Society of Medical Education & Research

2024, Volume 4, Page No: 228-243
ISSN: 3108-5059

Asian Journal of Ethics in Health and Medicine

Putting Real-Time Ethical Practices into Action to Enhance Ethical Attentiveness in Malawi's Agriculture–Nutrition–Health Studies

Rashmi Kulkarni[1]*, Sanjay Patil[1], Meenal Joshi[1]

[1]Department of Ethics in Health Care, Faculty of Health Sciences, Savitribai Phule Pune University, Pune, India

***E-mail** ✉ rashmi.kulkarni@outlook.com

Abstract

Large, collaborative research programs at the intersection of agriculture, nutrition, and health (ANH) often involve human participants and necessitate ethical oversight. Due to the complexity of these studies, ethical challenges may arise not only before fieldwork but throughout the research process, requiring flexible, embedded mechanisms to detect, assess, and manage ethical issues in real time. Drawing on the concept of 'ethics in practice,' this study introduces a novel "real-time research ethics approach" (RTREA) designed to integrate ethical reflection into research activities, fostering continuous dialogue between researchers and participants. This approach aims to enhance responsiveness to ethical concerns and improve participant experience, potentially supporting adherence and retention. In this case study, a bioethics team (BT) was embedded in a community-based randomized controlled trial in rural Malawi, known as Addressing Hidden Hunger with Agronomy. Data collection included ten focus group discussions, fourteen key informant interviews, two workshops, observations of five trial-related meetings, and review of fifteen reports spanning the trial from planning to implementation. RTREA helped uncover social and ethical issues and provided insight into participants' lived experiences within the trial. The BT worked alongside researchers to create dedicated "conversation spaces" for discussing these concerns, emphasizing participatory approaches and collaborative problem-solving, which enabled participants' voices and experiences to be directly incorporated into trial activities. Embedding RTREA demonstrated the benefits of ongoing, real-time engagement between participants and researchers. Such approaches can complement traditional ethics oversight, reinforcing principles of inclusion, autonomy, and empowerment, while promoting ethical awareness among researchers. This heightened ethical mindfulness may also contribute to improved operational outcomes, including higher recruitment, retention, and adherence rates.

Keywords: Ethical practices, Agriculture–Nutrition–Health (ANH), Malawi, Bioethics Team (BT)

Introduction

Research ethics establishes standards for conducting research grounded in ethical values and guiding principles [1], aiming to ensure the protection of participants' dignity, rights, and welfare throughout the design, execution, and reporting of research [2]. Certain research areas, such as biomedical studies, present particularly complex ethical challenges [3]. While formal ethical guidelines provide a framework for research conduct [4], they often fall short of addressing novel ethical issues that emerge during the course of a study, leaving researchers to navigate unanticipated dilemmas [4]. Engaging in dialogue with participants and fostering active researcher-participant interactions have been shown to encourage discussion of values, norms, and ethical virtues [5], forming a deliberative model that allows ethical challenges to be addressed collaboratively as they arise [6], commonly referred to as 'embedded empirical ethics.'

Approaches to embedded and responsive ethics

Access this article online https://smerpub.com/

Received: 14 August 2024; **Accepted:** 26 November 2024

How to cite this article: Kulkarni R, Patil S, Joshi M. Putting Real-Time Ethical Practices into Action to Enhance Ethical Attentiveness in Malawi's Agriculture–Nutrition–Health Studies. Asian J Ethics Health Med. 2024;4:228-43. https://doi.org/10.51847/aWzZ5QLcXs

Various strategies have been proposed to integrate ethics more closely into research practice, such as embedding clinical bioethicists in hospitals, establishing ethics advisory boards for large research initiatives, and conducting empirical ethics research alongside scientific investigations. Embedded empirical ethics involves active engagement with participants, generating insights that can contribute to bioethics scholarship. Its value lies in several areas: (1) fostering deliberative dialogue between participants and researchers, raising awareness of ethical issues [6]; (2) supporting ethical analysis and informed discussion about appropriate courses of action [7]; and (3) employing social science methods to collect and analyze experiences and perspectives from both participants and researchers before and during the study, informing anticipatory guidance for good research practices [8]. Building on these approaches, this study develops a method to facilitate ethical reflection within large research programs by combining applied ethics with elements of technology assessment, promoting real-time ethical mindfulness and co-production of inclusive research processes [9, 10]. This methodology is termed the Real-Time Research Ethics Approach (RTREA).

The RTREA emphasizes a relational approach between participants and researchers, where (1) ongoing reflection on ethical principles and guidelines is aligned with the study context, and (2) the realities of participants' experiences inform ethical decision-making. Unlike traditional empirical ethics, RTREA is characterized by continuous reflexivity, responsiveness, and transparent disclosure [6]. Its potential benefits include reinforcing respect for participants, supporting the assessment of researchers' responsibilities, and integrating empirical evidence with ethical guidance and expert advice to inform deliberation and decisions [3, 4, 9].

In this paper, we describe how embedding ethics expertise can enhance ethical practice and nurture ethical mindfulness in ANH research programs. The discussion also considers how this approach may influence practical outcomes such as participant enrollment, retention, and adherence. These insights are drawn from a community-based randomized controlled trial conducted in rural Malawi, known as the Addressing Hidden Hunger with Agronomy (AHHA) trial. The AHHA trial [11], which investigates the potential benefits of agronomic micronutrient fortification, involved distributing maize flour to participants, with some receiving selenium-enriched flour and others receiving control flour [11].

The AHHA trial

In 2019, the AHHA trial was carried out in Kasungu district, located in central Malawi, as part of a collaborative project involving Lilongwe University of Natural Resources (LUANAR), the University of Nottingham, the London School of Hygiene and Tropical Medicine, and the University of Malawi, College of Medicine. This partnership implemented a community-based randomized trial to tackle widespread micronutrient deficiencies, commonly referred to as "hidden hunger" in Malawi [12]. The study aimed to evaluate whether enhancing selenium intake via agro-fortified maize flour could improve selenium status. Agro-fortification entails increasing the selenium content of maize—the country's staple food—through the use of selenium-enriched fertilizers [13, 14]. The trial randomly assigned 180 households, each contributing one woman of reproductive age (20–45 years) and one school-aged child (5–10 years), to either receive selenium-enriched maize flour (n = 90 households) or non-enriched maize flour as a control (n = 90 households) [11].

All 180 households received sufficient maize flour to cover the daily needs of every household member (330 g per person per day) for eight weeks, while non-enriched maize flour was also distributed to other households in the area to minimize the risk of participants selling or sharing their allocated flour [11]. Study procedures included baseline assessments of anthropometry, blood samples, and dietary intake, followed by flour distribution and adherence monitoring during the intervention, and concluding with endline evaluations of anthropometry, blood biomarkers, and dietary intake.

Key Components of the Real-Time Research Ethics Approach

The Real-Time Research Ethics Approach (RTREA) applied in the AHHA trial comprised several essential elements: (1) defining the responsibilities of the embedded ethics team, (2) promoting social interactions among key stakeholders, (3) mapping diverse knowledge and experiences, (4) applying ethical analysis to identified issues, (5) addressing ethical challenges as they arise during the research, and (6) fostering partnerships and sustaining trust among stakeholders. The bioethics team (BT) highlighted several of these components as particularly critical for successfully implementing the

RTREA from the trial's planning stages through to execution.

A central aspect of this approach is the presence of an (1) embedded ethics specialist or team, typically consisting of bioethicists, who facilitate dialogue, identify ethical concerns, conduct structured ethical analyses, and communicate issues and perspectives. Importantly, the ethics team must operate independently from the broader research team. In this trial, the BT comprised four experienced bioethicists from the College of Medicine and the University of Nottingham, who engaged with all trial stakeholders—including trial participants, communities, and the Trial Implementing Team (TImT)—serving as a bridge between participants and the TImT.

Another key element (2) involves promoting social interactions between potential trial participants (TPs) and the TImT. In this study, formative research conducted one year prior to the baseline survey [15–17] helped assess community perceptions of the trial and anticipated ethical concerns, providing insights into social and contextual factors influencing participants' engagement and researchers' responsibilities.

The third feature (3) focused on mapping diverse knowledge sets and pluralistic experiences by acknowledging participants' social, ethical, and contextual perspectives and how these interrelate in real time. This practice aligns with classical principles of "respect for persons" [1] but extends further to include understanding participants' learning experiences, decision-making processes, and comprehension of trial objectives and activities.

Applying (4) ethical analysis was another essential component, supporting informed decision-making. The BT employed an iterative process that linked ethical analysis with empirical data and dialogue, ensuring that findings, ethical deliberations, and decisions were discussed and agreed upon by stakeholders, thereby promoting ongoing ethical mindfulness.

The fifth feature (5) emphasized responsiveness to ethical issues as they emerged during the trial, achieved by conducting empirical research in parallel with trial activities, gathering feedback, reaching consensus, and supporting trial design and implementation. This ensured that participants' priorities, perspectives, values, norms, and welfare were considered throughout the study.

Finally, (6) building and sustaining partnerships and trust among stakeholders facilitated deliberative interactions. The BT conducted information-sharing sessions and focus group discussions (FGDs) to encourage dialogue, enhance the informed consent process as an ongoing practice [18], and promote participants' skills, confidence, self-efficacy, and autonomy, thereby supporting the development of a responsive program and study activities.

Materials and Methods

Study design

Between May and October 2019, an action research project was carried out to document and critically assess how the Real-Time Research Ethics Approach (RTREA) was applied within the AHHA trial and to examine the interactions between the bioethics team (BT), the Trial Implementation Team (TImT), and trial participants (TPs). The study sought to enhance research practices by capturing TPs' experiences, encouraging reflective evaluation of decisions based on documented evidence, and identifying potential improvements or adjustments for future practice [19]. To contextualize ethical considerations and gather evidence on wider social factors, an empirical study explored TPs' and community members' experiences, with the BT embedded within the TImT to provide guidance grounded in both ethical principles and real-world insights.

Before trial activities began, the BT delivered research ethics training to the TImT. Ethical deliberations were guided by core principles such as beneficence, non-maleficence, justice, and respect for autonomy, alongside additional considerations including empowerment, social responsibility, participation, transparency, and accountability. This principle-based framework was chosen because it aligns with standards commonly used in Research Ethics Committee (REC) assessments and provides a practical approach for analyzing ethical challenges in field research [1].

To maintain ethical mindfulness throughout the trial, the team systematically reviewed emerging social and ethical challenges and evaluated their potential impact on participant adherence, retention, and wellbeing. The study focused on several guiding questions: What are the participants' lived experiences (ensuring no harm and promoting good)? How can informed consent be strengthened (respect for autonomy and openness)? How can dialogue, voluntariness, and collaboration be promoted (participation and empowerment)? How can the obligations and responsibilities of researchers and participants be clearly defined and upheld (justice,

accountability, and social responsibility)? The study followed RATS reporting guidelines, including the presentation of results.

Study setting

The study, including the AHHA trial, took place in Wimbe Traditional Authority, Kasungu District, located in Malawi's Central Region, an area primarily dominated by subsistence farming, along with smallholder and estate-level tobacco cultivation.

Participant sampling and selection

Among the 12 villages involved in the AHHA trial, the TImT identified that rumors and concerns about the trial were circulating in seven villages prior to its launch. Recruitment efforts focused on these communities. The selection process began with meetings involving the AHHA trial manager to analyze preliminary data gathered during interactions with villages during the baseline survey. Observations from informed consent sessions were also reviewed to identify social and ethical concerns that warranted further exploration in subsequent data collection rounds.

Recruitment for focus group discussions

The BT used purposive sampling to recruit TPs and their partners for focus group discussions (FGDs), targeting households with school-aged children to capture a broader range of experiences. This strategy allowed exploration of both the participants' and children's experiences. In total, 71 TPs participated in the first round of FGDs. Local volunteers assisted by approaching potential participants in their respective villages, while BT members and research assistants conducted meetings at schools, churches, community clinics, and flour distribution sites. Participants and their partners were informed about the study, and those who agreed completed the informed consent process. Inclusion criteria included willingness to participate in FGDs, having school-aged children who provided blood samples, and readiness to engage in a second phase of data collection. Including families with school-aged children allowed the study to capture both the children's experiences and community perceptions of trial participation through the perspectives of partners.

Pre-FGD orientation and self-assessment for participants and partners

Prior to initiating data collection, each trial participant (TP) and their partner attended a 40–60-minute orientation session led by a member of the bioethics team (BT) and a research assistant. These sessions were conducted during the first phase of data collection and served as a precursor to the focus group discussions (FGDs), which all participants were subsequently invited to join. The sessions were held in spaces that promoted open, unrestricted dialogue.

The primary purpose of these sessions was to enhance participants' understanding of the trial, address misconceptions, and evaluate their capacity to identify and report any serious adverse events, seek clarification, and communicate relevant information to others. Topics covered included informed consent procedures, the nature of interactions between TPs and the Trial Implementation Team (TImT), participants' knowledge of trial objectives, researchers' duties, governance structures for research in Malawi, and the role of the BT in supporting participants. The BT emphasized its function as a link between participants and the TImT and encouraged TPs to share their broader experiences of the trial.

At the end of each session, participants completed a brief assessment to gauge their comprehension of the trial and highlight areas requiring additional clarification. The outcomes of these assessments were combined with other reports and communicated to the TImT to inform follow-up actions.

Recruitment and selection of key informants for in-depth interviews

To gain deeper insight into participants' trial experiences, the BT identified and recruited key informants (KIs) based on their community roles and responsibilities. Seven individuals were selected: one local chief, two community volunteers, one religious leader, one village committee member, and two health surveillance assistants (HSAs). The local chief was included as a trusted figure likely to have knowledge of participants' concerns, fears, and experiences, while the HSAs—a male and a female—were selected to represent participants' and partners' perspectives and provide safety-related observations. The religious leader offered insights from a faith-based standpoint.

Eligibility criteria required that key informants be residents of the community for the trial's duration. In-depth interviews (IDIs) were conducted at the

informants' homes to ensure a private and comfortable setting for sharing experiences.

Data collection for focus group discussions

To support the bioethics team (BT), a female research assistant with expertise in research ethics was engaged to help collect FGD data and assist in identifying ethical and social issues. She underwent preparatory training to understand the study's procedures and the application of the Real-Time Research Ethics Approach (RTREA).

Prior to each discussion, participants received a detailed information sheet explaining the study. For those unable to read, the content was read aloud. Participants were reminded that their involvement was voluntary, would not influence their participation in the AHHA trial, and that discussions would be digitally recorded to ensure accuracy, with consent obtained from all. To protect confidentiality, each participant was assigned a unique identification code. FGDs were facilitated jointly by the BT member and the research assistant, with careful observation and documentation of non-verbal cues.

The FGDs were conducted in two distinct phases: the first phase followed the baseline survey but preceded the intervention, while the second phase occurred six weeks into the intervention, just before the endline survey. The BT aimed to hold six to eight discussions per phase, with 8–10 participants per group. Given the challenges of longitudinal data collection, including maintaining participant engagement [20], strict adherence to inclusion criteria and careful monitoring of participant numbers were prioritized.

All discussions were conducted in Chichewa using a pre-tested, unstructured guide anchored by the broad question: "What are your experiences in the trial?" Probing questions were used to gather detailed insights into participants' overall experiences and informational needs. Participants were invited to suggest improvements to trial procedures and identify areas requiring attention from the Trial Implementation Team (TImT). The unstructured format allowed participants' narratives to shape the conversation, revealing aspects of trial experience not captured in prior reports.

Following the initial discussions, an open-ended interview guide was developed, covering seven key areas: participants' perceptions of the AHHA trial; myths and misconceptions; experiences with informed consent; information needs of participants and the community; understanding of roles and responsibilities; local decision-making norms; and everyday experiences within the trial. The guide was prepared in Chichewa and translated into English.

After each FGD, the research assistant compiled session notes into a consolidated report, which was shared with the TImT for follow-up actions and used to refine questions for subsequent data collection. **Figure 1** illustrates the timeline for FGD data collection.

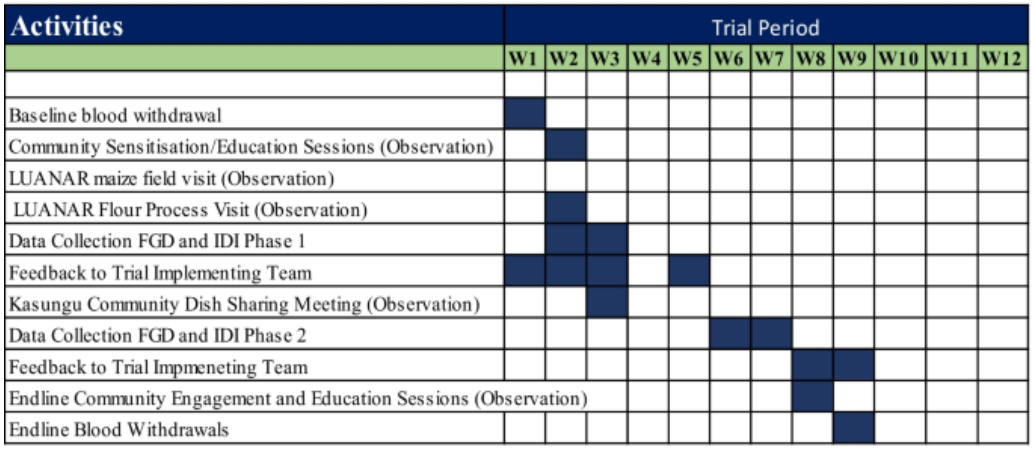

Figure 1. Timeline of data collection, reporting, and study activities (Weeks 1–12)

During the first phase, demographic information was collected from participants, including age, education level, marital status, and prior involvement in clinical research. Participants ranged in age from 35 to 50 years, most had completed primary school, and the majority were engaged in farming. Each FGD during this phase lasted approximately two hours.

The second phase involved follow-up FGDs with the same participants from phase one. These discussions focused on participants' experiences with the AHHA

trial, factors facilitating adherence to the intervention, perceptions of maize flour safety, challenges such as circulating rumors, and social and ethical issues identified by the participants themselves.

Key informant in-depth interviews (IDIs)

All IDIs with key informants (KIs) were conducted by the BT member and research assistant using open-ended questions. Interviews were conducted in Chichewa, each lasting 40–60 minutes, and participants provided consent for audio recording. A total of fourteen IDIs were conducted with local chiefs, community volunteers, TPs, and religious leaders. Participants were purposively selected to capture a diverse range of perspectives, social standing, and community responsibilities, including their roles related to the AHHA trial [18].

The IDIs explored similar themes as the FGDs: (1) perceptions of the AHHA trial, (2) myths and misconceptions, (3) experiences with informed consent, (4) informational needs of participants and the broader community, (5) understanding of roles and responsibilities, (6) decision-making practices, and (7) participants' everyday experiences within the trial.

Structured observations

Structured observations were employed to capture real-time interactions and behaviors, a critical component in action research [20]. An observation schedule was developed to systematically record interactions and activities between TPs and the TImT, including discussions about concerns, questions, and engagement during trial procedures [19]. These observations helped clarify trial procedures and strengthen trust between participants and the research team [21].

A total of five structured observations were conducted throughout the AHHA trial **(Table 1)**, with each session lasting between one and two hours.

Table 1. Number of interviews and activities conducted at each time point

Activity Type	Baseline Study (Pre-Intervention, After First Blood Donation)	Community Sensitisation Meetings	Pre-Flour Distribution	During Intervention (Flour Consumption Period)	Endline Study (Pre-Second Blood Donation)	Enumeration	Total
Reports/Documentation	2	5	1	3	2	2	15
Structured Observations	1	1	1	1	1	0	5
Focus Group Discussions (FGDs)	5	0	0	0	5	0	10
In-Depth Interviews (IDIs)	7	0	0	0	7	0	14

Trial reports

The development of the FGD and IDI guides was primarily informed by insights drawn from prior trial documentation and structured observation records. The research team reviewed 15 trial reports produced by the TImT, which detailed activities conducted throughout the AHHA trial, from initiation to completion. For example, the identification of circulating rumours and their potential effects on trial outcomes—highlighted in earlier formative studies and previous reports—directly informed the creation of interview questions addressing these challenges.

Data management and analysis

All interviews were audio-recorded and transcribed verbatim by two Malawian transcribers hired for the study. The transcripts were reviewed iteratively during data collection to gain a comprehensive understanding of participants' experiences, perceptions, and reflections on the AHHA trial [19]. Researchers documented actions, experiences, and events using memos [22], and coded the data continuously to map participants' overall experiences, perceptions, and trial events. Interactions and behaviors observed during trial activities were also examined. Initial findings from the interviews were compiled into reports and shared with the TImT. Following the first round of coding, a structured coding dictionary based on the decision-making triangle (DMT) framework was developed. All data management and analysis were conducted using NVivo 12.0 software.

Decision-making triangle (DMT) framework

The DMT framework [23] guided the analytical process, offering a structured approach that integrates empirical evidence and ethical reasoning to inform decision-making. At its core, the framework emphasizes reflection on ethical principles to support systematic ethical analysis. The BT applied these principles throughout the data collection and analysis process. Triangulation of multiple data sources—such as FGDs, IDIs, and structured observations—enabled identification of social and ethical challenges and informed the team's decision-making.

The DMT framework comprises three key constructs that facilitate ethically grounded decisions while considering practical implications and stakeholder responses. In the context of the RTREA, these constructs were applied as follows: (1) Researchers determined strategies to achieve desired health outcomes while minimizing potential harm. (2) In making these decisions, they adhered to principles reflecting their values, responsibilities, and obligations, including respect for persons, confidentiality, privacy, informed consent, and non-maleficence, which were consistently applied when addressing emerging ethical and social issues. (3) Researchers critically assessed available information and considered the consequences and feasibility of possible actions and responses.

The DMT framework supports an iterative process promoting stakeholder interaction, dialogue, and inclusion. During analysis, the BT combined deductive coding—applying ethical principles and concepts from empirical ethics—with inductive approaches to identify additional emerging codes and determine relevant ethical considerations.

Throughout the study, the BT systematically documented reflections, observations, research procedures, and analytical processes. Thematic content analysis [24], guided by the DMT framework, was used to evaluate the applicability of the RTREA in agriculture, nutrition, and health (ANH) research contexts.

Ethical considerations

Because this study involved enrolling women in a community context, the ethical obligations went beyond minimal risk. Approval for this ethics study was obtained from the College of Medicine Research Ethics Committee (COMREC; P.03/19/2633), while the AHHA trial itself had received clearance from both COMREC (P.11/18/2539) and the London School of Hygiene and Tropical Medicine Interventions Research Ethics Committee (16181).

Potential participants were approached through TImT-led sensitisation meetings, during which the trial sensitisation coordinator introduced the ethics study before any data collection took place. Written informed consent was obtained from all participants, and information sheets were provided to clarify the purpose and scope of the ethics engagement activities. For participants unable to read, a witness assisted in ensuring comprehension. Participation was entirely voluntary, and participants were reminded that declining or consenting would not influence their involvement in the AHHA trial. Anonymity and confidentiality were strictly observed, and FGDs and IDIs were held in neutral locations, such as school blocks or village court grounds, situated away from participants' homes to protect privacy.

Given that discussing personal views about the trial could potentially cause stress, the BT's role was carefully explained by the TImT. Prior to each FGD or IDI, participants were informed that these discussions were intended as safe spaces to share their experiences and opinions freely, enabling the team to identify and respond to emerging ethical or social concerns [20].

Results and Discussion

Before evaluating the broader implications of a real-time ethics approach for ANH research, it is important to summarise the findings from the embedded activities.

Implementation of the RTREA

The RTREA was systematically incorporated into the AHHA trial to create structured opportunities for collecting detailed data on ethical conduct and for facilitating participatory assessment. The approach allowed the TImT to review reports and analyses prepared by the BT prior to making decisions, integrating participants' suggestions and concerns. This process generated evidence **(Table 2)** that supported informed ethical deliberation.

Deliberative methods were employed among the TImT, BT, and trial participants to explore participants' values, preferences, and priorities, and to resolve conflicts between competing ethical principles while considering contextual factors. This iterative process ensured that decision-making was grounded in both empirical data and ethical reflection, reflecting participants' lived experiences and the practical realities of the trial setting.

Table 2. Overview of activities facilitated by the bioethics team and associated outcomes

Date/Time	Activity	Task	Participants	Key Issues	Data Type	Bioethics Team Role	Outcome
October 2018 – Annual Planning Workshop	In-person discussions with trial implementation team	Lead discussions to identify ethical challenges across study activities	Bioethics Team, Laboratory Team, Soil Experts, Trial Management Team, Economists	Patient safety, informed consent procedures, study design, participant compensation, community engagement, maize distribution	Ethno-Notes	Guided deliberation on study design impact, safety, and consent practices	Creation of safety reporting tools, community education strategy, ethics training for study staff, and informed consent evaluation methods
Formative Research	Surveys and questionnaires with potential participants and trial staff	Assess community perceptions and identify potential ethical concerns	6 Focus Group Discussions, 7 In-Depth Interviews with community members	Concerns about family planning and infertility, blood sampling fears, witchcraft beliefs, social stigma	Interviews	Ensured understanding of study objectives and procedures	Protocol revisions and integration of real-time ethical approaches
April 2019 – Maize Field Visit	Direct interaction with community representatives	Explore community views on maize production procedures	Community representatives, LUANAR team, Ethics Team	Rumors about maize fields, cultivation protocol, fertility concerns, double-blinding, flour consumption	Ethno-Notes	Communicated community experiences, concerns, and perspectives to trial team	Design of community education sessions
July 2019 – Baseline Study	—	—	—	—	—	—	—

September 2019 – Endline Study	September 2019 – Endline Community	August 2019 – Dish Sharing Meeting	July 2019 – Flour Processing Visit	July 2020 – Community Engagement & Information Session
Interactive discussions between trial participants and ethics team	—	In-person gathering with community representatives	—	Face-to-face meeting with broader community
Evaluate ethical and societal issues of the AHHA trial and identify best practices for respect for persons	—	Assess community perspectives on flour production process	—	Facilitate open discussion and interactive engagement between community and trial team
5 Focus Group Discussions, 7 In-Depth Interviews with community members	—	Community representatives, LUANAR team, Ethics Team	—	Community members, LUANAR team, Ethics Team
Blood donation procedures, trial access, participant compensation	—	Countering rumors, reducing fear about flour, building trust	—	Flour safety, consumption procedures, study milestones, participant responsibilities
Interviews	—	Ethno-Notes	—	Ethno-Notes
Promoted ethical awareness in result-sharing	—	Identified information needs and safety concerns	—	Reinforced consistency and trust in the trial process
Development of protocol for dissemination of study results	—	Reduced community fears, addressed safety issues, strengthened trust, enhanced informed consent, and increased participant engagement	—	Improved community engagement strategies, strengthened informed consent processes, addressed participant roles and myths

Ethical challenges: mapping and analysis

Drawing on the RTREA framework, the DMT constructs **(Table 3)** were utilized to detect and examine the central ethical issues. The identified codes were then organized into categories and overarching themes, which form the basis of the results. Five key themes emerged from the analysis: (1) employing adaptive and constructive strategies to address diverse ethical dilemmas during the research process; (2) serving as a driver for participant engagement and reflection on their roles; (3) enhancing

the informed consent process; (4) supporting participant empowerment; and (5) acknowledging and appreciating the participants' lived experiences and perspectives. The following sections elaborate on these themes.

Table 3. Theme development based on DMT concepts

DMT Constructs	RTREA Applications (AHHA Trial Decisions/Outcomes)	Emergent Themes
Ethical Principles: beneficence, non-maleficence, empowerment, social responsibility, participation, transparency, accountability, fairness	Conducting educational sessions with the trial team and participants	• Adaptive and constructive methods to address ethical challenges during study implementation • Stimulating participant involvement and reflection on their roles • Strengthening the informed consent process
	Field visits to maize plots, flour processing demonstrations, community gatherings, and customized educational sessions	
	Mobilization of community volunteers	
	Consultation with local leaders	
	Ethics workshops, protocol reviews, ethics approvals	
	Use of consent forms and participant information sheets	
Evidence	Focus group discussions	• Recognition of participants' lived experiences and perspectives
	Review of trial reports	
	Observational notes	
	In-depth interviews	
Guiding Assumptions	Upholding autonomy	• Enhanced informed consent
	Promoting voluntary participation	
	Respect for persons	
	Ensuring privacy and confidentiality	
	Maintaining participant safety	
Decision-Making	Planning study design and activities, prioritizing participant safety, community engagement, fostering positive participant experiences, results dissemination, community exit plans, ethics training	• Encouraging participant empowerment

To ensure ethical conduct throughout the AHHA trial, measures were implemented to strengthen informed consent, mitigate potential social harm, and enhance the experiences of trial participants (TPs). These measures included ethics training for the Trial Implementation Team (TImT), formative research activities, ethics workshops, and various trial procedures executed across the study setting **(Table 2).**

Responsive and constructive approaches to addressing ethical challenges

The RTREA framework facilitates the integration of ethical principles into the research process while maintaining real-time awareness of emerging issues. In the AHHA trial, this approach aimed to safeguard participants' welfare, support the well-being of research staff by providing structured mechanisms to discuss and analyse challenges, and uphold scientific integrity. Incorporating RTREA enabled a dynamic, ongoing engagement with ethical issues through systematic data collection, providing evidence to guide deliberations and decision-making.

Focus group discussions (FGDs) and in-depth interviews (IDIs) highlighted several social and ethical concerns. Participants expressed anxieties and rumours such as: (1) donated blood being sold, (2) blood donation leading to death, and (3) fortified flour causing male fertility problems. Additional challenges emerged around social interactions, misunderstandings about community randomisation, therapeutic misconceptions, views on compensation, misconceptions regarding voluntariness, and expectations regarding the return of study results. These issues presented both ethical obligations and practical implications for the research team.

Further evidence to support ethical mapping and analysis, as outlined in the DMT model, was collected as issues arose. TPs reflected on their study responsibilities, while the TImT were encouraged to consider the potential impact of their actions on participants and overall research outcomes. Consistent with the DMT approach, evidence was gathered to assess both positive and

negative experiences of TPs and the broader community. For instance, participants emphasized the importance of receiving study results:

"The main thing that we expect is that when this program is completed we should see the outcome" (FGD 201, Phase 1, participants and partners).

However, there was uncertainty about how researchers should fulfill this obligation. In community-based studies, especially those influenced by rumours, myths, or misconceptions, the way results are communicated can expose participants to social harm. TPs expressed concerns that trial results might show no effect, which could be interpreted as failure on their part:

"It would be very satisfying if what the Bunda people wanted from our bodies worked. But if it doesn't, it would be worrying because the ridicule we face would never end. If the results meet expectations, then we can answer those who mocked us" (FGD 304, Phase 2, participants and partners).

"Another worry is whether the researchers will just leave once the study ends. Will they say 'bye' and not follow up? Our concern is that after we stop consuming the flour and encounter issues, will they continue monitoring us, or will the relationship end?" (FGD 305, Phase 2, participants and partners).

Stimulating participant engagement and reflection on roles

Within the AHHA trial, the RTREA functioned as a dynamic mechanism supporting the Bioethics Team (BT) in its knowledge broker role [25], by identifying information gaps and promoting meaningful interactions among trial participants (TPs), local communities, and the Trial Implementation Team (TImT). This approach guided the creation of strategies to enhance participants' understanding and adoption of their study responsibilities. The BT leveraged insights from prior empirical studies on ethical challenges in low-resource research settings [26], issues arising from participation misconceptions without consideration of associated risks [27], and informed consent practices, particularly regarding the management of emotional responses and culturally sensitive concerns [28], to navigate potential ethical complexities during the trial. Moreover, the researchers examined how interpersonal engagement shapes participants' comprehension and the perceived value of their experiences [29, 30].

A careful examination of the contextual environment was essential, particularly in communities with limited exposure to clinical research, the involvement of minors or vulnerable groups, and potential for research-driven myths and blood-related misconceptions. The BT actively encouraged constructive feedback from participants, which helped identify potential ethical lapses and highlighted factors that could either support or hinder study participation, adherence, and retention. Being embedded within the trial allowed the BT to facilitate dialogue without compromising relationships with stakeholders. The "conversation spaces" they established emphasized the role of interpersonal, interactive, and social skills in unpacking complex trial issues or addressing sensitive topics. Through RTREA, the TImT was able to develop a shared understanding of emerging challenges and collaboratively design strategies to address them effectively.

Strengthening informed consent

Ethical principles were integral to the trial, and the RTREA created opportunities to actively engage participants while assessing their information needs at multiple points. Various approaches were used to determine the adequacy of information delivery, ensuring transparency, accountability, and active participant involvement. The BT played a central role in interpreting participant feedback and contextualizing it to meet local needs. This process allowed TPs to voice concerns, fears, and misconceptions openly, with the TImT responding by tailoring information-sharing sessions to address specific issues.

The RTREA fostered an enriched informed consent environment by enabling independent interaction between participants and the BT, creating spaces where participants could discuss their experiences, ask questions, propose solutions, seek clarification, and engage with key community stakeholders. As one participant expressed:

"…We would very much like our colleagues explaining these matters to continue visiting. They should come periodically to teach those left behind so they can catch up with the group, understand the process, and know where they are coming from and where they are going" (IDI 102, Male Volunteer, Phase 1).

Fostering participant empowerment

Empowerment was central to the RTREA, with procedures designed specifically to enhance trial participants' (TPs) agency. Mechanisms were implemented to capture and integrate TPs' perspectives

and experiences through participatory methods applied widely in the AHHA trial, including workshops, in-depth interviews (IDIs), focus group discussions (FGDs), field visits, sensitisation meetings, and shared meals. These activities promoted the development of trust through informal conversations and reciprocal information exchange. Tailoring information to participants' needs—making it understandable and relevant—required facilitation, a role undertaken by the Bioethics Team (BT). Insights from IDIs and FGDs were systematically reported to the Trial Implementation Team (TImT), ensuring participants' views were integrated into trial processes. This approach underscored the importance of responding to information needs while being attentive to context, emerging perspectives, and misconceptions that could influence participation and adherence. Although participants received information sheets, these interactive, participatory approaches were valued by TPs as critical avenues for engagement.

The RTREA adopted a participant-centered approach, placing TPs and their communities at the core of dialogue and knowledge sharing. Activities such as flour processing tours, maize field visits, and communal meals enabled participants to actively engage, seek information, and address negative perceptions or misunderstandings. This process encouraged participants to articulate concerns, challenge misconceptions, and reason through their experiences. As one participant noted:

"…For us to remain determined to complete this research, it is because we were brave from the beginning. Regardless of what others say, we want to see it through because we recognize its importance. The researchers visit us frequently to check changes in our bodies, any problems, or how we have adapted. They explain the purpose of the blood samples, so we understand zinc levels before and after consuming the flour. This motivated us to continue—we volunteered and are committed to seeing it through" (FGD 304, Phase 2, Study participants and their partners).

The BT's embedded presence in the community illuminated participants' informational needs and values, allowing researchers to foster trust and ensure relevant information was shared. This engagement also prompted the TImT to critically reflect on ethical responsibilities, particularly regarding privacy and confidentiality, and to weigh these against the context, participants' preferences, the importance of trust-building, and the need to share useful information. For example, decisions regarding whether to maintain confidentiality around adverse events versus publicly sharing outcomes to counter rumours and alleviate fears required careful ethical consideration. Ultimately, participants preferred transparency, valuing openness and the sharing of relevant information.

Recognizing participants' lived experiences

A central element of being responsive and reflective involves gathering and considering evidence, a core component of the DMT model. It is essential to understand the potential effects of an intervention and identify who may experience its consequences, emphasizing the importance of using relevant and appropriate evidence. A key aspect of the RTREA is its focus on acknowledging and reflecting on participants' experiences within the trial, taking into account how these experiences influence compliance, retention, and participant safety. This approach enables researchers to design strategies that mitigate negative impacts and enhance positive trial experiences by addressing the collective and individual values, beliefs, norms, and needs of participants.

Ongoing assessment of TPs' experiences revealed that the specific language and terminology used within communities significantly influenced participants' engagement and responsiveness to trial requirements **(Table 4).**

Table 4. Key terms reflecting the implied impact of study activity participation

Term	Data Collection Phase and Method	Interpreted Impact on Study Activities
"Chitonzo" ("ridiculed")	FGD Chimsekesa, Phase 2	Worries about negative trial results being shared with the broader community
"Kupopa" ("sucking")	FGD 203, Phase 1, Trial Participants and partners	Exaggeration of blood volumes collected; concerns regarding blood donation

"Chikondi cha Nkhwagwa chokoma pokwera" ("The love of an axe sweet during climbing")	IDI 101, Phase 2, Trial Participants	Anxiety about post-trial access to food and potential exploitation
"Kuchirandira" ("receptive")	FGD 203, Phase 1, Trial Participants and partners	Misunderstandings related to voluntariness of participation
"Ufa ndi moyo" ("food is life")	FGD 305, Phase 2, Trial Participants and partners	Therapeutic misconceptions regarding the study intervention
"Kuzipereka" ("special")	FGD 304, Phase 1, Trial Participants and partners	Misperceptions about voluntariness of participation
"Mwabetsa" ("sold")	FGD 203, Phase 1, Trial Participants and partners	Concerns and mockery related to blood donation practices

A careful reflection on these terms and participant interactions allowed the Trial Implementation Team (TImT) to refine their communication approaches. For instance, visual aids—such as showing vacutainers during sensitisation meetings—were used to complement verbal explanations and help participants understand blood donation procedures. In addition, information tailored to support formal consent processes and participant information sheets was widely disseminated to clarify misconceptions about blood and address concerns.

The operationalisation of the Real-Time Research Ethics Approach (RTREA) represents an innovative strategy, particularly in applying it within Agriculture, Nutrition, and Health (ANH) research to monitor and address ethical issues as they arise during the study. This approach appears to be an effective tool for reflecting on ethical principles and guidelines, aligning with initial study planning, Research Ethics Committee (REC) requirements, and broader ethical standards [6]. The RTREA facilitated the identification and management of key aspects necessary for conducting ethically robust research, including mindfulness toward ethical and social concerns, analysis through ethical principles, and practical implementation according to context-specific guidelines. Findings indicate that while ethical norms establish researchers' obligations—such as sharing study results with participants [29, 30]—the RTREA enables the application of meaningful, context-aware ethical practices that build trust and strengthen the research partnership. Researchers are encouraged to critically reflect on their ethical competence, acknowledging the ethical dimensions guiding good research practice and responding appropriately to emerging challenges [9]. The approach also allowed for contextual understanding, deliberation on social and ethical concerns, and the establishment of measures to protect participants from potential social harm [31].

Structured reflection sessions with TPs and key stakeholders created "conversation spaces" [25] that opened the complex ethical dimensions inherent in ANH research. These spaces, embedded within existing community structures, were driven by ongoing dialogue and learning from stakeholders. Facilitating discussion sessions and interactions proved essential to supporting participation and implementing ethical principles in real time. As Lorraine [26] highlights, participatory approaches help identify and resolve ethical dilemmas. Engaging participants actively in discussing trial experiences, sharing perceptions, and proposing solutions not only ensures that researchers uphold ethical obligations but also encourages responsive problem-solving [7].

The findings demonstrate that RTREA emphasises the value of interactive sessions, fostering dialogue with multiple stakeholders while considering group dynamics and information needs [32]. The BT played a critical role in supporting the ethical requirement of informed consent [32], offering guidance and insights on participants' informational needs. This approach enabled researchers to move beyond assumptions about protocol functioning in practice, providing real-time evidence of participants' experiences. RTREA further empowered participants, allowing them to ask questions and actively engage as research partners rather than passive subjects [33]. In identifying information needs, the process uncovered participants' prior knowledge and experiences, which are vital for constructing new understanding. Learning encounters for adult participants incorporated interactive methods, such as discussion and question-and-answer sessions, which facilitated engagement with TPs and their communities. Additionally, adult learners'

informational requirements were systematically explored by documenting rumours, myths, and misconceptions, enabling the TImT to develop tailored messages to address and correct them. Finally, drawing on existing frames of reference and participants' prior knowledge helped strengthen comprehension of study concepts, design, and activities, consistent with findings from other studies [29, 33, 34].

This study further illustrates that the RTREA enabled the Trial Implementation Team (TImT) to take empirical insights from trial participants (TPs) seriously, facilitating a deeper understanding of the cultural context, engaging directly with participants, and genuinely considering their experiences, including factors that could support or hinder enrolment, adherence, and retention. The Bioethics Team (BT) played a central role in fostering key communication practices, combining both informing and inquiring to help participants make decisions regarding trial participation [34]. The informing process involved providing participants and communities with evidence and explanations about study objectives, safety measures, benefits of adherence, and potential consequences of non-compliance [34]. Inquiring focused on assessing participants' prior knowledge, expectations, fears, and beliefs, often shaped by social networks or external sources, which could influence recruitment, retention, and compliance [32, 33]. Providing this information empowered TPs to make well-informed decisions about their involvement in the trial.

Through the RTREA, participants were actively involved and encouraged to share their lived experiences. Various engagement activities created opportunities to discuss trial experiences, reflect on ethical research responsibilities, and consider the consequences of participation [7]. The RTREA proved valuable by mapping and communicating the complex dimensions of participants' lived experiences in real time, giving the approach practical relevance. Strategies to keep staff motivated and informed on protecting TPs included iterative dialogue and feedback from the BT, supporting their ability to make ethical judgments about trial activities. By centering TPs' experiences, the RTREA not only strengthened informed consent but also fostered participant ownership of study responsibilities, enabling them to challenge misconceptions, reason through concerns, and build self-efficacy.

It is also important to acknowledge the positionality of the BT as facilitators of the RTREA while remaining part of the broader project. While this dual role carries some inherent risks, the combination of structured interactions with key informants, formal report writing, clearly defined focus group and interview protocols, local REC oversight, and adherence to ethical principles provided a framework that reinforced the integrity of the BT's work. Although further exploration of positionality is warranted, participatory approaches within the RTREA, as noted by Oviedo-Joekes *et al*., enhanced informed consent [14], promoted a sense of collective ownership [6], and created a research environment that respected and supported TPs' rights and welfare.

Participants' autonomy was assessed by considering how personal and contextual factors—such as relationships with significant others, environmental influences, personal beliefs, prior knowledge, life experiences, and historical context (e.g., previous research participation, interactions with regulators or gatekeepers)—affected their engagement with trial roles and sense of responsibility. Consequently, as highlighted above, the TImT's communication skills were critical for delivering accurate, consistent information and establishing a conducive environment for ongoing dialogue.

Conclusion

This study highlights the potential of the Real-Time Research Ethics Approach (RTREA) for enhancing research practices, particularly in low-resource settings. The RTREA offered a structured mechanism to raise awareness of ethical challenges in ANH research, anticipate the social impact of interventions, and provide support for education, interpretation, and facilitation throughout the study. By creating a platform to discuss and evaluate ethical issues as they arise, RTREA contributed to the wellbeing of both researchers and participants, while promoting scientific integrity and generating more defensible research outcomes.

The approach fosters ongoing dialogue between participants and researchers, facilitating the development of shared understanding and strengthening good research practices. Implementing RTREA through participatory methods and "conversation spaces" created interactive opportunities for stakeholders to engage in mutual learning and comprehension.

Findings from the AHHA trial indicate that participants value sustained, meaningful engagement with the research team beyond formal recruitment and consent requirements approved by Research Ethics Committees

(RECs). Such deeper engagement appeared to enhance recruitment, retention, and adherence, thereby supporting the trial's objectives. Moving forward, additional research is warranted to further refine RTREA and explore both the opportunities and potential challenges of using embedded, real-time ethics tools in ANH and other research contexts.

Acknowledgments: The authors would like to thank the study participants for their time and willingness to share their views and the AHHA trial team members with special mention to the LUANAR Team including Mr. Leonard Banda and Dr. Gabriella Chiutsi-Phiri and the wider GeoNutrition Project Team. The authors would like to thank Mrs. Ruby Zolowere for assisting with the data collection, Ms. Ida Meya for assisting with reviewing and editing the reference list, Dr. M Chikalipo, and Ms. Khama Mita for colleague support, and Mrs. M Khouge for providing a working space during Covid 19 schools lockdown.

Conflict of Interest: None

Financial Support: LM is a registered Ph.D. student from the Department of Health Systems and Policy from the University of Malawi, College of Medicine. This work was sup-ported, in whole or in part, by the Bill & Melinda Gates Foundation through the GeoNutrition project [INV-009129]. Under the grant conditions of the Foundation, a Creative Commons Attribution 4.0 Generic License has already been assigned to the Author accepted Manuscript version that might arise from this submission. The funders were not involved in any stages of the study design or implementation.

Ethics Statement: College of Medicine Research and Ethics Committee (COMREC), an institutional review board of the University of Malawi, College of Medicine reviewed and approved the study. Its ethics reference number is P08/17/1233. Permission was sought from all participating and their letters of support were submitted to the COMREC. Written individual informed consent was obtained from all research participants who participated in the observations, FGDs and IDIs before the interviews. Informed consent included permission to have the results of the study disseminated in research conferences and publications in peer-reviewed journals. All methods in the study were carried out following relevant guidelines and regulations.

References

1. Tom L, Beauchamp JFC. Principles of biomedical ethics. 5th ed. Oxford: Oxford University Press; 2001.
2. Gostin L. Macroethical principles for the conduct of research on human subjects: population based research and ethics. In: Brankowski Z, Bryan J, editors. Ethics and epidemiology: international guidelines. Geneva: CIOMS; 1991. p. 201.
3. Sugarman J, Bredenoord AL. Biomedical research. 2020:2–4.
4. Cordner A, Ciplet D, Brown P, Morello-Frosch R. Reflexive research ethics for environmental health and justice: academics and movement building. 2012:2837.
5. Domecq JP, Prutsky G, Elraiyah T, Wang Z, Nabhan M, Shippee N, et al. Patient engagement in research: a systematic review. BMC Health Serv Res. 2014;14:1–9.
6. Widdershoven G, Abma T, Molewijk B. Empirical ethics as dialogical practice. Bioethics. 2009;23(4):236–48.
7. Cascio MA, Racine E. Person-oriented research ethics: integrating relational and everyday ethics in research. Account Res. 2018;25(3):170–97. doi:10.1080/08989621.2018.1442218
8. Leese J, Macdonald G, Kerr S, Gulka L, Hoens AM, Lum W, et al. Adding another spinning plate to an already busy life: benefits and risks in patient partner–researcher relationships: a qualitative study of patient partners' experiences in a Canadian health research setting. BMJ Open. 2018;8(8):e022154.
9. Reid A, Brown JM, Smith JM, Cope AC, Jamieson S. Ethical dilemmas and reflexivity in qualitative research. Perspect Med Educ. 2018;7:69–75.
10. Guston DH, Sarewitz D. Real-time technology assessment. Technol Soc. 2002;24(1–2):93–109.
11. Joy EJM, Kalimbira AA, Gashu D, Ferguson EL, Sturgess J, Dangour AD, et al. Can selenium deficiency in Malawi be alleviated through consumption of agro-biofortified maize flour? Study protocol for a randomised, double-blind, controlled trial. Trials. 2019;20(1):1–9.
12. Phiri FP, Ander EL, Bailey EH, Chilima B, Chilimba ADC, Gondwe J, et al. The risk of selenium deficiency in Malawi is large and varies over multiple spatial scales. Sci Rep. 2019;9(1):1–8.

13. Chilimba ADC, Young SD, Joy EJM. Agronomic biofortification of maize, soybean and groundnut with selenium in intercropping and sole cropping systems. Afr J Agric Res. 2014;9(50):3620–6.
14. White PJ, Broadley MR. Biofortification of crops with seven mineral elements often lacking in human diets - iron, zinc, copper, calcium, magnesium, selenium and iodine. New Phytol. 2009;182(1):49–84.
15. Chiutsi-Phiri G, Kalimbira AA, Banda L, Nalivata PC, Sanuka M, Kalumikiza Z, et al. Preparing for a community-based agriculture-to-nutrition trial in rural Malawi: findings from formative research. Pilot Feasibility Stud. 2019. Available from: https://pilotfeasibilitystudies.biomedcentral.com/
16. Hawe P, Shiell A, Riley T, Gold L. Methods for exploring implementation variation and local context within a cluster randomised community intervention trial. J Epidemiol Community Health. 2004;58(9):788–93.
17. Bentley ME, Johnson SL, Wasser H, Creed-Kanashiro H, Shroff M, Fernandez-Rao S, et al. Interventions: an overview. Ann N Y Acad Sci. 2014;919:54–67.
18. Kadam R. Informed consent process: a step further towards making it meaningful! Perspect Clin Res. 2017;8(3):107.
19. Bryman A. Social research methods. 5th ed. Oxford: Oxford University Press; 2016.
20. Koshy V. Action research for improving educational practice. 2nd ed. London: SAGE Publications; 2010.
21. Tomamichel M, Sessa C, Herzig S, Dejong J, Pagani O, Willems Y, et al. Informed consent for phase-I studies—evaluation of quantity and quality of information provided to patients. Ann Oncol. 1995;6(4):363–9.
22. Charmaz K. Grounded theory method. 1997:397–412.
23. Tannahill A. Beyond evidence—to ethics: a decision-making framework for health promotion, public health and health improvement. Health Promot Int. 2008;23(4):380–90.
24. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101.
25. Cheetham M, Wiseman A, Khazaeli B, Gibson E, Gray P, Van Der Graaf P, et al. Embedded research: a promising way to create evidence-informed impact in public health? J Public Health (Oxf). 2018;40(suppl_1):64–70.
26. Caballero B. Ethical issues for collaborative research in developing countries. Am J Clin Nutr. 2002;76(4):717–20.
27. Mfutso-Bengo J, Ndebele P, Jumbe V, Mkunthi M, Masiye F, Molyneux S, et al. Why do individuals agree to enrol in clinical trials? A qualitative study of health research participation in Blantyre, Malawi. Malawi Med J. 2008;20(2):37–41.
28. Solomon SR. Protecting and respecting the vulnerable: existing regulations. Theor Med Bioeth. 2014;35(1):1–10.
29. Flory J, Emanuel E. Interventions to improve research in informed consent for research. JAMA. 2004;292(13):1593–601.
30. Mfutso-Bengo J, Ndebele P, Masiye F. Disseminating research results to research participants and their communities. Malawi Med J. 2008;20(2):64–6.
31. Milford C, Barsdorf N, Kafaar Z. What should South African HIV vaccine trials do about social harms? AIDS Care. 2007;19(9):1110–7.
32. Flory J, Emanuel E. Interventions to improve research in informed consent for research. JAMA. 2004;292(13):1593–601.
33. Slack C, Thabethe S, Lindegger G, Matandika L, Newman PA, Kerr P, et al. I've gone through this my own self, so I practice what I preach. J Empir Res Hum Res Ethics. 2016;11(4):322–33.
34. Rautenbach C, Lindegger G, Slack C, Wallace M, Newman P. I'm positive, but I'm negative: competing voices in informed consent and implications for HIV vaccine trials. J Empir Res Hum Res Ethics. 2015;10(2):151–6.