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IRB & Research Ethics at IPA, Explained

As administrator of the IPA IRB (Institutional Review Board), I found our institution in the spotlight recently when critics of an RCT in Kenya raised ethical concerns that went quickly from "How could the PIs do such a thing?" to "Who approved this study anyway?" As is common for IPA studies, the protocol had been reviewed by the IPA IRB and by a local IRB in Kenya, Maseno University. The PIs and the IPA IRB for that study have released documentation addressing the ethical concerns, and we are all using the experience to improve procedures and transparency.

Since then, a number of people have asked me about the difference between IPA IRB and university IRBs. With this blog post I want to clarify how these IRBs work, explain why the investigators used these IRBs instead of U.S. university IRBs, and most importantly, clarify the value of local review and how the IPA IRB is both rigorous and independent.

The IPA IRB is Rigorous and Independent

Most people who conduct or use research probably know that IRBs and research ethics committees (RECs) provide ethical oversight of human subjects research. But there is a lot of nuance that even people steeped in research practice may not appreciate. Most IRBs are hosted by a research institution but are independent of the researchers at that institution. This is true of the IPA IRB, which is independent of IPA in the same way that, say, the Harvard IRB is independent of the Harvard Department of Economics. **All of its decisions and guidance on study protocols, including what to approve, are completely independent** of the research teams and the principal investigators (PIs), including IPA staff. It is probably well known that IPA works hard to foster close relationships with university-based PIs. Nevertheless, we maintain a firewall between the parts of IPA that maintain these collaborations and the IRB itself. I know this because my role as IRB Administrator sometimes involves explaining this to PIs who may not agree with an IRB decision.

While IPA IRB's decisions and guidance are independent, it does rely completely on IPA, an international nonprofit NGO, as the host institution for administration. IPA has a Research Transparency, Data Ethics, and Governance team dedicated to running the IRB, ensuring that submissions are processed quickly and efficiently, answering questions from research teams, supporting required ethics training and certification, and assisting the Board with all its administrative operations.

IPA IRB Versus University IRB

Much of IPA's work involves collaboration with researchers at academic institutions, which typically have their own research ethics committees (RECs) or IRBs. It is possible to have multiple institutions review, but routinely there is an agreement where one IRB cedes review to the other. With so many institutions involved, which one should review the study? This is often a choice made by the PIs based on several factors.

The reviewing institution may be the one with the most expertise in the matter at hand. For example, IPA IRB is specialized in the countries and sectors where IPA works, while university IRBs may have a primary focus on the U.S. or on clinical (medical) trials. There may be a regulatory requirement. Or there may be other factors such as fees and turnaround time. The U.S. HHS Office of Human Subjects Protection provides guidance (here) for reliance agreements, but the reality is that investigators may "shop around" for an IRB when there is a choice of institution. **It is ok to select an IRB based on expertise and even customer service, fees, and turnaround time but never based on a perception of leniency**. In the case of the Nairobi water study, the research grew out of a World Bank project. Since the World Bank does not have its own IRB and IPA was a partner on ongoing related research, IPA IRB was already the international IRB of record when the study protocol was amended to add new interventions.

Some countries where data are being collected require a local IRB to provide additional oversight. This is a good practice that we encourage even when not required because local universities typically have greater knowledge of local context and institutions. But not all countries have IRBs/RECs, so the IPA IRB and hopefully other international IRBs may request input from local health officials or other experts in local institutions to support their deliberations.

Beware IRB Moral Hazard

IRBs review protocols and provide oversight, but they are not investigative bodies, nor can they be responsible for knowing what the PI does not tell them. PIs have a responsibility to report anything that could bear upon the assessment of risk to study participants in their submissions, whether initial protocols, amendments, progress reports, or unexpected/adverse event reports and to respond candidly to IRB questions. **Having an approval letter in hand from a reputable IRB does not relieve the investigators of responsibility for monitoring field operations for potential harm.**

Criticism of field trials involving human subjects often surfaces when a manuscript is published. At that point, the public finds out that an experiment was carried out, and sometimes that participants may have been exposed to violence, intimidation, retribution, humiliation, coercion, or denial of services they might otherwise qualify for. There is always risk in studying poverty, and the populations we study routinely face adversity. The big question is often: Did the study increase exposure to these harmful conditions or would they have occurred in the absence of the study? If it's a counterfactual that cannot be observed,

this makes the public discussion even more complicated. Add in the dynamics of colonialism and exploitation of vulnerable nations and populations by foreign actors, and there is potential for ethical lapse and abuse, whether intentional or not. IRB oversight is an important component of ethical research but cannot be the sole accountability mechanism. For example, at IPA, we have an escalation policy and management review where individual projects are assessed for risk and additional requirements and monitoring may be assigned to it. For in-person data collection during the COVID-19 pandemic, IPA has a separate process parallel to IRB, that requires a detailed project application form to be approved by a regional director and the global operations director, and for a project launch checklist to be reviewed by the country director before it can proceed. We also have separate guidelines and procedures for high-risk or sensitive areas of research like intimate partner violence.

Elevating Research Ethics in RCT Research

IRBs can do more to increase transparency, including sharing more documentation. Investigators have a role to play, by including IRB protocols, consent statements, approvals, and supporting documentation in their trial registries. These documents can be embargoed by posting (with time/date stamp) on the private side and moving to public access after the release of a manuscript.

Meanwhile, researchers and journal editors can head off concerns by addressing research ethics directly in manuscripts, either with an ethics appendix or a footnote that states the ethical concerns and how they were mitigated, a smart idea suggested to me by Berk Özler, who is promoting this norm in the World Bank's development research community and by Dean Karlan and Chris Udry, who have developed a template for a structured ethics appendix (read more here). Even if journals have strict page limits and cannot fit this information into published papers, being able to reference it in an online working paper version of the manuscript, the trial registry, or an online appendix would improve the public's ability to evaluate the work and adds some transparency and accountability.

For IPA's part, we are amending our risk management and escalation policy to more systematically identify, analyze, and address ethical risks arising from research, but that fall outside the purview of a typical IRB review. For research outputs disseminated by IPA, our communications staff can review complex studies to make sure we clearly address ethical considerations and avoid within-field jargon. How do we know when research outputs will require this kind of attention? For studies that rely on IPA IRB for protocol review, we can flag a project whenever a protocol or amendment is deemed "more than minimal risk" and elevated to full board review. It also involves IPA country office teams being well-trained in the ethical risks and pitfalls in our research, which we are currently improving through vignettes and case studies in our formal trainings. This whole effort may require engaging with researchers long after a grant has ended, so we rely on researchers to coordinate with IPA as partners over the life of the project to ensure that not only research is conducted ethically, but that the process is transparent and consumers of research can be reassured of the steps taken to avoid harm to vulnerable populations.

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