1949: pp. 181–182).

The key elements of this definition are both "free choice" and "sufficient knowledge and comprehension." Though the Nuremberg Code was and is not legally binding, it influenced the formation of national guidelines, rules and regulations on the conduct of research. The Helsinki Code, created by the World Medical Association (WMA) in 1964, further codified ethical behavior in biomedical science, building on provisions of the Nuremberg Code (WMA 2018).

In 1974, regulations were formalized and codified in law in the United States. 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 US system of ethical research (Childress, Meslin, and Shaprio 2005; Israel 2015). Three core principles were identified: respect for persons, beneficence, and justice (Belmont 1978). Belmont (1978) also defined three areas of application of these principles: informed consent (respect for persons), assessment of risks and benefits (beneficence), and recruitment and selection of participants (justice).

The Belmont Report does not explicitly specify rules for application in economics research specifically, though the profession has adopted many of the rules and regulations, including those related to informed consent.[6] The presence of IRBs at universities ensures the *de 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 and the increasing use of preanalysis plans in specifying research projects before approval and implementation of research also serve to dictate norms in the profession.[7] Applied economists at universities typically obtain approval of study design and survey instruments prior

[6]*Little consideration for social science, broadly, was given in the forming of the Belmont Report or the standards and practices derived from it. The application to social science and humanities today comes as a result of IRB "mission creep," resulting from regulations associated with the Common Rule (Schrag 2010).*

[7]*Relevant literature includes Burgess (1984), Alderman, Das, and Rao (2013), Duflo and Banerjee (2017), and Barrett, Cason, and Lentz (2020), Janzen and Michler (2020), among others.*

to fieldwork. 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 involving human subjects.

The Common Rule likewise effectively enforces the practices and standards associated with 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 under particular conditions, e.g., if 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 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, other accommodations may be stipulated. For example, an oral statement may be required at the outset of each interview or a cover letter that includes the essential elements of informed consent may be necessary when introducing a web or mail survey. Further, such waivers of writing documentation are increasingly rare (Schrag 2010).

Although the standards for informed consent seem straightforward, the process itself can be complex. Such complications arise, for example, when a service is provided to an entire community, in the interest of research, as an individual may be unable to opt-out of participation (Hutton, Eccles, and Grimshaw 2008; Glennerster 2017).[8] Extending this, there may be negative externalities from an experiment even when participants have been appropriately given an opportunity to engage in informed consent. An example of this is case of Bertrand et al. (2007), in which drivers were encouraged to secure drivers licenses, resulting in a number of potential drivers engaging in extralegal payments and thus obtaining licenses without actually knowing how to drive. These individuals may cause damage outside the scope of the experiment, to others who are unaware of the experiment and did not consent to participate. These community-level effects can result in unintended harm and thus may confound the meaning and practice of informed consent.

Further, it is possible to violate participants' rights, despite adherence to the written regulations of informed consent. An example of this is demonstrated in a case of medical research undertaken on the Kenyan Coast: Molyneux, Peshu, and Marsh (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 consented to interviews and sometimes invasive procedures. Despite the review of study design and consent forms by national and international committees, Molyneux, Peshu, and Marsh (2004) found that the study participants were not appropriately treated. Compliance with IRB

[8] *Examples from 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.*

regulations and informed consent procedures still failed adequately protect subjects, as such regulations purport to achieve.

The problems associated with informed consent and research ethics generally are well documented in the biomedical profession.[9] As the roots of ethical standards are set in this field, this is not surprising (Childress, Meslin, and Shaprio 2005; Schrag 2010; Israel 2015). However, 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 of low risk[10] to participants. Yet some of it may also be attributable to a minimal discussion of ethics within the field generally (Josephson and Michler 2018). With this article, we hope to broadly encourage the discussion of the ethical considerations and to specifically stimulate discussion on the process of obtaining IRB approval and engaging with informed consent procedures.

Method

The issues surrounding IRB are generally discussed and studied qualitatively, with case studies or anecdotes from the field. So, to contribute some empirical evidence to discussions on this topic, we make efforts to include quantitative perspectives. 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 issues raised by Josephson and Michler (2018), including: (i) the discrepancy between regulations and practice, and (ii) 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 downloaded a list of universities from the National Institute of Food and Agriculture's list of land grant universities or (LGUs; USDA-NIFA n.d.).[11] NIFA has lists of 1862, 1890, and 1994 LGUs. Of these, there are 191890 LGUs, 311994 LGUs[12], and 501862 LGUs, excluding the District of Columbia and the territories of the United States. We excluded our home universities, leaving us with 481862 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" (or permutations thereof) led to information about ethics review and/or research protocols. If the IRB location resulted, we then searched for informed consent language in the policy documents or online tools provided for researchers. Finally, we searched for language about the waiver of informed consent. The information from this search gives us an overall picture of the expectations for ethical review across universities.

Based on the findings of this search, and to examine how researchers at universities actually practice research ethics in agricultural and applied

[9]*For more details, see Kegley (2004), Wicher and Michalek (2005), Ilfeld (2006), Rady, Verheijde, and McGregor (2011), and Milner and Magnus (2013), among many others.*

[10]*The definition of low risk (also called minimal risk) follows the Federal Policy for the Protection of Human Subjects, Title 45 of the Code of Federal Regulations, Part 46, in which a study is low risk if the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

[11]*List available at https://nifa.usda.gov/land-grant-colleges-and-universities-partner-website-directory.*

[12]*Of these thirty-one, two were added in 2014. The original list from 1994 included only twenty-nine. We include all thirty-one universities for completeness.*

economics, we distributed a survey to agricultural and applied economics researchers. Our target respondent currently had work in the field somewhere outside of the United States. On October 9, 2018, a survey and short message[13] were sent to 283 researchers across the United States.[14] On October 18, 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. Fifty-five researchers ultimately responded to the survey. Although this gives us limited capacity to make inferences, we discuss briefly the practices and some of the perspectives of respondent researchers.

To consider the second issue, the use of IRB primarily within universities, the next component of our search focused on nonuniversity research institutions. These included the fifteen CGIAR centers, as well as organizations such as the Abdul Latif Jameel Poverty Action Lab (J-PAL) and Innovations for Poverty Action (IPA). As in the case of land-grant universities, we screened each center or organization with a search of their main website to see if using the terms "IRB," "Research Ethics," or "Protection of Human Subjects" led to information about the Institutional Review Board or research protocols. We also searched for informed consent language in the policy documents or online tools provided to researchers. The information from this part of our search gives us a picture of the expectations for ethical review outside of universities by institutions that are often partners in research conducted by university faculty or students.

Status of Ethical Review across Academic Institutions in the United States

We review the IRB procedures for land grant universities or LGUs, including the 1862, 1890, and 1994 LGUs. We focus our discussion on the 1862 LGUs, due to the emphasis within these institutions on research.

IRBs in 1862 Institutions

Results of screening the websites of 1862 LGUs are presented in table 1. In the vast majority of these schools, a search for "IRB" on the homepage yields links or the main page of the university's review process for research involving human participants.[15] In the case of the University of California system or the University of Massachusetts, more extensive web information is revealed by searching within the individual universities. 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.

[13] *The survey instrument and email request are included in the Appendix A2.*

[14] *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.*

[15] *Searching individual universities within the system (e.g., the University of California at Berkeley) leads to extensive web information. We do not modify our search, however, but follow the NIFA list. This may smooth over some larger systems, which have decentralized IRBs, across individual institutions.*

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
Clemson University	South Carolina	1862	0	Yes	Yes	Not easily found
Colorado State University	Colorado	1862	1	Yes	Yes	Yes
Cornell University	New York	1862	1	Yes	Yes	Yes
Iowa State University	Iowa	1862	0	Yes	Yes	Yes
Kansas State University	Kansas	1862	1	Yes	Yes	Yes
Louisiana State University	Louisiana	1862	1	Yes	Yes	Not easily found
Mississippi State University	Mississippi	1862	1	Yes	Yes	Yes
Montana State University	Montana	1862	1	Yes	Yes	Yes
New Mexico State University	New Mexico	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
Purdue University	Indiana	1862	1	Yes	Yes	Not easily found
Rutgers University	New Jersey	1862	1	Yes	Yes	Yes
South Dakota State University	South Dakota	1862	1	Yes	Inside training materials	
Texas A&M University	Texas	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

(Continues)

Table 1 Continued

Land Grant University	State	Type	Ag Econ Dept	IRB in homepage search	Informed Consent language	Waiver Option
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
University of Alaska	Alaska	1862	0	Yes	Yes	Yes
University of Arkansas	Arkansas	1862	1	Yes	Yes	Yes
University of California*	California	1862	1	Yes	Yes	Yes
University of Kentucky	Kentucky	1862	1	Yes	Yes	Yes
University of Maine	Maine	1862	1	Yes	Yes	Yes
University of Maryland	Maryland	1862	1	Yes	Yes	Yes
University of Massachusetts*	Massachusetts	1862	1	Yes	Yes	Yes
University of Minnesota	Minnesota	1862	1	Yes	Yes	Yes
University of Missouri	Missouri	1862	1	Yes	Yes	Yes
University of Nebraska	Nebraska	1862	0	Yes	Yes	Yes
University of Nevada	Nevada	1862	1	Yes	Yes	Yes
University of New Hampshire	New Hampshire	1862	1	Yes	Yes	Not easily found
University of Rhode Island	Rhode Island	1862	1	Yes	Yes	Yes
University of Tennessee	Tennessee	1862	1	Yes	Yes	Yes
University of Vermont	Vermont	1862	1	Yes	Yes	Yes
University of Wyoming	Wyoming	1862	1	Yes	Inside training materials	
Utah State University	Utah	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

Source: *USDA-NIFA (n.d.).*

Notes: *Forty-eight excluding District of Columbia, University of Arizona, Michigan State University, and 14 territories.*

**IRB information appears at specific university sites, such as Davis or Berkeley for University of California system, or Amherst for University of Massachusetts.*

Most 1862 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.[16] The 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 protection that would be required in the University's principal locations" (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.)." Both statements draw attention to context and the importance of cultural circumstance and also acknowledge the intrinsic power differences which may arise in the research context of developing nations.

Some IRBs draw attention to the power dynamics inherent with research. Iowa State University states that researchers need to be aware of any process that includes "power imbalances" between investigators and potential participants, or "undue influence or coercion" (Iowa State University 2018). This is essential to consider, particularly when 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. These power dynamics may lead to the informal waiving of rights.

IRBs emphasize requirements clearly. Although 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. This is perhaps unsurprising: universities are adhering to regulations and have little incentive to do more than this.

IRBs in 1890 Institutions

Detailed tables for the 1890 and 1994 LGUs, akin to Table 1, are presented in the Appendix A1 (Tables A1 and A2, respectively). We include a brief discussion of these results here. Generally speaking, the 1890 LGUs are Historic Black Colleges and Universities (HBCUs). For these schools, a search of "IRB" on the homepage led to a webpage with supporting materials. It is more difficult to find detailed information about informed consent and waiver options on these websites, although this may reflect receipt of research-related funding from the US government.

IRBs in 1994 Institutions

The 1994 LGUs are often known as the Tribal Colleges and Universities. A number of the home pages of these colleges were not searchable as of late 2018. Even when they were, most when searched with "IRB" did not lead to further information about review boards. But, detailed and well-developed IRB websites were found for a number of schools. Notably, tribal colleges

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

and universities 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, "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.). The IRBs associated with many of the 1994 institutions 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 and, as such, research should be to the benefit and enhancement of the community. Informed consent in this environment includes sharing all mediums in which the research may be utilized. Other messages draw attention to the importance of individual and Tribal rights and benefits of research to these people and communities who participate in it.

Across the LGUs, existence and requirements of IRBs are heterogeneous, though there is consistency between the 1862, 1890, and 1994 institutions. The 1862 LGUs largely have IRBs that are easily found, with extensive, clear language about informed consent and waivers. For the most part, the 1890 LGUs have IRB policies that can be located on websites with some difficulty; 1994 LGUs have IRB policies that uniquely reflect the history of these universities and the populations they serve. This heterogeneity likely reflects variation in research funding received from the federal government, but it is surprising 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 research done by the university.

Practice by Agricultural and Applied Economists within Academic Institutions

Beyond stated regulations of IRBs, we also seek in this article to better understand how researchers within a university environment perceive and practice ethical research. We asked researchers in agricultural and applied economics to respond to a brief survey.[17] The majority of respondents were professors of various rank. Responses were also received from research directors, emeritus professors, adjunct professors, and postdoctoral fellows. Respondents were mostly male (two-thirds), with PhD completion dates ranging from 1953 through 2018. Respondents provided specific details as to location and nature of projects, including sampling methods and questions of interest. Of the forty-eight respondents collecting primary data with projects outside of the United States, just over four-fifths received IRB approval for their project and most (thirty-seven) used a consent form or waiver before initiating data collection. Seven did not. The remaining researchers were waiting for final IRB approval, but intended 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.[18] The two most reported forms of obtaining informed consent are signed and oral. Signed consent

[17] *IRB approval was obtained prior to distribution from the University of Arizona protocol #1809927014.*
[18] *The signed consent form is perhaps the most familiar, in which details about the participant rights are given on a form that 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.*

and witnessed consent are the standard methods for research with human participants, as they provide a written record and the identity of the person who consented. Oral consent, however, was the most frequently used method of informed consent in our sample of researchers.

We also inquired about the level of consent obtained, which is also an essential consideration in the informed consent process. The standard level is for the individual. However, attaining individual consent may be complicated. Over three-quarters of consents among our survey respondents were obtained from individuals, though consent was also obtained from spouses, parents (in the case of minors), small groups, and villages. Several respondents also reported 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.

Changes and Extensions to Practice

The practices of researchers who responded to our survey were in line with university requirements, standard field work practices, and US federal regulations for research with human subjects. In this section, we discuss possible changes, extensions, and problems with some of the current practices. We focus on the method of obtaining informed consent and on the level at which informed consent is obtained.

Many of these methods used by researchers who responded to our survey, although in accordance with IRB regulations, are inflexible to the challenges which may be associated with informed consent in a lower income or developing country. Chief among them is the concern about the method of consent. In areas with lower literacy rates or average years of formal education, written consent forms may not be comprehensible or may be daunting. However, the emphasis is on obtaining informed consent with written documentation, rather than ensuring that research participants understand the research process and their rights within that process. Further, it may be the case that other observed forms of consent have drawbacks. For example, oral consent is often used when it is not feasible to provide participants with an information sheet with a place for a wet signature. Oral consent frequently reduces the lengthy process of adhering to signed informed consent and other IRB procedures in these contexts, also avoiding issues arising in areas of low literacy. However, oral consent practices may 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 audio recording of informed consent or witnessed consent by individuals may be appropriate. Similar practices are often used by oral historians, ethnographers, and/or psychologists. Such methods of informed consent may be more contextually suitable than written forms and could be explored moving forward by researchers in agricultural and applied economics.

The level of consent obtained is also an essential consideration in the informed consent process. The standard level is for the individual. However, attaining individual consent may be complicated in low-income or developing-country contexts. In these environments, local chiefs or leaders (both traditional leaders and government representatives) may provide day-to-day guidance, research clearance, and protection of villagers, or where the understanding of the individual may differ from conceptions in the

United States. To this latter point, Tindana, Kass, and Akweongo (2006) observe that individual-based models of consent may be challenging where decision-making does not give emphasis to individual autonomy.[19] Some work may ignore the traditional role of the extended family in decision-making or fail 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. An iterative and collective process is one alternative. In such a model, after sharing the informed consent script, participants would convene and discuss, ultimately returning to individually sign or provide witnessed consent. Such accommodations allow for a collective aspect to what is, characteristically, an individual decision.

The concern around consent given by a local leader is that the ability to consent is taken away from the individual. This persists in another case: when a spouse gives consent for his or her 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. The observance of a partner consenting on behalf of another is common in studies in low-income or 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.[20]

Regardless of context an individual base must remain at the center of informed consent. Tindana, Kass, and Akweongo (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." This consultation of a partner allows for research participants to provide individual consent, while encouraging discussion between parties, as with group discussions and community engagement. These consultations can allow for both perspectives of individual and group to be taken into consideration.

To be clear, obtaining communal consent is not inherently a bad idea. Cultural importance in many developing countries lies with a local chief, headman, or other leader. 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).

[19]*Tindana, Kass, and Akweongo (2006) also indicate that illiterate populations may benefit from group consent. However, acknowledging that individually written and signed forms may not be appropriate in these cases, 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 and revisions that can be made.*

[20]*It is imperative to be attentive to these cultural norms and customs. Many thanks to the reviewer who shared experience on using "tiered consent," wherein, as contextually appropriate, a male head of household is asked to consent for a female enumerator to interview his wife or daughter. Then the enumerator gets informed consent from the female respondent. The tiered process allows for multiple consent levels, as appropriate for the context.*

Culture is never fixed, but 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. All this discussion emphasizes that it is essential to acknowledge the difference in cultural standards researchers and researched. We do not suggest that researchers obligate the participants in their studies to hold the same views as themselves, but rather that knowing the context, including the cultural norms and customs, in which one works is imperative (Barrett, Cason, and Lentz 2020).

Status of Ethical Review within Other Development Institutions

In low-income and/or developing countries, a great deal of research in agricultural and applied economics is conducted in the CGIAR system, by other research organizations such as J-PAL and IPA, or in projects that are jointly implemented by these institutions and universities. Using a similar search procedure from the search of the LGUs, adapted for these other institutional systems, we perform another search for IRBs. Table 2 presents relevant information about IRB requirements and status of development within these CGIAR institutions and the other development research organizations of interest.

Both J-PAL and IPA post detailed procedures, akin to those at 1862 universities, which are easily found on their websites. However, the lack of review boards is acute within the CGIAR system. During our initial search in December of 2018, only eight of the fifteen CGIAR centers require research involving human participants to be cleared by an ethical review board. Broadening our scope and re-conducting the search in July of 2020, we found that ten of the fifteen CGIAR centers either had IRBs in place for social science research or ethical research policies. The latter does not imply that approval for research with human subjects is required, however. Because of the disparate nature among the conditions of the IRBs in the CGIAR, compared with J-PAL and IPA, we focus our discussion on the CGIAR institutions in this section.

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" were easily obtained on websites. We found ILRI's research compliance website, with information about the research process with animal and human participants. Additionally, policies on research ethics were available and easily found from CIMMYT, ICARDA, and ICRAF. Codes of conduct, which include references to research ethics, were often available on CGIAR institution websites, as well.

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) found that CGIAR social scientists were often unaware of IRBs and routinely failed 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." 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." At that time, 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).[21] Though often known for their applied research in the agricultural sciences rather than social science, the system as a whole and cross-center, multidisciplinary projects include a sizeable number of social science researchers. Particularly due to recent emphasis on impact assessment, the role of social science within the CGIAR is increasing, but without attention to human subjects in the process of research. Similarly, there is increasing attention to ethics review and the creation of related boards, but the process is slow.

There is a continued to push for use of IRBs within the CGIAR. 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, there are "… 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). Of course, this holds for many interventions of interest in economic studies, not just agricultural technologies.

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 technology or intervention developed and/or distributed by the CGIAR 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. Due to existing synergies, the CGIAR system would be well suited to a centralized IRB system, which could serve all the centers in a consistent manner.

Conclusion and Recommendations

In this article, we investigated the process and practice of informed consent, particularly as implemented in the developing country context by researchers based in the United States. We consider informed consent material on IRB websites of LGUs in the United States, as well as at the centers of the CGIAR and other development research organizations. We also use a survey of researchers at universities to evaluate informed consent practices. We find heterogeneity in the presence of IRBs among LGUs in the United States and within the CGIAR centers. Without well-developed systems for tracking research conducted with federal funds, many 1890 and 1994 LGUs, as compared to the 1862 LGUs, have weak IRBs. Further, IRB systems often do not exist in well-funded CGIAR institutions.

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

[21]*The Science Council was disbanded and was replaced by the Independent Science and Partnerships Council, which has since been replaced by the Independent Science for Development Council.*

Table 2 IRB, Status of IRB and Relevant Documentation, CGIAR Centers

Center	Status of IRB or Ethics Policy	Documentation provided
BIOVERSITY	Rely on partners' or external IRB processes.	No.
CIAT	Yes.	No.
CIFOR	Yes.	Yes.
CIMMYT	Yes.	No.
CIP	In the process of defining IRB procedures.	No.
ICARDA	Yes.	No.
ICRAF	Yes.	No.
ICRISAT	No.	No.
IFPRI	Yes.	Yes.
IITA	Yes.	No.
ILRI	Yes.	No.
IRRI	Yes.	No.
IWMI	Yes.	No.
WORLDFISH	Yes.	No.
J-PAL	Yes.	Yes.
IPA	Yes.	Yes.

Notes: *Thanks to Frank Place for sharing information relevant to this table. Initial of IRB information as of August 2017. Initial status of documentation provision, following search in December 2018. Updates made to both columns in July of 2020.*

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?[22] IRBs and informed consent procedures are largely motivated by the protection of university interests and focus attention on issues of confidentiality and data privacy, rather than the protection of participants themselves. This is an acceptable incentive: good can come from impure motives. Still, 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. This checklist of requirements is simply a lower bound on researchers' ethical obligations. Moreover, many researchers and institutions fail to even achieve and respect that lower bound. We, as a discipline, can and must do better to conduct research ethically, particularly with respect to ensuring the protection of research participants through procedures like securing informed consent. It is imperative that we acknowledge and practice research and informed consent as ongoing processes, which are culturally appropriate and recognize the rights of the individuals and groups involved (Michler, Masters, and Josephson 2020). To this end, more attention should be given to research participants: how do 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, in the field of agricultural and

[22] *Some debate 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 article, however.*

applied economics, should turn our attention more closely to the participants—the individuals, households, and communities with whom we interact in our research. 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 in our work around the world.

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Appendix

Table A1 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: *USDA-NIFA (n.d.), accessed September 18, 2018.*
Notes: *There are 191890 land grant universities today out of over 100 Historic Black Colleges and Universities.*

Table A2 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		

(Continues)

Table A2 Continued

Land Grant University	State	Type	Ag Econ Dept	IRB in homepage search	Informed Consent language	Waiver Option
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: *USDA-NIFA (n.d.).*
Notes: *291994 land-grant colleges, originally, with two added in 2014 (College of Muskogee Nation and Keweenaw Bay Ojibwa Community College).*

Appendix 1890 and 1994 LGUs

Appendix 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,

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)