



Ethical reviews for refinement studies: A Case Study from Titukulane in Malawi

Abstract

Human rights violation while researching human participants, especially in the biomedical field, and later in social and behavioral science has mandated ethical review of research. Simultaneously, digital privacy breaches and sharing of biometric data is a widespread problem. This has led to the establishment of Institutional Review Boards or similar Ethical Review Boards, which have a significant role in protecting the rights of human participants by holding the researcher accountable. So, in this learning note, we will examine the need, standards, and process of ethical review, particularly for refinement studies, by using the refinement phase of the USIAD-funded Titukulane Development Food Security Activity. Using this case study, we will also explain the process Titukulane used to choose which studies needed to be approved by the Institutional Review Board and which did not.

Introduction

The Institutional Review Board (IRB) reviews proposed or ongoing research that involves human subjects to protect their rights, dignity and safety. The IRB was initially established for medical research, but recently it also applies to social and behavioral.¹ The purpose of ethical review for social research is to allay fears of objectification of research participants, potential harms, and coercive, exploitative, or intrusive practices as well as to maintain the privacy or confidentiality of the participant. According to the Office for Human Research Protections (OHRP), the primary significance of the Ethical Review is to ensure the protection of the rights, welfare, and wellbeing of human subjects involved in biomedical and behavioral research².



In the USA, the Office for Human Research Protections, within the U.S. Department of Health and Human Services,

¹ <https://www.britannica.com/topic/institutional-review-board>

² <https://www.hhs.gov/ohrp/about-ohrp/index.html>

is responsible for the registration of IRBs and their oversight. While it's mandatory for Federal funded research to get the approval of the IRB when it involves human participants, these are fast becoming international standards with many other Institutions and countries following suit by demanding similar IRB oversight.

In this learning note, we will examine the ethical review process for refinement studies through Malawi's Titukulane Activity, which is a consortium led by [CARE](#), in partnership with [International Food Policy and Research Institute \(IFRPI\)](#) as the Learning Partner, and [Emmanuel International](#), [National Smallholder Farmers' Association of Malawi \(NASFAM\)](#), [Save the Children](#), and [WaterAid](#).

Background Information – Refinement Studies in Titukulane

Refinement studies must seek consensus and participation of program participants. As a result, these studies might involve asking personal questions and collecting personal and biospecimen data, in order to learn the needs of the vulnerable populations. This process invariably intrudes on the personal lives of the stakeholders, and they may be concerned about the data privacy and sharing policies. So generally, one must obtain the prior approval of the IRB before carrying out a refinement study.

Titukulane first examined existing literature and previous studies to identify evidence and knowledge gaps, and consulted with many stakeholders to further refine the learning questions.

Not all studies must go to the IRB for approval, which presents a double challenge to implementation. Some studies are exempt, so researchers must carefully select studies for submission to the board. As the IRB process involves both human and financial resources, as well as extends the period before research begins, proper choices can speed up the research while cutting costs. The second challenge is to adhere to the ethical research standards set by the IRB process for submitting institution and the host country (Malawi, in this case). Other than these, there is an overall challenge to navigate through the IRB process.

Refinement Study Checklist

- ✓ Review existing literature
- ✓ Identify evidence & knowledge gaps
- ✓ Consult with stakeholders
- ✓ Refine learning questions
- ✓ Determine which studies go to IRB for approval

International and National Standards

There aren't any International Standards for the ethical review of social and behavioral research. Instead, the most commonly used standard among International Organizations like the World Bank stem from USA's Federal Policy for Protection of Human Subjects, or the '[Common Rule](#)'. The Belmont Report, 1979, heavily influenced this Rule. The Common Rule sets three pillars of protection of human subjects:

- (1) Review of the research by a properly constituted ethics committee (Institutional Review Board, or "IRB");
- (2) An assessment of risks and benefits of the research by the IRB; and
- (3) An informed consent process for research subjects.

The Common Rule recognizes that there is no formula to apply to ethical decisions and vests the responsibility for making such decisions with the IRB³.

³ <https://www.eccnetwork.net/sites/default/files/media/file/IRB-Policy-Brief-FINAL.pdf>

In Malawi, the National Committee on Research in the Social Sciences and Humanities (NCRSH) is the committee established to promote, support, coordinate and regulate research and development in the social sciences and humanities. Any researcher or stakeholder intending to conduct research in the social sciences and humanities in Malawi is legally required to have the research protocol/proposal ethically reviewed and approved by NCRSH or by any NCST (National Commission for Science and Technology) recognized and accredited institutional research ethics committee in the social sciences and humanities. This organization has an ethical framework⁴ to scan the study for ethical problems. It is preferred that researchers get the approval of the local IRB as local sensitivities, culture, and moral perspectives would better be analyzed by them.

Process and Criteria to Select Study for Review

As already mentioned, it isn't mandatory that all the research studies involving humans needs to pass the IRB for approval (exempt studies). Those studies which entail public observation of behavior, anonymous surveys, or interviews with adults who are not vulnerable in any way (e.g., due to pregnancy, diminished capacity, or incarceration), usually carry only minimal risk and fall into the exempt studies category. So then, one dilemma is to determine whether the study has to be sent for IRB clearance or not.

To address this, Titukulane held an internal discussion with Project Technical Leads on the data collection methodology and subject matter. In addition, a two-week consultation with the internal experts and USAID program officers took place in July 2020 during an Inception Report Writing Workshop. As written in the workshop report, certain criteria were determined for submission to the IRB process and ethical clearance.

Select criteria for sending studies for ethical review (hegtvedt, 2014):

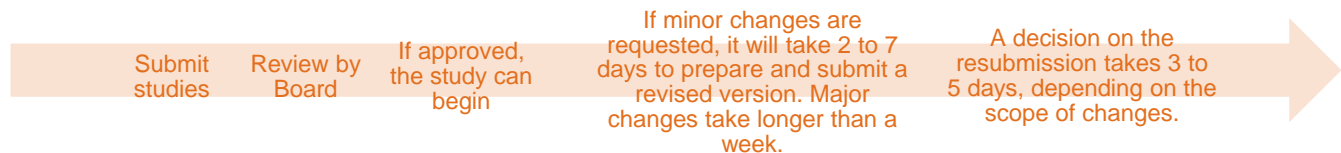
- ✓ When studies entail public observation of behavior, anonymous surveys, or interviews with adults who are not vulnerable in any way (e.g., due to pregnancy, diminished capacity, or incarceration), they usually involve only minimal risk, so they are 'exempt' from ethical review according to IRB.
- ✓ Minimal risk studies with written documentation of consent, possible risk of loss of confidentiality, collection of voice, video, and/or image recording for research purposes, or collection of small biological specimens through noninvasive clinical procedures are subject to ethical review under the 'expedited' review category by IRB.
- ✓ IRBs reserve full board review, which is a mandatory ethical review for studies involving greater than minimal risk, vulnerable populations (e.g., children, prisoners, pregnant women when there is a threat to the fetus, and individuals with diminished capacity), and/or deception. At some institutions, changes in or waivers of informed consent elements may also attract full board review.

⁴ <https://www.ncst.mw/wp-content/uploads/2014/03/NATIONAL-FRAMEWORK-OF-GUIDELINES-IN-SSH.pdf>

Ethical Review Timeline

Of Titukulane’s 12 studies, six were selected for submission to the National Committee on Research in the Social Sciences and Humanities.

Studies submitted for ethical review	Studies not submitted for ethical review
<ul style="list-style-type: none"> ✓ The Youth Needs Analysis youth under the age of 15 are questioned and they are considered a vulnerable community. ✓ The Social Behavior Change Formative Research because participant behavior is recorded and judged. ✓ The WASH Feasibility Assessment and Hygiene Formative study because it asks personal health and related behavior questions. ✓ The Gender Analysis because it asks personal health, violence, and wellbeing questions. ✓ The On-Farm study because it asks about food preferences and crop patterns. 	<ul style="list-style-type: none"> ✓ <u>Climate Vulnerability and Capacity Analysis</u> ✓ Economic Analysis ✓ Irrigation Feasibility ✓ Local Needs Governance Assessment ✓ Political Economy Analysis ✓ Youth Labor Market Assessment <p>These six studies weren’t selected for ethical review because data collected isn’t personal-- it is related to demographics, economics, infrastructure and systems. These studies can begin field work immediately, and results can be published more quickly than those needing ethical review.</p>



Illustrative Chronological Timeline for Ethical Review for Titukulane

DATE	ACTIVITY	IMPLICATION
08/15/2020	Submit research proposal to Review Board	The Board would begin the ethical review of the research in two days
08/17/2020	Review process starts	The decision to approve or modify the research proposal
09/07/2020	Research is approved	The research can begin
	The Board suggests minor corrections	Resubmit a revised proposal in 2-7 days
	The Board suggests major corrections	Resubmit a revised proposal in 1 week
09/09/2020-09/14/2020	Resubmit a revised proposal after correcting minor changes	The decision to approve or modify the research proposal in 3-10 days
09/14/2020	Resubmit a revised proposal after correcting major changes	The decision to approve or modify the research proposal in 3-10 days

Moving forward with ethical review

Ethical review is important, yet it may absorb more resources than expected. The IRB and review process is becoming a norm rather than an exception in all research projects involving human participants. Many programmatic professionals are new to the process and but find the bureaucratic setup frustrating, but they must engage with technical leaders and the review board members collaboratively and inclusively. Titukulane recommends thoughtful following factors for organizing ethical reviews and institutional considerations for ethical review.

Organizing the Ethical Review

- ✓ Read the internal procedure of the Review Board to understand the ethical principles and obligations of the board and the required documents.
- ✓ Determine which studies should be submitted for approval.
- ✓ Consult with researchers that have prior experience in the process for clarity.
- ✓ Prepare and submit the select studies for Board approval.

Institutional Considerations for Ethical Review

- ✓ Collaborate early to determine which studies to submit for ethical review.
- ✓ Plan for ethical review by investing resources and time. Up to 10% of the research cost may be sunk into ethical review and itpending ethical reviews delay implementation.
- ✓ Expediting the process is possible but costs more money.
- ✓ Collaborate inclusively with technical leaders and Board members.

Titukulane:

Titukulane is a five-year USAID-funded Development Food Security Activity, running from 2019 to 2024. Titukulane meaning “let’s develop together” in Chichewa, supports the implementation and effectiveness of the Malawi National Resilience Strategy (NRS), which is established to guide investments in agriculture, reduce impacts and improve recovery from shocks, promote household resilience, strengthen management of Malawi’s natural resources, and facilitate coordination between government institutions, civil society organizations, and development partners.

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