

Navigating through Institutional Review Boards for HCD Research

Insights from a Learning Circle by HCD Researchers

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HCD EXCHANGE

Since 2020, the HCDEXchange has advanced learning and practice related to the integration of human-centered design and adolescent sexual and reproductive health (HCD+ASRH). We are a Community of Practice that brings together young people, program implementers, designers, evaluators and funders. It is our collective mission to uncover, drive, and share learning in this emergent area of global health programming, address sexual and reproductive health needs, and fulfill rights in low-resource settings.

JSI and inSupply Health are grantholders. JSI is a global health consulting and research organization dedicated to advancing health equity and improving the health of individuals and communities. inSupply Health is a JSI affiliate based in East Africa. inSupply designs people-centered, scalable, sustainable health solutions.

Authors: Kubai E.R. Ikiugu.

Reviewers: Muthoni Wachira, Sarah-Jane Boden, Kate Sheahan, Liz McNeil, Beatrice Nguo, Munyaradzi Chinguwa, Peter Nasokho.

IRB and Ethical Research

Institutional Review Boards (IRBs) or Institutional Ethics Review Committees (IERCs) are independent advisory bodies composed of research professionals who provide guidance and approval for formal research. IRBs have a core mandate of defining and overseeing the adherence to and implementation of ethical research standards, acting as a bridge between the researcher, ethical guidelines, and research practices. They review research protocols and related documents before any research is conducted to ensure that all practices comply with the global and country-specific ethical standards and requirements, to ensure the safety and welfare of the research participants.

The role of IRBs is particularly important when engaging vulnerable populations, such as youth and adolescents, and when engaging on sensitive topics, such as sexual and reproductive health. The IRBs ensure that a comprehensive plan for obtaining consent is explicitly outlined in the research protocol, safeguarding the welfare of research participants and mitigating the potential risks of harm.

These institutions play a critical role in ensuring the integrity of the research process and the reliability and quality of research findings. As a result of this rigorous ethical review process and approval, the research outcomes and findings are widely accepted as valid and credible. They can then be used with confidence to inform the development of policies and to improve current programming practices that are responsive to the needs of the key populations.

Considerations for HCD Research

The practice of human-centered design (HCD) in development programming has been accelerating over the past 5-10 years. Having its roots in the private sector, HCD research has been largely grouped together with market research practices. There is clear commitment to the ethical and empathetic treatment of the research participants at the core of HCD, however historically HCD research has largely

not required the same rigorous approvals as any other health-related research methodology.

Now that the use of HCD research is becoming an established practice in global health programming, HCD researchers and health practitioners are seeking the same rigor and credibility in their research by subjecting it to IRB approval. HCD and Adolescents and Youth Sexual Reproductive Health (AYSRH) programs tend to encounter challenges when navigating through the IRB ethical process for the approval of their HCD research protocols.

This brief highlights some insights on the IRB process, challenges and recommendations synthesized from a learning circle that was held by HCDEXchange and that brought together a team of HCD researchers and practitioners to discuss and share their experiences, challenges and solutions of navigating through the IRB process when seeking the ethical approval of HCD research. We hope that some of the findings in this technical brief will assist in making it easier for the IRB approval of HCD research.

Learning Circles at HCDEXchange

A Learning Circle is a flexible, peer-directed learning approach that brings together a group of individuals often with a common interest to learn from each other, about a self-identified topic and in a format that the group has decided upon.

Learning Circles are built upon the idea that every member has something to contribute and that every member has something to learn.¹

HCDEXchange uses the learning circle format to generate evidence and highlight best practices on the application of HCD in AYSRH to help them improve the understanding of the landscape and current state of programming, the gaps and challenges in integrating and applying HCD into Adolescents and Youth Sexual Reproductive Health programming, and to identify future areas of exploration that might strengthen the application of HCD in AYSRH.²

HCDEXchange convened the learning circle in July, 2023, with participants drawn from seven organizations, including Kenya Medical Research Institute (KEMRI), Ipas Kenya, Marie Stopes Kenya, Population Council-Kenya, Noora Health India, Aga Khan University and the National Institute for Medical Research in Tanzania.

Learning Circle Objective

The IRB learning circle's objective was to bring together Human Centered Design into Adolescents and Youth Sexual Reproductive Health researchers, practitioners and IRB staff to share their experiences, challenges, solutions and to generate insights on best practices when navigating through the IRB process for ethical approval of HCD research and research protocols.

“There are some activities that won't require IRB approval. For example, programs or interventions that are meant to generate internal program learnings or learnings that improve on an already existing program.” Inviolata Kenya

The IRB Process

Insights from the learning circle indicate that the IRB process mainly involves the pre-review screening of research protocols by IRB analysts to ensure the completeness and compliance of the ethical guidelines and standards of each research protocol submitted. Researchers must ensure that the research protocols submitted meet minimum submission requirements before they undergo the pre-review screening process. When the research protocols are submitted, an IRB analyst often conducts an initial pre-review screening process, to check for completeness and compliance of each submission.

It was noted that across many IRBs, the level of review

of a research protocol dictates the type of review and the number of reviewers required. The level of review reflects the level of risk to the participants. The risk level is measured against “minimal risk” as defined by the federal regulations.³ Full committee review studies are often reviewed by the IRB committee at a convened meeting. Examples of studies that require full committee reviews include randomized treatment studies, studies using investigational drugs and/or devices and behavioral studies involving risky interventions, observations of illegal behavior or very sensitive data/questions. Expedited and exempt studies are reviewed by a small number of IRB reviewers outside of an IRB meeting. This process may however differ from one IRB to another across different countries.

The learning circle participants suggested that the IRB review process of traditional research is usually straightforward because of its structured nature, clear hypothesis and well defined outcomes. On the other hand, HCD research is iterative in nature and unstructured with undetermined outputs. For example, researchers may be required to go back to refine the tools, redefine the target population, the sample, which makes it challenging during the ethical review process

“Most of the IRB reviewers have a medical background and then you know, HCD comes from a business sphere and therefore reviewers who were assigned to review my protocols were unaware of what HCD is, so my role was largely educating them about HCD.

So I had to educate and explain the HCD methodology to the reviewers from a business sphere to a public health sphere and to give some examples of the HCD projects from Nairobi.” Dr. Isangula, Tanzania

“You might face challenges in the approval process if you haven’t previously submitted any protocol for review to the IRB. After submission of many protocols, I became known by the IRB and this has built connections and relationship that has made the approval process of my research protocols easier and faster.” Dr. Isangula, Tanzania

of HCD research. For instance, the intervention or the prototype is likely to change from a rough prototype to a high fidelity prototype that is different from what is described in the research protocol. For the HCD process to be understood by reviewers, HCD researchers must ensure that all the intervention and research processes, including anticipated changes, are described in detail in the research protocols and that IRB anticipate these changes as part of the HCD process.

Distinctions Between Traditional research and Human-centered research

The learning circle participants highlighted some of the differences between traditional research methodology and HCD methodology. The insights show that traditional research methodology usually has very clear bounds, and a structured process. For example, the participants indicated that researchers using this methodology will typically undertake research to either confirm, validate or to understand more about a certain topic of interest. It’s a very formal and structured methodology with a clear hypothesis and expected outputs. Traditional researchers are usually very clear from the start in terms of how they are going to collect data, the target population, and the sample size of people they will speak to.

While HCD research can do that, it is meant to inspire and encourage exploration outside of the research scope to understand, for example, the experiences of young people accessing reproductive health services. The participants cited that HCD research methodology

is less formal where researchers want more natural conversations with the research participants.

Another difference between traditional research and HCD research arises in or when applying for donor funding. Most donors are interested in research and programs with clearly defined outputs and solutions to the problem. Therefore, when approaching donors with the traditional research approach, researchers are able to articulate to the donor the problem they want to solve. HCD research requires an explanation for how the solutions will be achieved to convince the donors to fund the intervention, often because the HCD process may not have clearly defined outputs. HCD is more participatory and collaborative in nature, but the danger is the possibility of having social desirability bias among the users because they are present and since researchers are supposed to observe them within their natural setup, drawing the lines between the two usually become difficult when conducting human centered design focused research.

Challenges experienced by HCD researchers during IRB approval process

The insights generated from the experiences shared by HCD researchers during the learning circle cited a number of challenges and barriers faced by HCD researchers when navigating through the IRB process for ethical approval of HCD research.

a) Undetermined outputs for HCD research

HCD research protocols may not have clearly defined research outputs due to its iterative nature its iterative nature that may lead to changes of the initial protocol. This may therefore delay the IRB approval process of HCD research protocols.

b) Reviewers unfamiliarity with HCD methodology and delays in the review of HCD protocols

IRB reviewers are always keen to ensure that what they approve aligns with accepted research standards and guidelines. Insights from the learning circle indicate that if the reviewers are unfamiliar with the HCD process, the IRB review process might take longer than anticipated. This may be a result of the back and forth between the reviewers and HCD researchers to clarify

the process. In addition, the researchers attributed delays in the approval process of HCD research to few HCD trained IRB reviewers.

"We now have many institutions that are building the capacity of experts in Africa on HCD in Tanzania. For example, Tanzania Food and Nutrition has partnered with American University to build experts capacity. I was invited to speak there and so HCD is picking up and I can say we have quite a number of HCD experts in the country. That's why IRB, perhaps, may need to consider recruiting people who have done some work in HCD to review the protocols", Dr, Isangula, Tanzania

(c) Participant consent:

When designing and planning HCD research, the researchers may plan to engage with the same target population throughout the HCD research process, however due to the iterative nature of the HCD methodology, sometimes the researchers may end up engaging with different users in different activities for various reasons thus sometimes making the consenting process sometimes becomes a challenge. *"For instance, a woman could take part in the initial HCD research and then she might be invited for the prototype testing or at some point she might be invited for an in depth interview (IDI) or a focus group discussion (FGD)".* Sometimes, the consenting process becomes a challenge also because of the research logistical reasons. For example, one of the participants said, *"I worked in a project that was targeting minors who were mobile migrants and it was really difficult to go back to the same population to seek consent for the subsequent research activities".*

Recommendations by HCD practitioners to improve IRB approval of HCD research

HCD researchers and practitioners have the potential to improve the process of navigating through IRB review and approval of HCD research protocols.

Develop detailed HCD research protocols: HCD researchers and practitioners recommended that during the design and development of HCD research protocols, HCD researchers and practitioners should ensure that the research protocols have as much detail as possible, particularly when explaining the HCD research processes, the tools, and any anticipated

changes that may take place during the research period. A detailed and clear definition of the HCD process helps in justifying and bringing clarity about the HCD research process and any adaptations and iterations inherent to the IRB reviewers.

Sensitize IRB reviewers, HCD researchers, practitioners: Participants also recommended holding learning forums to sensitize, create awareness and build capacity of IRB reviewers, HCD researchers and practitioners around HCD research methodology as well as the IRB ethical approval process. This will build a shared understanding of the HCD methodology among the IRB reviewers and HCD researchers and practitioners and help the practitioners to better understand the necessary requirements for the ethical approval of HCD research. Additionally, it was recommended that IRBs invest in increasing the number of HCD trained IRB reviewers to review HCD research protocols as this is likely to have a ripple-down effect in terms of making the process faster and thus reducing the amount of time wasted during the back-and-forth responses when clarifying the HCD research protocols.

Include IRB reviewers into research design: Ensure the inclusion of IRB reviewers as participants/partners during the design of HCD research and, after the research is completed, allow the reviewers to interact, experience and familiarize themselves with the entire HCD process and methodology.

Practical sessions about HCD to HCD practitioners: Speaking about HCD is theoretically exciting but one gets a more robust understanding of the methodology when they see how it works. Therefore, having practical sessions for practitioners to interact, experience and be part of the HCD process will likely assist more people in understanding HCD methodology and how it works.

Hold dissemination forums for IRB reviewers: With HCD research outcomes usually being unclear or undefined, it's very important to close the loop of the research approval process by having

dissemination forums for IRB reviewers where the researchers can showcase the final HCD research solutions, outcomes and take the reviewers through the research process and activities that they approved. By doing so, HCD researchers are able to show the value and benefits of the HCD methodology to the IRB reviewers, which may facilitate subsequent reviews.

Consenting: With the HCD methodology, the researchers might end up engaging with different users for different activities at different phases of the HCD process. To ensure the welfare of research participants is well protected and a smooth ethical IRB review process, participants recommended that researchers consider having different consent forms for each of the HCD phases where participants are different. When the same group of people participates across all HCD phases, or have one broad consent form with as many different activities as possible.

Conclusion

HCD researchers and practitioners ought to ensure that ethical standards are followed and implemented across all the programs and those involved in the design and review of research work understand and adhere to the ethical requirements.

The emphasis on adhering to ethical research guidelines during research work ensures the protection of research participants, and the integrity and quality of HCD research practices. Therefore, the investment by IRB institutions/committees in recruiting HCD-trained reviewers is paramount. HCD researchers, practitioners, and partner organizations conducting HCD work should consider developing strategic plans and setting aside resources to facilitate awareness and HCD capacity building forums to equip future reviewers and with the relevant skills in HCD methodology. Doing so will not only increase knowledge about HCD methodology among IRB reviewers but will also reduce the back-and-forth between HCD researchers and IRB reviewers during the review process of HCD research work.

HCD research continuously builds iteration and adaptation to the process and therefore, HCD researchers and practitioners should ensure that the research protocols clearly define and explain in detail the HCD processes, including the anticipated changes and the consenting process before submission of the protocols to IRB institutions/committees for ethical review and approval. Additionally, HCD researchers and practitioners should ensure the involvement and active participation of IRB reviewers both during the development of HCD research protocols and during the dissemination of HCD research findings. The involvement and participation of the reviewers is important in ensuring continuous learning by IRB reviewers that will gradually help in building a shared understanding of HCD methodology between the reviewers and HCD experts.

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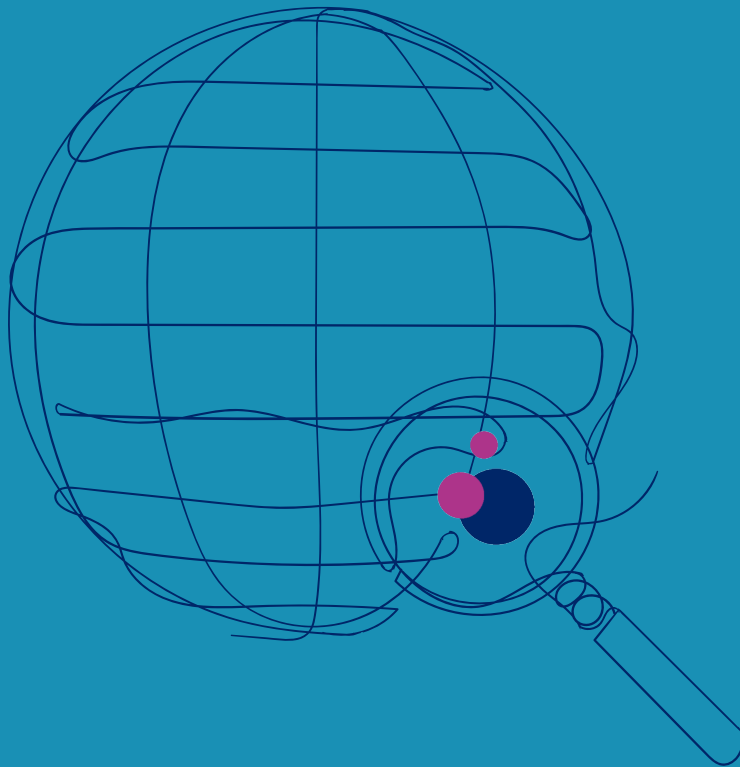
¹Senior Analyst, Population Council, Kenya, ²Clinical Research Scientist and Principal Investigator, KEMRI, Kenya, ³Assistant Professor, Aga Khan University, Tanzania, ⁴Associate Director for Learning and Sharing, Noora Health, India, ⁵HCD Advisor Ipas, Kenya, ⁶Marketing, Evidence and Impact Director, Marie Stopes Kenya.

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