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THE EXPERIENCES OF INSTITUTIONAL REVIEW COMMITTEES IN CONDUCTING POST-APPROVAL AND SITE MONITORING OF RESEARCH PROJECTS IN ETHIOPIA: A MIXED METHOD RESEARCH

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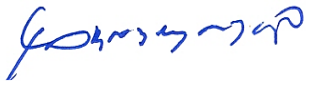
Professor Damen Haile Mariam		8/21/2024
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Acronyms and Abbreviations

AAU-CHS	Addis Ababa University College of Health Sciences
AE	Adverse Event
AHRI	Armauer Hansen Research Institute
CRM	Clinical Research Monitor
EC	Ethics Committee
EMA	European Medicines Agency
EPHI	Ethiopian Public Health Institute
FDA	Food and Drug Authority
FERCAP	Forum for Ethical Review Committees in the Asian and Western Pacific Region
FWA	Federal Wide Assurance
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
IRB	Institutional Review Board
IRERC	Institutional Research Ethics Review Committee
MoE	Ministry of Education
NRERB	National Research Ethics Review Board
OHRP	Office for Human Research Protection's
PAM	Post-Approval Monitoring
PD	Protocol Deviation
PI	Principal Investigator
RA	Regulatory Authority
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Document Verification
SIDCER	Strategic Initiative for Developing Capacity in Ethical Review
SM	Site Monitoring
SMV	Site Monitoring Visit
SOP	Standard Operating Procedure
UK	United Kingdom
US	United States
WHO	World Health Organization

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Abstract

Background: Research showed a high magnitude of research misconduct in Africa. Despite the need, ethics committees in Africa seldom monitor studies after approval. Moreover, research showed inconsistencies in post-approval monitoring by ethics committees and a lack of data supporting the practice. Thus, the study aimed to explore the experiences, opportunities, and challenges of post-approval and site monitoring of studies by ethics committees in Ethiopia.

Methods: A concurrent mixed-method study involving an institution-based cross-sectional, descriptive qualitative study, and a document review of on-site monitoring was done on the fourteen institutions. The quantitative survey was done on 84 members using a self-administered structured questionnaire and 14 in-depth interviews were conducted with purposively selected members from each institution. Moreover, a review of site monitoring reports was done using a checklist. The survey data and document review were analyzed descriptively and the in-depth interviews were analyzed thematically and integrated using MAXQDA software.

Results: Less than half of the members, 39 (46.4%), indicated they had prior on-site monitoring experience and over 84% of the members had previous experience of ongoing review of protocols. The most frequent challenges were a lack of system, resources, and contextual difficulties. The data revealed procedure infractions and deviations during site monitoring, along with the corresponding measures. In addition, the capacity, availability of universities and research institutes, and the existence of trigger factors all presented opportunities for continued follow-ups.

Conclusions and Recommendations: The common passive way of monitoring of studies by ethics committees is inadequate to protect the study participants. Given the presence of such research flaws, it is imperative to strengthen the capacity of the ethics committees and more emphasis should be given to active monitoring of studies by ethics committees and all research stakeholders should support the monitoring activities.

Keywords: Post-approval monitoring, on-site monitoring, ongoing follow-up, research ethics committee

1. Introduction

1.1.Background

A Research Ethics Committee(REC) is an established committee for the primary purpose of the protection of the rights and the safety of the research subjects (1). One of the ways to safeguard these roles is through post-approval monitoring (PAM). Following initial approval, RECs monitor research to make sure that researchers are adhering to protocol and that their work meets the RECs' approval criteria (2). The Institutional Research Ethics Review Committee (IRERC) conducts two types of monitoring visits: passive and active. Passive monitoring is an evaluation of research progress based on information from the approved project. Active visits include a site visit and the use of checklists for monitoring intended activities (3).

Regarding the type of monitoring, several studies agree that on-site monitoring of studies is beneficial for detecting issues that couldn't be addressed by passive monitoring; nonetheless, it is difficult to carry out efficiently due to limited resources. Challenges such as insufficient infrastructure, personnel, money, and time create difficulties in ensuring proper monitoring. This obstacle needs to be addressed, and a way out should be explored to ensure successful research (4–7).

In Africa, limited studies have been done to assess the capacity of RECs despite the need for evidence to support capacity-building activity in ethical oversight (8). Monitoring of studies following clearance by the ethical committee, with the goal of handling protocol modifications and unfavorable outcomes through field visits (if possible) was recommended in Africa (9).

Ethiopian research ethics guidelines require the REC to assess the ethical compliance of clinical trial applications, monitor the trial to ensure adherence to standards, and inform relevant authorities of any violations. The latter may revoke permission if necessary (10). A site visit is needed to make sure the protocol is followed, and REC must set up a tracking system to monitor research with ethical approval (3). However, this system is not working well; budget constraints and researcher non-compliance are the main causes (11).

1.2.Statement of the problem

A study done in the United Kingdom (UK) demonstrated that around 58% of interviewed researchers or research participants were aware of research misconduct (12). In addition, A Nigerian study showed a 69% prevalence of research misconduct among researchers (13).

There have been concerns that REC interference could be seen as excessive and could lead to mistrust between researchers and REC (14). However, in practice, investigators were usually pleased to find issues early and quickly take corrective action. The bigger issue is what to do when GCP violations are detected. Stopping the study should only happen in the most extreme cases, and a gradual process is preferable, which is also in line with REC policies (4).

In the United States (US), plenty of organizations have created monitoring systems, but there's no set protocol for how often they should be done, what kind of things should be monitored, or what methods of monitoring should be followed (15). There's not much evidence from other countries either, so it's pretty much a shot in the dark for organizations to set up monitoring programs. That could mean they don't do enough to make sure their rights and well-being are respected (16).

It is unclear what kinds of onsite monitoring should be required, desired, or not. The oversight procedures that must be adhered to are not made very apparent in the present guidelines (4).

Research has shown that a large number of RECs in Africa seldom monitor studies for compliance with the approved study protocol (17).

As a potential solution, RECs could establish an internal monitoring board for supervising all funded research above-minimum-risk, for which the protocol does not refer to external monitoring. To help their members monitor clinical trial sites more effectively, RECs can also provide training. On the other hand, a Scottish study demonstrated, onsite monitoring of research should be performed on at least 10% of projects, with questionnaires used to track the other projects (18).

Another possible solution is risk-based monitoring puts a lot of weight on source document verification (SDV). SDV helps check that the data on case report forms is appropriate and accurate by comparing it with the data on the source document (15, 16). Although not convenient to do SDV for all the study participants, risk-based monitoring is still a better option when compared to those mentioned above (21).

The review of the body of literature showed disparities in the onsite monitoring conduct, and a lack of data to back up the practice (22).

This study aimed to explore the experiences, opportunities, and challenges faced by RECs in conducting PAM and SM of studies in Ethiopia, in so doing augmenting the ethical conduct of research involving human subjects in Ethiopia and giving a hand to global research ethics revelation.

1.3.Rationale and significance of the study

Practices for gathering and reporting data as well as monitoring experiences should be taken into consideration when creating useful recommendations to ensure maximum effectiveness and efficiency in conducting ongoing monitoring of research (23).

Additional research, including in-depth interviews and surveys with important stakeholders such as REC members, as well as a report review, would give further insight into the PAM (24).

Thus, exploring the experiences of PAM and SM by RECs would help to understand the current status, the contextual features, and the potential advantages of post-approval and site monitoring by RECs.

The results of this study are instrumental for the RECs, policymakers like the Ministry of Education (MoE), and future researchers to plan and implement the appropriate post-approval monitoring of studies.

2. Literature review

2.1. Overview of the current PAM and SM by IRBs

According to the content analysis of the normative papers in the US and European Union (EU), the roles of RECs after approval are periodic oversight of selected studies for reports of the progress, the change of protocols, the occurrence of adverse events, the practice other than the study protocols, and violation of the study protocols (25).

IRBs usually follow a study after initial ethical approval depending on the reports submitted to them by the researchers. A survey of REC members showed that most of the member secretaries do participate in post-approval activities; this includes regularly reviewing protocols, amendments, and completion reports (26). Similarly, A study on the experiences of REC representatives in Europe shows that, once a study has been approved, the main activities include looking over protocol amendments and getting reports at the end of the trial (27). They think RECs should monitor the trials by passively looking at annual progress reports while the trial is going on, and get a final report once the trial is over (27). These studies showed that most of the post-approval follow-ups of a study by the IRBs conducted in a passive approach.

On the other hand, RECs seldom conduct site monitoring of approved studies. A qualitative study in India showed that none of the 5 IECs involved had been out to check the clinical trial sites (28). Also, according to a survey done on IRB members, around 38% of member secretaries didn't take part in the site monitoring. That pretty much sums up how poor the monitoring was (26).

The reason for PAM appears in the routine internal audit results of post-screening audit compliance checks in "non-responding" and "critical" studies (29). According to the study in the US, the most common reasons for site-monitoring by IRBs were as a usual practice regularly and in response to a cause. Routine monitoring could be done for studies involving novel drug tests, studies with significant risk, and studies involving vulnerable subjects (24,30,31).

In Ethiopia, ongoing oversight of a study is recommended (32). It includes active follow-ups using a checklist to visit study sites and passive monitoring by accepting reports from researchers. Follow-up visits include a surprise visit without the knowledge of the investigator and a prearranged visit following the announcement. The kind and the time of visit should be based on the potential harm to the study participants and the level of difficulty in conducting the study. The reasons for the conduct of site visit includes: responding to the reports given to the IRBs, increase

in SAE reports, delayed or non-submission of reports of a study progress as well as end of the study, notification of protocol violations, suspicion regarding change of study methods without the knowledge of IRBs (33).

2.2.Research misconducts found by PAM

Previous studies on site monitoring found several lapses. For instance, a study conducted based on the reports of the European Medicines Agency (EMA) discovered that inspectors, clinical assessors, rapporteurs, and the Committee for Medicinal Products for Human Use (CHMP) routinely come across ethically significant findings that at least might adversely affect the rights, safety, or well-being of the subjects, or GCP non-compliance findings that are at least graded major by inspectors (34).

Moreover, based on the results of a retrospective study carried out in India, which evaluated 12 studies that were both investigator-initiated and sponsored, violations of the informed consent process were discovered at eight out of the twelve sites. The IEC monitoring teams discovered that at six out of the twelve study sites, there was a lack of knowledge about the study protocol and/or the ICD; five of the study teams were deviating from the original study plan; at four of the twelve study sites, the monitoring team discovered that the study teams had not submitted their progress reports on time; and at three different study sites, the monitoring team discovered that there were missing source documents, that trial-related documents were not properly stored at the study site, and that there had been either late or total the failure to report the SAE by the study teams and the sponsor's refusal to compensate the patient(s) for the SAE (35).

Furthermore, according to a US study, problems with the recruitment processes, discrepancies between informed consent, and episodes of non-compliance were found (24).

Regarding the breaches, according to a study conducted in Korea, the novel screening audit approach was able to identify significant GCP breaches (29).

According to the study done in Uganda, a review of a total of 28 site monitoring visits on 40 research projects showed that 25% of the site monitoring reports didn't meet the regulatory requirement for valid ethical approval, 36% had problems with informed consent, 28% saw violations of research participants' rights and welfare, 38% didn't report any SAEs to the relevant authorities, and a lot of sites lacked adequate GCP and Good Clinical Laboratory Practice (GCLP).

On the plus side, most of the sites had enough facilities and good working practices (36). In summary, during the ongoing monitoring of studies, issues related to ICD, PD, non-reporting of SAEs, and inadequate protection were some of the findings.

2.3.Actions taken by IRBs to the identified deviations

In response to the identified gaps through PAM, several corrective actions were taken by IRBs depending on the type of the problem. For instance, **For Protocol deviation:** clarification requested along with a strong cautionary note about potential recurrence; **Deviation from the investigational plan:** limitation on hiring in the future and sponsor submission of audit reports; **Failure to disclose research progress to IEC:** Provide an explanation along with a strong caution not to repeat the study in the future; **Inadequacies in research supervision:** It is proposed that more individuals be added to the study team; **SAE reporting:** AE reports must be submitted; **Lack of investigator awareness (protocol and ICD):** It is advised that GCP training continue (37).

Similarly, the corrective actions taken by the IEC included ordering the retaking of consent, retraining in good clinical practice (GCP), requiring interim reports, explanations for deviations, upgrading of facilities, and payment of pending compensation. The IEC even froze the review of protocols from a frequently defaulting Principal Investigator's (PI) site and delaying recruiting for studies involving the same PI (35).

2.4.Objectives of post-approval monitoring

Monitoring medical research that involves humans has a lot of different purposes. Basically, it is all about making sure that the research is done in a way that meets scientific, safety, and ethical standards. The aims of ongoing follow-up of studies by IRBs are enabling the practice of research in accordance with ethics, guaranteeing the wellbeing and safety of the research subjects (6), maintaining ongoing support to researchers through education (38), guaranteeing the integrity of research as well as quality enhancement (38,39). Generally, the main objectives of PAM are, research integrity, well-being and safety of the research subjects, educational support to the researcher, and quality ascertainment.

2.5.Challenges and opportunities of conducting post-approval and site monitoring

A bunch of studies have pointed out that there can be some challenges when it comes to PAM and SM by IRBs. For instance, there have been a lot of arguments regarding the role of IRBs after the

initial approval and whether this role should be given to them or other stakeholders of research like the Data Safety Monitoring Board (DSMB) as well as CRMs. For instance, a study in the US found that sponsor monitors might not have the expertise or medical training to spot some violations. It could be argued that sponsor monitors might be biased in favor of keeping a study going, so they could miss out on issues that an IRB might consider vital. This same idea could be applied to GCP inspectors who are more concerned with the safety of the drug than ethical matters (24).

In addition, as a qualitative study in India, most of the people in charge of the IEC think a third party should be responsible for checking out the clinical trial site unless someone from the IEC is specifically assigned to do it. Moreover, an IEC member from a private hospital said the sponsors and investigators should be the ones in charge of tracking the trial's progress (28). Another study in India reported that an already existing monitoring system in a clinical trial could be a challenge, despite prior monitoring by sponsors' representative Clinical Research Monitors (CRMs), the REC uncovered GCP violations and discrepancies. This may be due to a lack of expertise, experience, or training in terms of monitoring. CRMs generally focus on documentation and verifying source documents, but may neglect other aspects (4).

Another study in India concluded that, even though researchers and IRBs disagree on some issues regarding the role of continuing review, such as those that could compromise the element of trust between them, and some consider continuing monitoring to be exceptionally expensive, ongoing monitoring and timely project reviews by IRBs ensure that research is conducted ethically. In order to accomplish the ultimate goal of training researchers and ensuring the safety and well-being of participants, ongoing evaluation by IRBs should be acknowledged as a method of quality assurance rather than as moral policing (6).

According to an Australian study, the difficulties are as follows: research ethics committees have historically monitored reports, but because of their volume and frequency, particularly in pharmaceutical research, this role is imaginary because the committees lack the knowledge, access to scientific expertise, or technological know-how necessary to evaluate the reports' implications. The role of research ethics committees, however, appears to be minimal or nonexistent given that the difficulties go outside their normal areas of competence and demand power they do not possess (40).

Active or passive monitoring may be challenging due to concerns including organizational structure, resources, and legislative support. On the other hand, the PAM program gets legislative support in the US even though it is not required by law. This is particularly true for organizations that receive federal funding for their research (24). "Most challenges are resource related, such as insufficient training and insufficiently varied expertise on existing ECs and overstretched EC members," according to another Indian study that corroborated the resource issue (4). Apparently, RECs didn't have enough staff and were already stretched thin with various activities on hand, so they couldn't make it happen. As a result, they are totally dependent on the investigators to give them updates on progress, reports on serious adverse events, and information about any protocol amendments (28).

Moreover, many post-approval submission challenges were mentioned by the study conducted in India, including late submissions, a lack of reviewers, prolonged review periods, and an excessive amount of paperwork, faced by RECs. REC members also experienced problems with SAE, PD, and SMV. Regular training, SOP awareness, hiring more employees and assistants, acknowledging REC's work as a full-time position, and a digital monitoring system were among the solutions suggested by this study (26).

On the other hand, a research project conducted in Uganda showed that it is possible and budget-friendly to monitor compliance even in low-income countries. Nonetheless, it's important for REC to review and approve studies, and have plans for monitoring compliance. On-site monitoring is usually the best way to make sure everything is done properly, but it's often overlooked by RECs because it's expensive and takes a lot of resources in terms of human and financial (36).

The mainstreaming of monitoring activity in the program of educations, the development of self-assessment of PIs, and the need for trust development between the community were the opportunities of PAM (39).

AAU-CHS also had mechanisms in place for the follow-up of approved proposals. However, the ability to effectively follow up on approved proposals is hindered by inadequate budget and lack of researcher compliance. Follow-up is a critical step in the process of protecting research subjects, yet the IRB lacks the capacity to ensure it is completed (11).

In conclusion, the challenges can fall into five themes; an unclear role for EC/IRBs, human or financial resource constraints, overburdened EC/IRBs with their main workload, lack of training,

competency, and culture to conduct ongoing monitoring among ECs, and lack of established supportive system for the conduct of ongoing monitoring of medical research for the good outcome in terms of scientific, safety and ethical standards.

Moreover, despite PAM being a recommended practice according to various literature and guidelines, the experiences of RECs were scattered, and the approach for the PAM and SM was not clearly stated.

2.6.Conceptual framework

The PAM experiences were classified under active and passive monitoring. The reasons for the PAM were as a routine activity and for specific reasons. In the SM, several gaps have been identified and corrective actions taken. The most common challenges were resource gaps and lack of competency. On the other hand, the opportunities were trust issues, mainstreaming in the education system, and the need to avoid misconduct. Several suggestions were given by the RECs.

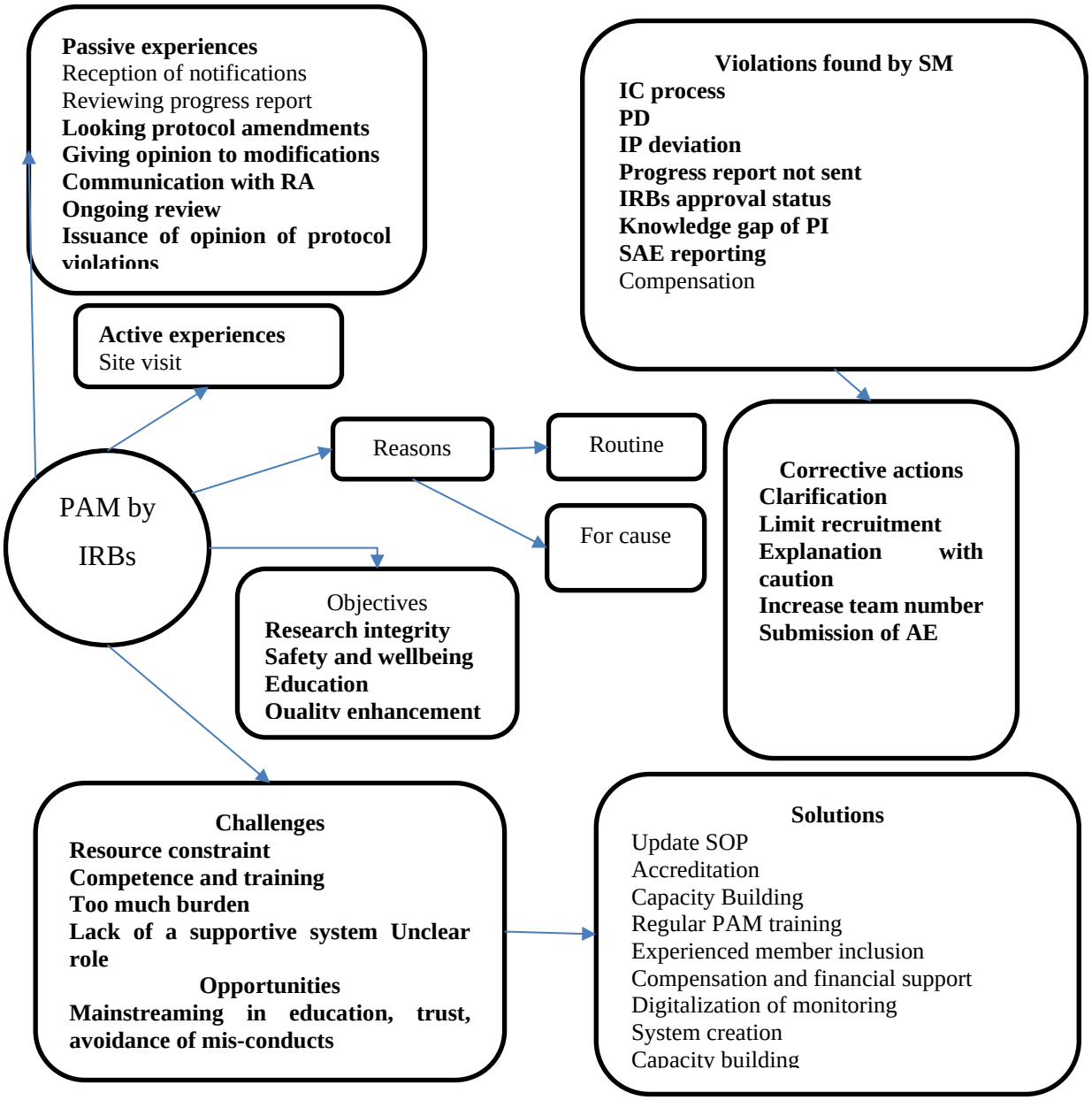

Figure 1: Conceptual framework developed from the literature reviews (25-40).

3. Objectives

3.1.General objective

To explore the experiences of research ethics committees in conducting post-approval and site monitoring of research projects in Ethiopia.

3.2.Specific objectives

1. To assess the experiences in post-approval monitoring by IRB/ ECs in Ethiopia;
2. To explore the opportunities and challenges in conducting post-approval and site monitoring by IRB/ECs in Ethiopia.

4. Method and materials

4.1.Study setting

Nationally in Ethiopia, a system for research ethics is coordinated by the Ministry of Education (MoE). Based on the capacity and the functional level, all IRBs in Ethiopia are categorized as level A and level B RECs **(Table 10)** and should be registered by the NRERB Secretariat (3). Level A RECs are assigned based on their roles, for instance, they can handle the responsibilities of NRERB on their respective institutions; all members have had ethics and GCP training; Adhere to the international Guidelines, and have clear SOP; Have good support from their institutions; adequate research volumes at least once annually. There are 19 institutions registered at the NRERB, MoE. Out of them, thirteen institutions are registered as "level A" IRERC. Thus, the study was conducted in four research institutes, five academic institutions, three professional associations, and one hospital.

There are only three IRBs have been registered and recognized by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) as well as, Pan-African Bioethics Initiative (PABIN). Those are AAU-CHS-IRB, the Ethiopian Public Health Institute (EPHI), and the Armauer Hansen Research Institute (AHRI). Except for the above IRBs, the others have not been assessed for their adherence to international and national guidelines. In Ethiopia, there is no formal registration public database for IRBs (41).

4.2.Study Design and Approach

An institution-based cross-sectional study was conducted, and a document review of site-visit reports was done from March to April 2024.

In addition, a descriptive qualitative study was conducted concurrently. The descriptive qualitative approach is a flexible design, minimal theory-based, and permits the investigators to analyze closer to the data (42,43).

Mixed methods allow the researcher to explore phenomena thoroughly and triangulate the findings (44).

4.3.Study population

The quantitative survey was done on all active members. New members served less than 3 months, community representatives, and severely ill participants were excluded from the study. The qualitative interviews were carried out with the selected REC members.

4.4.Sample size determination

The quantitative data was targeted to be collected from 96 REC members and 84 respondents were included. The in-depth interviews were done with fourteen selected members from each institute. Among them, six were chair members, one Secretariat, four secretaries, and three REC members.

4.5.Sampling procedure

Level A IRERCs were selected based on their function as NRERB at their respective institution and can take the responsibilities of reviewing clinical trials, international collaborative research, genetic studies, and nationally sensitive protocols (33). The Secretariat, chair member, secretary, or member of the RECs were selected for in-depth interviews purposively based on their level of experience and knowledge.

4.6.Data collection tools and process

The survey was carried out using paper-based and online enketo forms sent to the members through email using the structured self-administered questionnaire prepared in English and Amharic. The questionnaire was adapted from the literature (24,26,27,35). It consisted of 3 parts. The first part was about general information and sociodemographic characteristics. The second part consisted of 15 dichotomous (Yes/No) questions regarding experiences of post-approval follow-up of research projects by IRBs. The third part included challenges in RECs' post-approval follow-up of research projects. The responses were assessed using Likert-scale questions (1=strongly disagree 2=Disagree 3=Neutral 4=Agree 5=strongly agree). The final part was dichotomous (Yes/No) questions about the suggested solutions.

Furthermore, a review of site monitoring reports was done using a checklist adapted from the SOP of AAU-CHS IRB and the Indian study(7,45).

Moreover, In-depth interviews were carried out with a semi-structured interview guide **(Annex 4)** which was prepared in English language and translated into Amharic. It was adopted from the study

conducted in the EU (27). All interviews were conducted in places free from noise. The audio was recorded and notes were taken during the time of the interview.

4.7.Operational definitions

Passive monitoring experience: Experience of RECs depending on the reports submitted to them such as ongoing review of the protocols, looking for the protocol amendments and giving opinions of the protocol changes, acceptance of the violation of the protocol notices, accepting the notification of the commencement of the study, acceptance of the study termination notice, and premature suspension or termination of the study, and communication with the RA.

Active monitoring experience: The field visit experiences/on-site monitoring of studies by RECs.

4.8.Data processing

The quantitative data was exported into SPSS version 26 software. A data entry template was used for the review of site visit reports and entered by using the Kobo Toolbox mobile application.

4.9.Data analysis

The quantitative data and the SM report review were analyzed using descriptive statistics, like frequency, tables, and graphs using SPSS version 26 analysis software. The Likert scale was analyzed by categorizing the agree and strongly agree group as an agreement, the strongly disagree and disagree groups as the dis-agreement group, and the neutral category.

On the other hand, all the recorded audio data were transcribed verbatim and translated into English language by the PI. The translations were cross-checked with the verbatim to confirm the correctness. The translated data were read and re-read by the PI before analysis. A coding system or frame was developed deductively from the literature on an Excel sheet and exported to the MAXQDA for further inductive coding process and modified until no new code emerged. The data was analyzed thematically by MAXQDA qualitative data analysis software.

The quantitative and the qualitative data were merged during data analysis and reporting using the special feature for mixed-method analysis using MAXQDA software.

4.10. Data quality assurance

The survey data were checked for consistency and completeness. A pre-test was done on the RECs of Saint Paul Hospital Millennium Medical College. After the pre-test, questions that lacked clarity were modified.

4.10.1. Trustworthiness

The in-depth interviews were done by the PI and experienced research assistants, all had a master's degree, specifically in Public Health Nutrition (S.A), Health Promotion (A.N), Public Health, Sociology and Anthropology (K.B). Bradley defines confirmability as the degree to which the researcher's assumed characteristics of the data can be verified by other readers or reviewers of the research findings, whereas dependability is the coherence of the internal process and the researcher's ability to account for changing conditions in the phenomenon (46). The PI recorded and documented the raw data, field notes, and other related files for the audit trail that has been checked by the advisors. The methodological and analytical decisions and procedures were written in detail. Triangulation was done on the method and data. Member's check was sent for interviewees during report writing.

4.11. Ethical approval and consent

The actual gathering of data was started after the study was approved by REC of AAU-SPH with reference letter SPH/296/2024. Official letters of cooperation were written to the study sites from AAU SPH. Informed consent was taken from the study participants before the start of the interview. The responses of the participants were kept in a password-locked computer and were not shared with a third party. Identifiers were not used during and after data collection. Codes were used to keep the anonymity of the data. The PI signed a confidentiality agreement before the review of site-monitoring reports.

5. Results

5.1. Sociodemographic characteristics and background information

Responses were obtained from 84 REC members out of 96 active members from 14 institutions across the country (See **Table 10**), giving the study a response rate of 87.5%. Among the study participants, 63(75%) were males and the rest were females. The median duration of stay of participants as members of the REC was 4 and the mean age of the study participants was 44.64 with SD of 9.64. Regarding the role in REC of the study participants, the majority 48(57.14%) were IRB members, followed by 26(30.95%) IRB chair or Administrator or Co-chair, and 10(11.9%) were member secretaries and secretariat.

On the other hand, the qualitative data were categorized under seven themes: the context of the IRB and general information, experiences, challenges, opportunities, gaps, corrective actions, and suggestions given.

Table 1: Sociodemographic characteristics of interviewees

Institution	Age	Sex	Experience in Years	Role in the IRB
A	36	M	2	Chair
B	45	F	2	Secretary
C	36	M	3	Member
D	62	M	6	Chair
E	33	M	4	Chair
F	29	M	3	Secretariat
G	49	M	6	Chair
H	42	M	3	Secretary
I	65	M	4	Chair
J	57	M	2	Chair
K	61	F	5	Member
L	42	M	4	Secretary
M	35	M	3	Secretary
N	47	M	7	Member

5.2.Theme 1: Context of the IRB and general characteristics

Under this theme, one of the sub-themes was the structure and functions of IRBs. In line with this, twelve REC members pointed out the presence of a clear Standard Operating Procedure (SOP) for PAM and on-site monitoring and half of the REC members said the ongoing review is mandatory. On the other hand, eight REC members mentioned the presence of good institutional support for the RECs. In this regard, the on-site monitoring experience was noted among those who said there was good institutional support.

> *"The institutional support is supreme. Firstly, eh… simply, infrastructure, staffing, resource, in relation to that when it is called IRB, it is the institution's review board, it uses the institutions resources like offices, an equipped office and has its own secretary, tables, computers and the likes. The institution financially supports accreditation processes, training and the like. To make an institutional review, most of the members are from the institution, even if the ones who review are few, there are staff to support. So, the institutional support is helping us to move smoothly." (R1 MALE CHAIR MEMBER)*

On the contrary, six members said that the institutional support was not good in terms of supporting the IRB's PAM function.

> *" It is a challenge for the staff to go to the field. It is a challenge that the university does not meet the necessary preparations when they leave for work." (R5 MALE CHAIR MEMBER)*

On the other hand, the views of RECs were grouped and two members mentioned there was no study done on the views of researchers towards IRBs. In addition, most participants agreed upon the lack of attention for PAM by IRBs. And, they forwarded the need for PAM and SM of studies by RECs.

> *"Monitoring is something we should work on and it demands preparedness. So far it has been something neglected." (R9 MALE CHAIR MEMBER)*

Regarding the role of PAM, most members said RECs have a responsibility to follow the studies after approval. In addition, some members mentioned conducting PAM is a shared role and the role of other research stakeholders. Furthermore, The RECs mentioned that RECs have responsibilities

in PAM such as having the necessary plan, finding resources, updating SOPs, Notifying the stakeholders, and empowering the participants.

> *"Eh… I don't think it is the responsibility of a sole body. When a study is implemented, it is a coordination of multiple stakeholders. There are researchers, donors, data collectors then there may be the regulators, and there is the IRB. For the study to be successful, it is the cooperation of many stakeholders. I think the goal of the PAM is the same thing as well." (R7 MALE CHAIR MEMBER)*

> *"It would be preferable if it is from the board members because they know the protocol, they approved reviewed, and discussed the protocol. The other would-be co-members the reviewers in addition to the board members. always maybe when it is too much, they may not finish all, for example we have a research advisory committee, in addition to review board members, and there are also additional." (R3 MALE MEMBER)*

Concerning the objectives of PAM, most members said the objectives of PAM are: ensuring compliance, the protection of safety and well-being of study participants, teaching-learning and building trust, and ensuring the quality, and real understanding of the contextual challenges.

> *"One and the main thing to ensure compliance is a site visit, which will help to ensure the safety of the participant and the quality of the data." (R2 FEMALE SECRETARY)*

5.3. Post-approval Monitoring Experiences of the Research Ethics Committees

As the survey results the majority 75(89.3%) of participants reported that they had the authority to terminate or suspend an ongoing study. Regarding the monitoring experiences, below half of the study participants had an experience of on-site monitoring. Over 84% of the REC members had an experience of continuing review of the study. (Table 1).

Table 2: Post-approval Monitoring Experiences of the Research Ethics Committees

Variables to assess the experience of RECs	Responded yes (n, %)
Reception of notification of the start of the study	29 (34.5)
Ongoing review of the study	71 (84.5)
Reception of notification of adverse events	36 (42.9)
Notification of premature suspension/termination of a study	39 (46.4)
Reception of notification of protocol modifications or deviations	65 (77.4)
Reception of notification of protocol violations	33 (39.3)
Issuance of opinion/approval of protocol modifications	70 (83.3)
Issuance of opinion/disapproval of protocol violations	35 (41.7)
Verification of a study procedure like an informed consent process	48 (57.1)
Reception of declaration of end of a study	43 (51.2)
Reception of final report	46 (54.8)
Maintenance of recordings of proceedings	51 (60.7)
Site monitoring	39 (46.4)
Communication with regulatory authorities	41 (48.8)
Having the authority to suspend or terminate the study	75 (89.3)

5.4. Theme 2: Experiences

5.4.1. Active monitoring experiences of RECs

According to the in-depth interview, only five members mentioned they had experience with on-site monitoring so far. The view of participants regarding the approach for the SM was as the prearranged or scheduled type of monitoring and others mentioned the need for a surprise visit rather than telling the researchers in advance since they may change their behaviors and may not show the right kind of work.

"Sometimes, there are prearrangements before visits where participants may act according to what they think aligns with the observer's interests, known as social desirability bias." (R14 MALE MEMBER)

"When you visit a site, you have to notify in advance, so you will be prepared for the review about to happen." (R8 MALE SECRETARY)

"Sometimes when we hear some rumors or when we think there are violations or when there are reports from the participants, we make accidental visits. These things should be maintained especially for critical studies, where we believe there will be a challenge to the protocols for the participants. We focus on those and make accidental visits." (R1 MALE CHAIR MEMBER)

Moreover, the reasons for the selection of studies for on-site monitoring were reported as a routine activity and for the specific causes like the occurrence of SAE, and whistle-blower information. In addition, more than half of the participants agreed on risk-based selection.

"So, what we do is risk-based. When the study is a high-risk like a new drug test, the outcome is not known even if it comes after phase 1 and phase 2. If there are human challenge studies and others like any clinical trial, and if it has any invasive procedures, the extent of the invasiveness must be known. Especially when it is an invasive procedure with vulnerability. When the impact goes beyond the participants to the society. The risk we say might not be just for the participant but also for the community. It might be necessary to review it case by case, but we believe that it must be based on risk assessment and vulnerability." (R7 MALE CHAIR MEMBER)

"Site visit is advisable for studies that will take a long time and have a potential risk, the IRB has an SOP for the site visit 1. high-risk studies, 2. if the PI is implementing multiple studies like more than 3 as well as more than 3 sites for some study. another is if the study PI is not submitting the final report, if there is no compliance or suspicious things of non-compliance, if there a multiple protocol deviations this study should also be monitored, if there are SAEs frequently reported, if it is a new site or inexperienced site for study." (R2 FEMALE SECRETARY)

5.4.2. Passive monitoring experiences of RECs

On the other hand, most of the RECs said they have a passive experience of PAM like an ongoing review of the protocols and review of progress reports, reception of the protocol modifications, and giving opinions for the protocol amendments.

"The routine follow-up that is done here is a desk-level monitoring. What I said earlier was desk-level monitoring. It might be asking them through calls, it might be passive reporting and like I said receiving those reports within the given interval is for any study." (R7 MALE CHAIR MEMBER)

5.5.Challenges in post-approval and site monitoring of studies

5.5.1. Potential or faced challenges in post-approval submissions

Based on the quantitative survey, the RECs agreed on the most common challenges related to post-approval submission of the documents. For instance, over there-fourth 71(84.5%) of the REC members agreed on PIs non-adherence to timeliness and also late submission of document 66(78.6%). (Figure 2).

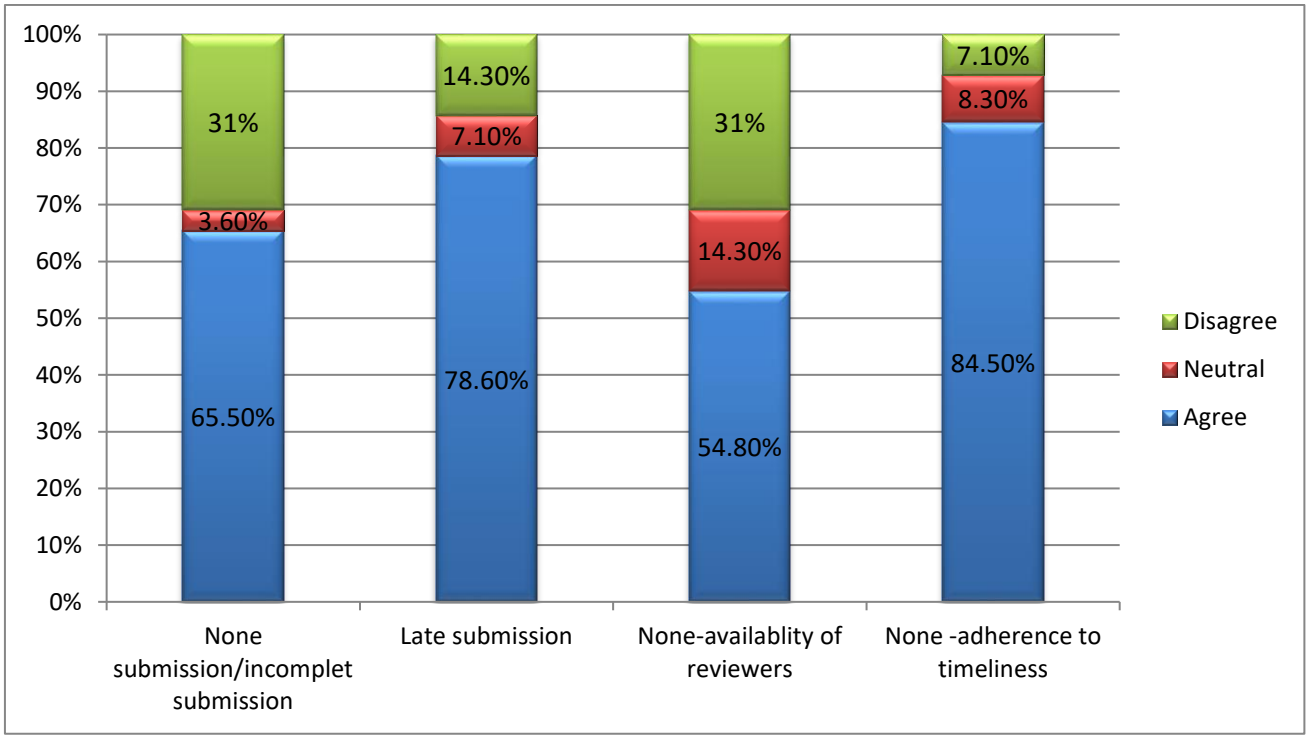

Figure 2: Faced or potential challenges to RECs regarding protocol submission

5.5.2. Potential or faced challenges in the review of post-approval submissions

Based on the survey result, challenges in the review of the post-approval submissions were assessed and nearly two-thirds 54(64.3%) of the RECs agreed that the long time taken by the reviewers was a challenge. Moreover, about half 44(52.4%) of the RECs agree that too much paperwork was a challenge during a post-approval review process and 20(23.8%) of the RECs didn't agree on this.

On the other hand, Findings in qualitative data also identified issues about the burden on the committees.

> *"It has challenges; looking for a reviewer, trying to set a meeting of the committee and it has many paper works." (R9 MALE CHAIR MEMBER)*

5.5.3. Potential or faced challenges related to site monitoring visit (SMV)

In terms of the site monitoring visit, of the study participants nearly two-thirds 54(64.3%), 50(59.5%), and 50(59.5%) agreed that time shortage, lack of training to RECs and lack of institutional support respectively were challenges to conduct on-site monitoring. (Figure 3).

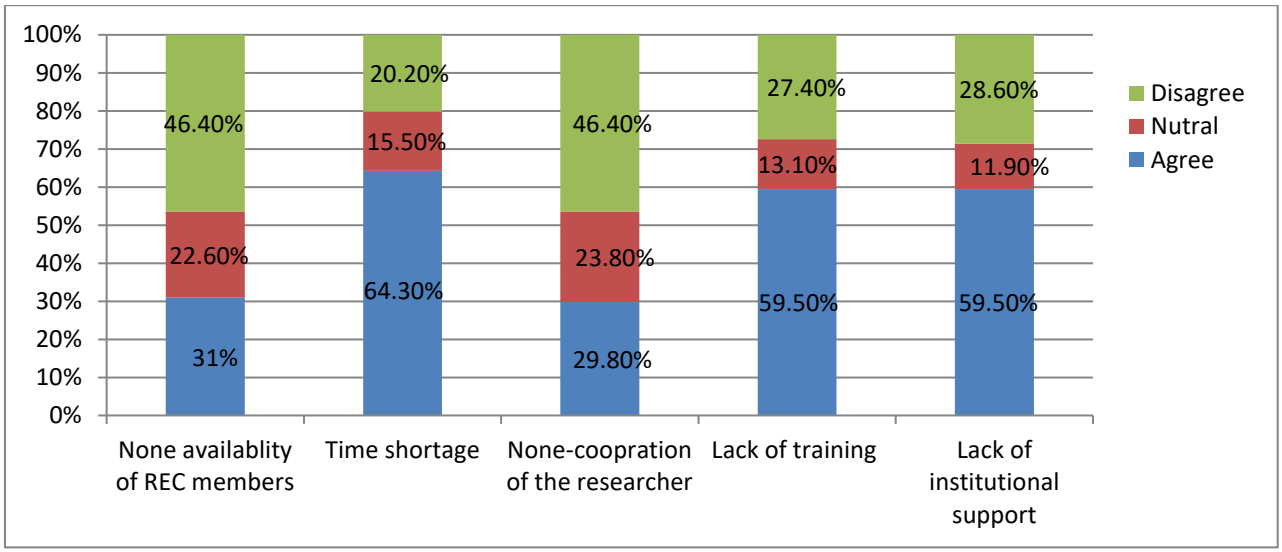

Figure 3: Potential or faced challenges related to site monitoring visit

5.5.4. Potential or Faced challenges regarding the review of serious adverse events

The survey data also identified the challenges related to the SAE review. For instance, about half 43(51.2%) of the RECs agreed that establishing causality and a compensation decision are the challenges during the review of SAEs. Of the RECs, more than three-fourths 67(79.8%) agreed that no submission or incomplete submission of the SAEs by the PIs was a challenge for the review of the SAEs (Figure 4).

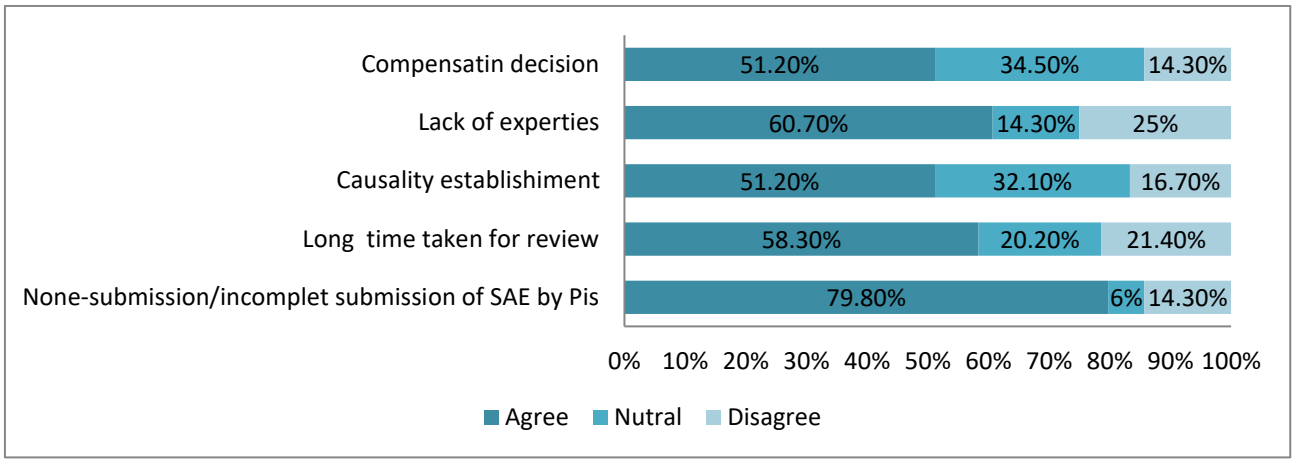

Figure 4: Potential or faced challenges regarding the review of serious adverse events

5.5.5. Potential or faced challenges in the review of protocol deviations

The survey data also identified the challenges related to the review of protocol deviations (PDs) and the majority 71(84.5%) of the RECs agreed on noncompliance by Principal Investigators (PIs) in reporting PD, and over half 47(56%) agreed that PIs do not accept PDs and lack of institutional support. 46(54.8%), (Table 2).

Table 3: Potential or faced challenges in the review of Protocol deviation (N=84)

Variables	Agree		Neutral		Disagree	
	n	%	n	%	n	%
Noncompliance by IXs in reporting PD	71	84.5	6	7.1	7	8.3
Lack of acceptance of PD by IXs	47	56	25	29.8	12	14.3
Time shortage to detect PDs	34	40.5	21	25	29	34.5
Absence of clear SOP	23	27.4	15	17.9	46	54.8
RECs inability to take action against researchers	11	13.1	16	19	57	67.9
Lack of institutional support	46	54.8	13	15.5	25	29.8

PD= Protocol Deviation, SOP= Standard Operating Procedure, IXs= Investigators

5.6.Theme 3: Challenges

According to the in-depth interview, the challenges related to the conduct of PAM and SM were grouped under sub-themes resource, attitude, lack of system, high burden, access to the database, and contextual challenges.

Generally, most of the REC members faced challenges related to the resource issue and the burden of the conduct of PAM and on-site monitoring.

> *"What we take as a challenge in post-approval monitoring is eh… it is difficult to facilitate the logistical issues for the post-approval monitoring." (R1 MALE CHAIR MEMBER)*

In addition, several contextual challenges were reported. For instance, the security issues and instability in the country pose a challenge to go to the field to monitor the studies. In addition, some REC members said the progress report non-submission was a challenge to the RECs.

> *"So currently in Tigray we are in the emergency response and research is considered a luxury right now. And for that luxury, you will find no funding partner. Research is not a luxury but, in our case, we are worrying about what to feed the people." (R13 MALE SECRETARY)*

> *"Mostly there is nothing much. As you know it, there is the security issue that restricts us from going out for site monitoring." (R11 FEMALE MEMBER)*

Moreover, a lack of a supportive system for the PAM and SM was identified, and under this sub-theme, there was a lack of ethical culture, poor institutional support, lack of clear guidance for on-site monitoring or unclear role for the RECs, and loss of trust were the reported challenges by the RECs.

> *"When I observe it now, except for some kinds of research, it is not mainstreamed as a main issue in the main cycle. It might be due to lack of system." (R7 MALE CHAIR MEMBER)*

> *"The primary challenge lies in defining the scope and responsibilities associated with post-approval monitoring. Unclear mandates can lead to confusion regarding the level of control IRBs should exert over researchers after the approval." (R14 MALE MEMBER)*

Furthermore, the views and awareness gap of researchers towards RECs were mentioned as a challenge. The REC members said that there may be fear towards them, perceived simplicity, ignorance, influence on the RECs when the study secured funding from some other sources or politically driven studies, and trust issues.

"Most researchers fear the IRB but they still have complaints at the same time." (R7 MALE CHAIR MEMBER)

"Eh… some of them just require it to be approved on the very day they brought the proposal just like renewing an ID. When we try to explain to them the actual process some of them accept it well and some of them respond as if we were exaggerating the process." (R12 MALE SECRETARY)

"However, I believe that awareness of these issues is not as strong in our country, leading researchers to perceive IRB matters as simple. Therefore, I advocate for mandatory training for researchers to address this gap in awareness." (R10 MALE CHAIR MEMBER)

"Secondly as we are seeing the nationally based studies, usually, there are some politically driven or politically motivated studies eh… they maybe studies which must be made after you secure a fund with your partners, you observe some tendency to influence the IRB from the investigators, for example, eh… if the study is funded by MOH they'll have an attitude that it should be implemented despite anything, but the protocol might not violate the ethical principles." (R1 MALE CHAIR MEMBER)

5.7.Suggested solutions by the RECs

Most RECs who participated in the survey suggested various solutions. These include regular training of EC focusing on post-approval monitoring given much emphasis (100%) (Figure 5).

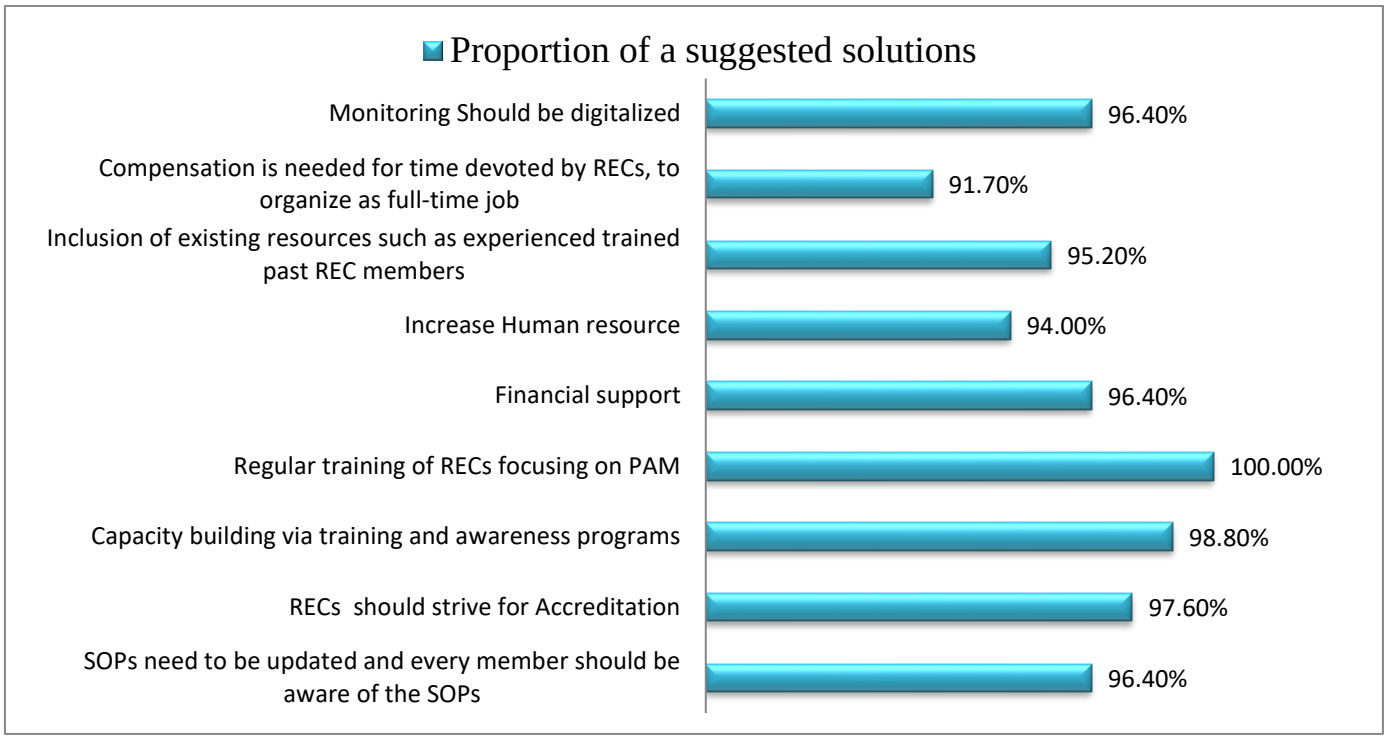

Figure 5: A bar graph showing suggested solutions for the research ethics committees

5.8.Theme 4: Suggestions given

Similarly, the suggested solutions for the PAM by the RECs in the in-depth interviews were digitalization of monitoring, suggestions for researchers to be followed, the need for mechanisms and approaches, and the need for capacity building. Moreover, some participants strongly suggested the need for trained surveyors to conduct site visits on behalf of RECs.

"By clarifying expectations and ensuring transparent communication, we can foster trust and compliance within the research community." (R14 MALE MEMBER)

"But in the future, it must be done in a planned way and for that, it demands capacity building. Especially we need to train the so-called surveyors and facilitate the process. As a whole, after projects are approved, it's really weak when it comes to site visits." (R9 MALE CHAIR MEMBER)

To solve the issue of resource problems, one suggestion was a fee to be charged from the research for the function of RECs, half of which could be used for the IRBs function and the rest for the PAM.

"But right now, we are planning on solving it internally. We have proposed a 1% charge for every proposal that is submitted, which is 0.5% for monitoring and evaluation and the other 0.5% for review. It is just a proposal which is not accepted yet. We hope that it will be approved. If it is approved, we will be able to implement the expected monitoring and evaluation." (R12 MALE SECRETARY)

"It is supposed to be like eh… after being given a proper budget, we need to care even more upon monitoring than we did while we were reviewing it." (R12 MALE SECRETARY)

Moreover, the need for system creation for the PAM was emphasized by RECs including a uniform and diversified system.

"I believe that we can create a system that is inclusive of everyone. It might be adding a checklist or may be having reports with some intervals or part of the training and especially those who are part of the research must not be seen isolated. I fear it might be a theoretical suggestion but I think it would be much better if we can create a system for it. That's the only solution we have because it is impossible to follow everyone in the field. Even if we see it risk wise, we may know those studies with high risks but there may be studies which will be overlooked. So, I believe it will be very good if we can create an inclusive system after a very deliberate discussion amongst scholars and professionals and after it is thoroughly checked." (R7 MALE CHAIR MEMBER)

"However, in Ethiopia, there should be consistent and uniform monitoring of research ethics committees established at every level. This oversight should be carried out by the Ministry of Education to ensure that IRBs are not established carelessly." (R10 MALE CHAIR MEMBER)

In addition, the self-assessment of PIs was encouraged to facilitate the monitoring practice by RECs.

"Just when the letter for proposal approval is given, along with it they will be given the self-assessment tool. They will be told to fill out the form and submit

it maybe once or twice a year. Also orienting them on how to fill out the form. If they are well aware of the form, they would not consider it as a surprise." (R9 MALE CHAIR MEMBER)

Furthermore, the approach for the PAM should not be fault finding or like police but rather a teaching-learning process.

"The IRB is not like police fetching for problems rather it is more of preventive way to identify problems before happening in the study." (R7 MALE CHAIR MEMBER)

5.9.Theme 5: Opportunities for post-approval and site monitoring

Generally, the presence of supportive activities like mandatory presentations about the progress of the PIs to the RECs, stakeholder oversight, self-monitoring of the PIs, and summit of stakeholders and annual forum were considered an opportunity for the PAM.

"Yeah, the situations a... maybe if there are forums to share experiences...one research ethics committee one research institute an institute which gives an ethical clearance better have an experience sharing sessions annually. this will be an opportunity for learning from others and to share things to avoid others from repeating the same things" (R3 MALE MEMBER)

Moreover, the presence of new methods, interventional studies, and scale-up of research were pointed out as an opportunity for the PAM.

"When there are large-scale country-based studies, they'll draw our attention. Another thing is, when it's a newly introduced device like medical equipment, drugs, or interventional studies, they draw your attention too." (R1 MALE CHAIR MEMBER)

Furthermore, the presence of factors that necessitate the on-site monitoring was seen as an opportunity. For instance, the presence of rumors, and whistle-blower information, the presence of complaints, the mandatory requirement for the publication, and obligatory, accreditation and the need to avoid harm were considered as triggers to the on-site monitoring.

"Another, if there is someone who communicates the IRB directly from the site, from participants, or any feedback, that will catch our attention and could be seen as an opportunity." (R1 MALE CHAIR MEMBER)

Lastly, backed by the law, the presence of many universities and research institutes, the availability of resources, and expertise were among the opportunities for PAM and on-site monitoring.

"I believe that even the law supports this." (R14 MALE MEMBER)

"If we take Ethiopia eh… there are many universities, many research centers, and since it is a requirement there are many places where study reviews are made directly or indirectly. We can take that as one opportunity." (R7 MALE CHAIR MEMBER)

"So, the availability of budget by itself can determine. That is how we think". (R3 MALE MEMBER)

"Most of the members of the ethics committee are from different backgrounds and they have a very good capacity. Since they have the adequate expertise for the job that is another good opportunity." (R11 FEMALE MEMBER)

5.10. Review of the site monitoring visits (SMV) reports

In the current site monitoring reports review (SMV), we have attempted to evaluate the monitoring review from 46 SMV report documents that were conducted in Ethiopia between 2017 and 2023. The reports include monitoring reports from the monitoring organizations on various studies, ranging in length from a single visit to five repeated visits.

Among 44 completed SMV reports for appropriateness of study sites and ICF update status, 44 (100%), and 35(79.6%) agree that the facilities were appropriate to conduct trials and that the study teams were using an approved ICF by the IRB respectively. Among the 43 SMVs that documented the presence of any SAEs, 39(90.7%) reported that there were no SAEs that happened during SMVs. Of the 42 SMVs reported, 16(38%) reported that there were protocol non-compliance/ violations during the visit. Moreover, regarding the confidentiality of the stored documents, 7 out of 42 (16.7%) reported that the storage cabinets of data and investigational products (IP) were not

locked. Among the 44 SMVs reports, 29(65.9%), 11(25%), and 4(9.1%) concluded that the participant's protection was Good, Fair, and poor respectively see **(table 11)** for details.

5.10.1. Theme 6: Gaps identified in the review of site monitoring reports and in-depth interviews

In the current study, both the document review and interviews showed several lapses made during the site visit of studies by RECs. Those gaps were grouped into the following sub-themes; Informed consent issues, deviation from an investigational plan, none-reporting of SAEs to RECs, a breach in privacy and confidentiality of the study participants, PI-related issues, ethics approval-related issues, and other findings.

Under the informed consent issues, 19 documents had some kind of violations. The most IRB's address not written in the consent form (47.4%), no contact address on the consent form (15.8%), copy of the consent form not given to the participants (21%), no consent form found (26.3%), no assent form (15.8%), Incomplete ICF (26.3%), no hard copy of the information sheet was found during the visit (15.8%), the informed consent form has no version, and date (10.5%), No space for guardian, parent and witness name and signature in the assent form (21%), some data collectors were not using local language for the 15.8% and the other issues like placing signed ICF publicly and no witness signature for illiterate are found in 1 SMV each.

Similarly, the qualitative data also identified the informed consent problems.

"And there is not giving adequate information for consent and these are all violations." (R9 MALE CHAIR MEMBER)

I. Deviation from the investigational plan (protocol), (N=14)

No compensation was given to participants and the discrepancy between the expected and enrolled participant number each reported by 28.6% of the SMVs, nonrandom allocation of the study participants reported (21.4%) of the reports, and outsourcing the research to a consultant without explanation in the protocol and obtaining permission from the IRB was a violation reported by 14.3% of the reports. Furthermore, change of the study site without the request for amendment from the IRB, poor perception about the autonomy of the participants by data collectors, unknown number of total study participants at the end of study, commencing data collection without obtaining permission from local government institutions, absence of monitoring plan, lack of

quality assurance, not applying exclusion criteria to all study subjects uniformly, asking leading questions and being not neutral during the interview and investigator refusal to give direct patient data for IRB for monitoring purposes, all happened once in different studies.

The data identified from the qualitative interview also highlighted the presence of gaps during SMV, for instance, ignorance of compensation for the participants, protocol violation in study participant recruitment and inappropriate site selection.

> *"For example, if there was an agreement to provide incentives but they were not given as promised, then we could consider it a breach of protocol." (R14 MALE MEMBER)*

> *"I can say it is a routine thing, for instance; one time it was a campaign study to be conducted in 2 sites on 1000 samples and supposed to take 500 samples from each site but they took 1000 subjects from only 1 site. So these types of protocol violations or deviations happened" (R2 FEMALE SECRETARY)*

> *"There is doing study in unallowed places" (R9 MALE CHAIR MEMBER)*

II. No reporting of SAEs to RECs (N=2)

None reporting SAE happened in 2 different studies despite the requirement of the ethical and patient safety criteria. There was a related finding from the in-depth interviews.

> *"When there is a harm or when a harm happens to study participants, they need to report it. Because if they don't report they are hiding it and that's a major violation. These examples I'm mentioning do happen. There is hiding harms" (R9 MALE CHAIR MEMBER)*

III. Privacy of the study participants and the data confidentiality (N=9)

In this theme there were three different issues identified the privacy of the study participants hadn't been maintained in 6 reports, the study-related files were not locked in the cabinet in 3 of them and the data collectors' tablets have not been locked in the 2 study sites.

One participant reported that similar issue related to the breach of the privacy and confidentiality identified during SM.

"When we saw the database, we identified a confidentiality breach. There is the whole personal identification of the participant. There is his full name, address, phone number eh… there is the full address and so on. When we see each recorded data, there is full information of all participants. It has no confidentiality and there is a privacy breach. We witnessed this in a large institution research." (R9 MALE CHAIR MEMBER)

IV. Issues related Principal investigator

Deficiency of study supervision by the principal investigator and the shyness of the investigator to monitor happened each 1 time on different studies from SMV report.

One interviewee reported the presence of tension when the interview was observed by the RECs.

"What we observed on the field is some individuals becoming nervous, showing tension, and making mistakes while asking questions." (R14 MALE MEMBER)

V. Ethics approval status

Approval not requested/no valid approval document was available in 2 studies and amendment was not given at all in another study. No ethical clearance letter / ethical clearance letter not renewed in 1 study.

Similarly, some interviewees also indicated the commencement of the study without the approval and before the approval and requested retrospective clearance for the sake of publication.

"There is one who started before getting approval; we didn't give approval and he started the study. This is a violation. Without receiving." (R4 MALE CHAIR MEMBER)

"There may be a lack of request for amendment on a timely basis; sometimes by rushing to start the work or without considering the need for an amendment they will directly commence the work," (R2 FEMALE SECRETARY)

"Sometimes there are those who request retrospective ethical clearance. They do the research prior and then they ask. This is not allowed ethically. It is after its feasibility is checked and it is not only about ethical clearance but the

institution will need to have permission. They just go with the research because they are friends with the institution employees and they ask us for ethical clearance later on when they are requested upon publication. This is a crime" (R12 MALE SECRETARY)

VI. Other findings

Other findings from the review included the safety of data collectors (throat irritation from chemicals use without PPE), documentation problems; no hard copy CRF, protocol, investigator file, and enrollment log, and No GCP training of researchers that happened once on different studies.

On the other hand, additional gaps mentioned by the respondents were the issue of Conflict of Interest and data cooking by the data collectors.

"Sometimes there is also an issue of conflict of interest. We try to settle it as much as we can. Either way we can only be able to identify a certain protocol violation if we are able to monitor them every three months or so according to its protocol." (R12 MALE SECRETARY)

"It is just that the data collectors want to manipulate the data. They just fill the forms by themselves without going to the necessary study areas." (R11 FEMALE MEMBER)

5.11. Theme 7: Corrective actions

According to the identified gaps during the on-site monitoring, several actions were taken as the report of SMV and the qualitative data which ranged from minor recommendations given to legal proceedings.

As per the SMV report, the actions taken for the ICS issues were training recommendations, feedback, a warning, and an explanation request. The interviewees also mentioned similar actions and other additional actions like termination of the study sites, and legal measures.

For less severe violations, such as minor breaches, we may issue oral or written warnings. (R10 MALE CHAIR MEMBER)

"It might be a major one like I mentioned earlier, the one where data was collected on trauma patients, the protocol we received said that the data was to be collected on psychiatric patients but the data was being collected on trauma patients. We actually were able to control it on the first study participant when our healthcare providers reported the incident. We prohibited the study and took the paper. We didn't allow her to collect the data in our hospital and like I said she had other two or three hospitals". (R6 MALE SECRETARIAT)

"For instance, there are some sites which are completely closed. Of course, it is through a consensus. After everyone agrees that it is a violation, it will be decided not to do the study at a certain site. Or it may stop the study too." (R9 MALE CHAIR MEMBER)

"Eh… at first after we faced those who asked us the retrospective ethical clearance we took administrative action. We decided not to give them the ethical clearances. We discussed informing them through the board discussions about the process and after that, we decided on continuing into legal actions." (R12 MALE SECRETARY)

6. Discussion

This study explored the experiences of RECs in conducting PAM and SM. Both the qualitative and the quantitative findings showed that the main activities of RECs after initial approval were passive monitoring like ongoing review of protocols and less on-site monitoring. This is similar to the other studies (25–28). Below half of the participants (46.4%) had experience with SM, similarly only five interviewed RECs mentioned their previous site visit experiences. The SM experience result from the survey (46.4%) was slightly higher than another study done in India on 61 secretariats, which was 37.7% (26). This could be due to the difference that this study included all members compared to the Indian study, which included only member secretaries. This implies the emphasis is given to passive monitoring. Good institutional support was instrumental for RECs to conduct site monitoring.

Regarding the approach to the SM, contradicting views were raised in the present study. Some participants mentioned the scheduled visit and others surprise visit. The scheduled visits were encouraged for the sake of preparation and to foster trust between the researchers. The surprise visit was pointed out since researchers could change their behavior when they know in advance about the presence of SM. One participant mentioned both of the approaches are needed depending on the situation. If suspicion or any information reached the RECs, the approach should be a surprise visit. On the other hand, some participants explained the approach should not be like fault finding or policing, but rather a supportive to foster smooth relationships between the researchers and RECs. This was supported by other studies (6). The surprise visit was mentioned as essential in another study (28). Generally, a smooth relationship between the RECs and PIs is crucial.

The objectives of PAM as the qualitative interviews were compliance ascertainment, participant safety protection, quality assurance, trust development, support for researchers, and institutional protection similar to other studies (4,24). RECs primary purpose is the protection of study participants, to ensure its objective PAM is crucial.

Lack of attention to PAM after approval was identified by the qualitative interviews. Most participants said PAM was mentioned as a role of RECs' followed by a shared role by research stakeholders. This is contradictory to the study done in the EU, which forwarded the responsibility of RA rather than RECs' (27). This may be attributed to the study type, which was clinical trials explored in the EU. This study does not differentiate the study type. An on-site visit is needed for

studies selected based on the level of risks, the type of study like clinical trials, and the involvement of vulnerable groups mentioned in the qualitative interview. This is similar to another study, which pointed the high cost of on-site monitoring and the need for monitoring based on the level of risks (30) similarly the Ethiopian guideline suggested it (33). It is difficult to visit all studies. So, the studies should be selected based on their level of risk to the study subjects, and the involvement of vulnerable groups.

The data from the quantitative part showed the main challenges for RECs were the submission-related challenges, on the review of SAE, SM, and PD review. This is similar to another quantitative survey (26). In addition, the qualitative part identified several challenges related to the resources and burden for the committees to monitor studies. These findings were comparable with other studies (11,26–28). The qualitative data identified additional challenges related to lack of a supportive system, unclear role related to the PAM, contextual challenges like internal conflict, and the attitude of researchers hindering the function of RECs. The research itself is seen as a luxury in conflict-affected areas. Another study in vulnerable groups in Ethiopia identified gaps in ICS comprehension of the participants (32). This implies the need for urgent response especially in the conflict-affected areas, since research is needed to enhance the quality of policy decisions, it should be backed by ethical practices, and the need for ethical awareness and capacity building.

The present study identified several gaps through qualitative interviews and document reviews of on-site monitoring reports. As per the review of 46 SMV reports, (16/42) completed documents had protocol deviations/violations. All SMRs showed the investigators used appropriate sites. This was similar to the study done in Uganda (36).

Based on the review (19/46) issues related to ICS were identified, (14/46) deviations from the protocol were found and (9/46) gaps related to the breach of privacy and confidentiality were identified. Also, some issues related to the approval status of the study were found, like proceeding without protocol amendments and ethical clearance. In addition, starting before the approval, requesting retrospective approval letters, protocol violations, and deviations were reported by the participants. Other studies also identified similar gaps (24,29,34–38). This implies the need for on-site monitoring, since without the conduct of SM, it was difficult to identify these gaps. The main objective of RECs is the protection of the rights and well-being of study participants, appropriate PAM, especially SM is essential to ensure the objective.

For the identified gaps both in qualitative and document review data, the corrective actions taken were recommendations for the PI given, warning, requesting further information, continued GCP training, protection of confidentiality and privacy, and legal proceeding with a case from the retrospective request of ethical clearance. Other document review studies have also taken similar actions (31,35,37).

The suggested solutions of RECs as the quantitative and the qualitative data implied, most members responded the digitalization of monitoring, regular trainings, increasing the capacity including human resources, updating SOP, financial support and compensation for the time, and previous member inclusion. Similarly to other study (26). The qualitative data also identified several themes such as the need for capacity buildings, digitalization, and system creation for the RECs. One way mentioned for RECs was, hiring surveyors by the RECs to conduct the field visit and report the results for RECs. The other main reflection was the self-assessment tool, to be filled out by the investigators and controlled by the NRERB also recommended. Self-reporting was forwarded. Similar to another study (40).

The qualitative data also explored the opportunities for the PAM. As such, the availability of supportive activities, research scale-up, the presence of triggering factors, and the capacity to conduct PAM were identified. Thus, the presence of Many universities, the increase in the number and type of studies, and the increase in supportive activities and triggering factors like being obligatory, and compliant from the participants were identified. Research misconduct prevention as an opportunity was similar to another study (39). The present study raises the need for PAM and the availability of resources, the number of universities and research institutes could be a good opportunity to enhance the PAM by the RECs.

7. Strengths and Limitations

The strengths of the present study are the inclusion of all members in the study, and the inclusion of different institutions, like Research institutes, Universities, Professional associations, and hospitals making the study holistic and able to identify the experiences in different contexts.

In the SMV report, different monitors in different institutions could report things differently because of subjective judgment.

8. Conclusion

The current study identified the overall IRBs' function of PAM and SM is not strong. In addition, this study identified that active post-approval monitoring can uncover protocol deviations not reported by researchers, including failure to report serious adverse events, and can improve the protection of participants' rights and ensure ethical conduct in research involving human subjects. Given the identified violations and gaps by the on-site monitoring, the author argues active follow-up should be done in addition to passive monitoring.

9. Recommendations

All research stakeholders should support the PAM, and capacity building is needed and MoE and institutions should support RECs in capacity and resources. Moreover, further studies are needed to explore the perspectives of different stakeholders including researchers regarding the PAM and SM.

To enable effective and efficient PAM, research ethics committees should prioritize conducting site monitoring visits and seek financial support to ensure smooth operations by collaborating with other stakeholders, sponsors, and researchers to avoid resource obstacles that can hinder post-approval monitoring efforts.

10.Disclaimer

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12.Annexes

12.1. Participant information sheet

Date……..

Greetings!

Introduction

Hello, how are you?

My name is _____and I am a data collector for the research entitled 'Exploring the experiences of institutional review committees in conducting post-approval and site-monitoring in Ethiopia: A mixed-method research". I kindly request you to lend me your attention and time to explain to you about the study as you are selected as a study participant. You are selected to participate in this study because you are the member of level A REC.

Purpose of the study: The objective of this study is exploring experiences of institutional review committees in conducting post-approval and site-monitoring in Ethiopia.

You are invited to participate in a study to be conducted by Mr. Girum Tamiru from Addis Ababa University, College of health sciences, School of public health, Research ethics track.

The findings of this study have paramount importance for the improvement of post- approval and site-monitoring by RECs and will help in emphasizing the protection of human subjects in clinical research.

Procedures: The interview will be done after getting informed consent, and it will take around 45-60 minutes. For the qualitative interview, audio will be recorded using tape recorder.

Risk and Benefits: There is no harm happening to you by participating in this study except demanding a few minutes of your time. There is no direct benefit in cash. The information you will provide will be kept confidential. If you have any questions or inquiries at any time, please contact us at the following address; Cell phone, +251926881004 or by E-mail: **girumtam95@gmail.com**

For additional information, please contact Addis Ababa University, College of health sciences, School, of public health.

What is expected from you as a participant in this study?

As a participant in this study, we ask you to agree to give answers to some questions about your experience as a research monitor, and as a part of REC your experience in post approval and site monitoring and related questions. Your name, address, and position will not be disclosed.

How much time will I spend to participate in this study?

You will spend 45-60 minutes.

How is our information to be kept secret?

The information you give and the results will be used only for this research. All the information will be encoded in a computer and password protected.

What are your rights as a participant in this study?

You are welcomed if you have any questions or need for further explanations about the study. Participation in the study is voluntary. You also have the right to withdraw from the study at any time you want. You can get the results of the analysis if interested.

IRB chairperson: Prof. Abera Kumie Email: aberakumie2@yahoo.com

IRB secretary: Dr. Wubegzier Mekonnen Email: wubegzierm@gmail.com

12.2. Consent Form

I have been informed about the study which is aimed to explore experiences of institutional review committees in conducting post-approval and site-monitoring in Ethiopia.

For this study, I am expected to give answers to questioner, and give some of my time to engage on the study. The aims of the study were explained to me.

I am also informed that audio will be recorded and all the information contained within the questionnaire is to be kept confidential. Moreover, I have been well informed of my rights to decline to cooperate and withdraw from the study at any time.

It is therefore, with full understanding of the situation that I gave the informed consent voluntarily to the researcher to take part in this study.

In addition, I have had the opportunity to ask questions about the research and received clarification to my satisfaction.

Agree to participate?

Yes ☐

No ☐

Participant code: ……Signature: …….……..Date: …….

Interviewers' name: …… ……Signature: …… Date: …….

12.3. English version questionnaire and study checklist

Research topic: Exploring the experiences of institutional review committees in conducting post-approval and site monitoring in Ethiopia.

Date:

Table 4: Questioner to assess the Basic Information

Institution

Please check on your institution

AHRI ☐	EKGH ☐
NRERB ☐	AMHSC ☐
AAU-CHS-IRB ☐	ACIPH ☐
EPHI/SERO ☐	ESSSWA ☐
UoG-CMHSSH ☐	EMwA ☐
AMU-CMHS ☐	EPHA ☐
Tigray Health Research Institute of Review Board ☐	Mekele University college of Health Sciences ☐

Demographics

1. Gender:

2. Age:

3. Occupation:

4. What is your background?

5. What is your role/job on this committee?

6. How long have you been on/in this committee?

Table 5: Questioner to assess Experiences of Post-approval and site monitoring

7. Have You Participated in Post-approval activities?	Yes: No:
If yes, what was the activity/authority?	
8. Reception of notification of start of trial.	Yes: No:
9. Continuing review of trial.	Yes: No:
10. Reception of notification of adverse events/ safety issues.	Yes: No:
11. Notification of premature suspension/termination of trial.	Yes: No:
12. Reception of notification of protocol modifications/deviations.	Yes: No:
13. Reception of notification of protocol violations.	Yes: No:
14. Issuance of opinion/approval on/of protocol modifications.	Yes: No:
15. Issuance of opinion/disapproval of protocol violations.	Yes: No:
16. Verification of trial procedure/informed consent process.	Yes: No:
17. Authority to suspend/terminate.	Yes: No:
18. Reception of declaration of end of trial.	Yes: No:
19. Reception of final report.	Yes: No:
20. Maintenance of recordings of proceedings.	Yes: No:
21. Site Visit	Yes: No:
22. Communication with regulatory authorities.	Yes: No:

Table 6: Questioner to assess Challenges faced during post-approval and site monitoring of research by RECs

(1=strongly disagree 2=Disagree 3=Neutral 4=Agree 5=strongly agree)

Post-approval submissions:	**Rank 1-5**				
Face non-submission/incomplete submission of protocol	1	2	3	4	5
Late submission	1	2	3	4	5
Non-availability of reviewers	1	2	3	4	5
Non-adherence to timelines	1	2	3	4	5
Challenges in the review of post-approval submissions:					
Too much paperwork	1	2	3	4	5
Long time taken by the reviewers	1	2	3	4	5
SMV:					
Non-availability of REC members	1	2	3	4	5
Time	1	2	3	4	5
Noncooperation of researchers	1	2	3	4	5
Lack of training	1	2	3	4	5
Lack of support from the institute	1	2	3	4	5
SAE review:					
No submission/incomplete/late submission of SAE reports by PI	1	2	3	4	5
More time taken for review	1	2	3	4	5
Too much paperwork work	1	2	3	4	5
Causality Establishment	1	2	3	4	5
Compensation decision	1	2	3	4	5
No availability of reviewers	1	2	3	4	5
No adherence to timeline	1	2	3	4	5
Lack of expertise	1	2	3	4	5
The review of PDs:					
Noncompliance by PIs in reporting PD	1	2	3	4	5
Lack of acceptance to PDs by PIs	1	2	3	4	5
Time shortage to detect PDs.	1	2	3	4	5
Absence of clear SOP	1	2	3	4	5
REC's inability to take action against PI	1	2	3	4	5
Lack of institutional support	1	2	3	4	5

Table 7: Suggested solutions for the RECs

SOPs need to be updated and every member should be aware of SOPs	Yes No
The Ethics committees should strive for Accreditation	Yes No
Capacity building via training and awareness programs	Yes No
Regular training of EC focusing on PAM	Yes No
Financial support	Yes No
Increase Human resource	Yes No
Inclusion of existing resources such as experienced trained past EC members	Yes No
The need for compensation for time devoted by EC to be recognized as full-time job status	Yes No
Monitoring Should be digitalized	Yes No

Table 8: Checklist for site visit report

	Comment
Application No.:	
Date of visit	
Study Title	
Institute:	
Total number of expected subjects:	Total subjects enrolled:
Are site facilities appropriate?	Yes No
Are they using Informed Consents approved by REC?	Yes No
Is confidentiality of data maintained?	Yes No
Any serious (or serious unexpected) adverse events found?	Yes No
Any protocol non-compliance /violation?	Yes No
Are all Case Record Forms up to date?	Yes No
Are storage of data and investigating products locked?	Yes No
How well are participants protected?	Good Fair Not good
Any outstanding tasks or results of visit?	Yes No

Decision:	No Further Action Required Request Information Recommend Further Action

Table 9: Corrective actions taken by RECs

Explanation asked for with a clear warning against future repetition	Yes No
Restriction on future recruitment, submission of audit reports from sponsor	Yes No
Explanation asked for with a clear warning against future repetition	Yes No
Recruitment of additional members in the study team advised	Yes No
Submission of AE reports	Yes No
Continued GCP training of study recommended	Yes No

12.4. Interview guide for IRBs/ECs

Research title: Exploring the experiences of institutional review committees in conducting post-approval and site monitoring in Ethiopia.

Starting time and date of interview:

Code:

1. Does your REC do ongoing review of protocols that has been approved? If yes, is this mandatory?
2. What has been your experience with evaluation/approval/review/audit (inspection) of study protocols after initial approval?
3. What is the objective of monitoring?
4. What are the challenges faced when conducting post-approval and site monitoring of studies?
5. In your opinion, who should do monitoring/whose role is to conduct PAM of a study after initial approval?
6. What is your opinion on the opportunities of conducting post-approval and site monitoring of a study?
7. Explain the role of your committee, if any, in the monitoring of studies?
8. What is your opinion on how studies should be monitored for compliance?
9. During the time on the Committee, were you aware of any protocol violations by study sponsors/investigators and if yes, how were these addressed by your committee?
10. What are some ways you think the REC should or could manage protocol violations in studies?"
11. In your opinion, what should be the role of RECs in ensuring compliance post study approval?
12. What is your opinion on RECs having the right to access recorded research data directly?
13. How should studies selected for site-monitoring?
14. What do you think should happen when ethical violations are identified in studies after an inspection audit?
15. Do you have anything else you would like to share from your experience or recommendations you would like to make?

12.5. በስምምነት ላይ የተመሰረተ የተሳታፊዎች የ መረጃ ቅጽ

ሰላም ጤና ይስጥልኝ!

ሰላም እንደምን አለህ/ሽ?

ስሜ ___ እባላለሁ እና ‘Exploring the experiences of institutional review committees in conducting post-approval and site-monitoring in Ethiopia: A mixed-method research” በሚል ርዕስ ለሚደረገው ጥናት መረጃ ሰብሳቢ ነኝ። የጥናት ተካፋይ በመሆን ስለተመረጠዎት ስለ ጥናቱ ለእርስዎ ለማስረዳት ትኩረትዎን እና ጊዜዎን እንዲሰጡኝ በአክብሮት እጠይቃለሁ። በዚህ ጥናት ላይ ለመሳተፍ ተመርጠዋል ምክንያቱም እርስዎ የደረጃ A REC አባል ስለሆኑ ነው።

<u>የጥናቱ ዓላማ፡-</u> የዚህ ጥናት ዓላማ በኢትዮጵያ post-approval and site-monitoring በተመለከተ የ IRB/REC ን ልምድ ማሰስ ነው።

መምህር ግሩም ታምሩ ከአዲስ አበባ ዩኒቨርሲቲ፣ ጤና ሳይንስ ኮሌጅ፣ የህብረተሰብ ጤና ትምህርት ቤት የጤና ምርምር ስነምግባር ትምህርት ክፍል ለ መመረቂያ ጽሁፍ በሚያጠናው ጥናት ላይ እንድትሳተፉ ተጋብዘዋል።

የዚህ ጥናት ግኝቶች የድህረ ማፅደቅ እና የመሰክ ክትትልን በ RECs ለማሻሻል ከፍተኛ ጠቀሜታ ያለው እና በክሊኒካዊ ምርምር ውስጥ የተሳታፊዎችን ደህንነት ጥበቃን ለማጉላት ያግዛሉ።።

<u>ሂደቶች፡</u> ቃለ መጠይቁ የሚደረገው በመረጃ የተደገፈ ፈቃድ ካገኘ በኋላ ነው፣ እና ከ45-60 ደቂቃዎች አካባቢ ይወስዳል። ለ ኳሊቴቲቭ ቃለ መጠይቁ፣ ኦዲዮ የሚቀዳው በቴፕ መቅጃ ነው።

<u>ስጋት እና ጥቅማ ጥቅሞች፡</u> በዚህ ጥናት ውስጥ በመሳተፍ ጥቂት ደቂቃዎችን ከመጠየቅ በቀር በአንተ ላይ የሚደርስ ጉዳት የለም። በጥሬ ገንዘብ ምንም ቀጥተኛ ጥቅም የለም።። የሚሰጡት መረጃ በሚስጥር ይጠበቃል። በማንኛውም ጊዜ ማንኛቸውም ጥያቄዎች ወይም ጥያቄዎች ካሉዎት እባክዎን በሚከተለው አድራሻ ያግኙን;

ሞባይል ስልክ፣ +251926881004 ወይም በኢሜል፡ girumtam95@gmail.com

ለተጨማሪ መረጃ እባክዎን አዲስ አበባ ዩኒቨርሲቲ፣ የጤና ሳይንስ ኮሌጅ፣ ትምህርት ቤት፣ የህዝብ ጤና፣ አይአርቢ ያነጋግሩ።

<u>በዚህ ጥናት ውስጥ እንደ ተሳታፊ ከእርስዎ ምን ይጠበቃል?</u>

የዚህ ጥናት ተሳታፊ እንደመሆኖ፣ እንደ የጥናት ሞኒተር ያሎትን ልምድ እና እንደ REC አካል በድህረ ማፅደቅ እና የመስክ ክትትል(post-approval and site-monitoring) እና ተዛማጅ ጥያቄዎች ላይ ስላሎትን አንዳንድ ጥያቄዎች መልስ ለመስጠት እንዲስማሙ እንጠይቃለን። ስምህ፣ አድራሻህ እና ቦታህ በህትመቱ ላይ አይገለጽም።

<u>በዚህ ጥናት ለመሳተፍ ምን ያህል ጊዜ አጠፋለሁ?</u>

45-60 ደቂቃዎችን ያጠፋሉ.

<u>መረጃዎቻችን በሚስጥር መያዝ የሚቻለው እንዴት ነው?</u>

የሰጡት መረጃ እና ውጤቶቹ ለዚህ ጥናት ብቻ ጥቅም ላይ ይውላሉ። ሁሉም መረጃዎች በኮምፒውተር እና በይለፍ ቃል ተጠብቀው ይቀመጣሉ።

<u>በዚህ ጥናት ውስጥ እንደ ተሳታፊ የእርስዎ መብቶች ምንድ ናቸው?</u>

ስለ ጥናቱ ማንኛውም አይነት ጥያቄ ወይም ተጨማሪ ማብራሪያ ከፈለጉ በማንኛውም ጊዜ የመጠየቅ መብት አለዎት። በጥናቱ ውስጥ መሳተፍ በፈቃደኝነት ነው፤ እንዲሁም በፈለጉት ጊዜ ከጥናቱ የመውጣት መብት አልዎት። ፍላጎት ካለው የትንታኔውን ውጤት ማግኘት ይችላሉ።

IRB ሃላፊ: ፕሮፌሰር አበራ ቁሜ ኢሜል: aberakumie2@yahoo.com

IRB ጸሃፊ: ዶ/ር ውብእግዜር መኮንን ኢሜል: wubegzierm@gmail.com

12.6. የስምምነት ቅጽ

በኢትዮጵያ የድህረ ማፅደቅ እና የመስክ ክትትል ስራዎችን የተቋማዊ የጥናት እና ምርምር ስነ-ምግባር ገምጋሚ ኮሚቴዎችን ልምድ ለመቃኘት ስለታቀደው ጥናት ተነግሮኛል።

ለዚህ ጥናት፣ ለጠያቂው መልስ እንድሰጥ እና በጥናቱ ላይ ለመሳተፍ የተወሰነ ጊዜዬን እንድሰጥ ይጠበቃል። የጥናቱ ዓላማዎች ተብራርተውልኛል።

በተጨማሪም ኦዲዮ እንደሚቀዳ እና በመጠይቁ ውስጥ ያሉት ሁሉም መረጃዎች በሚስጥር እንዲጠበቁ ተነግሮኛል። በተጨማሪም፣ በማንኛውም ጊዜ የመተባበር እና ከጥናቱ የመውጣት መብቴን በደንብ ተነግሮኛል።

ስለዚህ ሁኔታውን ሙሉ በሙሉ በመረዳት ተመራማሪው በዚህ ጥናት ውስጥ እንዲሳተፉ በፈቃደኝነት ፈቃድ የሰጠሁት።

በተጨማሪም ስለ ጥናቱ ጥያቄዎችን ለመጠየቅ እድል አግኝቻለሁ እናም እርካታዬን አግኝቻለሁ።

ለመሳተፍ እስማማለሁ?

አዎ

አይ

የተሳታፊ ኮድ፡ ..... ፊርማ፡ ..... ቀን፡ .....

የጠያቂው ስም፡ ..... ፊርማ፡ ..... ቀን፡ .....

12.7. አማርኛ መጠይቅ

7 በድህረ ማጽደቅ ተግባራት ውስጥ ተሳትፈው ያውቃሉ?	አዎ: አይ:

እንቅስቃሴው/ስልጣኑ ምን ነበር?

8. የጥናቱ መጀመርን ማሳወቂያ መረጃ መቀበል	አዎ: አይ:
9. ቅጣይነት ያለው የ ጥናት ግምገማ ማካሄድ	አዎ: አይ:
10. አሉታዊ ክስተቶችን/የደህንነት ጉዳዮችን ማሳወቂያ መቀበል	አዎ: አይ:
11. ያለጊዜው መታገድ/የሙከራ መቋረጥ ማስታወቂያ መቀበል	አዎ: አይ:
12. የፕሮቶኮል ማሻሻያዎችን / ልዩነቶችን ማሳወቂያ መቀበል	አዎ: አይ:
13. የፕሮቶኮል ጥሰቶችን ማሳወቂያ መቀበል	አዎ: አይ:

14. የፕሮቶኮል ማሻሻያዎችን አስተያየት መስጠት/ማፅደቅ	አዎ: አይ:
15. የፕሮቶኮል ጥሰቶችን አስተያየት መስጠት / አለመቀበል	አዎ: አይ:
16. የሙከራ ሂደት / በመረጃ የተደገፈ የስምምነት ሂደትን ማረጋገጥ	አዎ: አይ:
17. የማገድ/የማቋረጥ ስልጣን።	አዎ: አይ:
18. የጥናት ሂደት ማብቂያ መግለጫ መቀበል	አዎ: አይ:
19. የመጨረሻ ሪፖርት መቀበል	አዎ: አይ:
20. የሂደቶች መረጃ ጠብቆ ማቆየት	አዎ: አይ:

21. የመስክ ጉብኝት	አዎ: አይ:
22. ከተቆጣጣሪ ባለስልጣናት ጋር ለ ምሳሌ ከ FDA ጋር ግንኙነት ማድረግ/መረጃ መለዋወጥ	አዎ: አይ:

በድህረ-መፅደቅ ወቅት እና የምርምር መስክ ክትትል ላይ ያጋጠሙትን ተግዳሮቶች ለመገምገም

(1= በጣም አልስማማም 2=አልስማማም 3=ገለልተኛ 4=እስማማለሁ 5=በጽኑ እስማማለሁ)

ድህረ ማጽደቂያ ማስገባቶች፡-	**ከ 1-5 ይምረጡ**				
ፕሮቶኮል አለማቅረብ/ያልተሟላ ማስረከብ	1	2	3	4	5
ዘግይቶ ማስረከብ	1	2	3	4	5
የገምጋሚዎች አለመገኘት	1	2	3	4	5
የጊዜ ገደቦችን አለማክበር	1	2	3	4	5
በድህረ ማጽደቂያ ማቅረቢያ ግምገማ ውስጥ ያሉ ተግዳሮቶች፡-					
የወረቀት ስራ መብዛት	1	2	3	4	5
በገምጋሚዎች ረጅም ጊዜ መውሰድ	1	2	3	4	5
የምርምር መስክ ክትትል (SMV)፡					
የ REC አባላት አለመገኘት	1	2	3	4	5
ጊዜ አለመኖር/እጥረት	1	2	3	4	5
የተመራማሪዎች አለመተባበር	1	2	3	4	5
የስልጠና እጥረት	1	2	3	4	5
የተቋሙ ድጋፍ እጦት።	1	2	3	4	5
አደገኛ አሉታዊ ክስተቶችን (SAE) ግምገማ፡-					
የ አሉታዊ ክስተቶችን (SAE) ሪፖርቶችን ተመራማሪዎች አለማስረከብ/ያልተሟላ መረጃ ማስረከብ/ዘግይቶ ማቅረብ።	1	2	3	4	5

ለግምገማ ተጨማሪ ጊዜ መውሰድ	1	2	3	4	5
የወረቀት ስራ እጅግ መብዛት	1	2	3	4	5
የምክንያት መመስረት/Casuality establishement	1	2	3	4	5
የማካካሻ ውሳኔ	1	2	3	4	5
የገምጋሚዎች አለመኖር	1	2	3	4	5
የጊዜ ገደብን አለመከተል	1	2	3	4	5
የባለሙያ እጥረት	1	2	3	4	5

የ የፕሮቶኮል ጥሰቶችን ግምገማ;

የ ተመራማሪዎች የፕሮቶኮል ጥሰቶችን ሪፖርት ለማድረግ አለመታዘዝ	1	2	3	4	5
የፕሮቶኮል ጥሰቶችን በ ተመራማሪዎች ተቀባይነት ማጣት	1	2	3	4	5
የፕሮቶኮል ጥሰቶችን ለማግኘት የጊዜ እጥረት።	1	2	3	4	5
ግልጽ SOP አለመኖር	1	2	3	4	5
REC በ ተመራማሪዎች ላይ እርምጃ ለመውሰድ አለመቻል	1	2	3	4	5
የተቋማዊ ድጋፍ እጦት።	1	2	3	4	5

ለ RECs የተጠቆሙ መፍትሄዎች

SOPs መታደስ አለባቸው፤ እና እያንዳንዱ አባል ስለ SOPs ማወቅ አለበት።	አዎ: አይ:
የጥናትና ምርምር ሥነ ምግባር ኮሚቴዎች እውቅና ለማግኘት መጣር አለባቸው	አዎ: አይ:

በስልጠና እና የግንዛቤ ማስጨበጫ ፕሮግራሞች አማካኝነት የአቅም ግንባታ	አዎ: አይ:
በ PAM ላይ የሚያተኩር የ የጥናትና ምርምር ሥነ ምግባር ኮሚቴዎች መደበኛ ስልጠና	አዎ: አይ:
የገንዘብ ድጋፍ	አዎ: አይ:
የሰው ሀብትን ማሳደግ	አዎ: አይ:
ልምድ ያላቸውን ነባር የጥናትና ምርምር ሥነ ምግባር ኮሚቴ አባላትን ማካተት	አዎ: አይ:
እንደ የሙሉ ጊዜ የሥራ ሁኔታ እውቅና መስጠት እና በ የጥናትና ምርምር ሥነ ምግባር ኮሚቴ ለተሰጠው ጊዜ የማካካሻ አስፈላጊነት	አዎ: አይ:
በቴክኖሎጂ ክትትል ማድረግ	አዎ: አይ:

12.8. **ለተቋማዊ የጥናት እና ምርምር ግምገማ ኮሚቴዎች IRBs/ECs የቃለ መጠይቅ መመሪያ**

የጥናቱ ርዕስ፡ የድህረ መፅደቅ እና የመስክ ክትትልን በማካሄድ ላይ በኢትዮጵያ የሚገኙ የተቋማዊ የጥናት እና ምርምር ግምገማ ኮሚቴዎችን ልምድ ማሰስ።

የቃለ መጠይቁ መጀመሪያ እና ቀን እና ሰዓት፡ ኮድ፡-

1. የእርስዎ REC የጸደቁ ፕሮቶኮሎችን ቀጣይነት ያለው ግምገማ ያደርጋል? አዎ ከሆነ፣ ይህ ግዴታ ነው?

2. ከመጀመሪያው ፈቃድ በኋላ የጥናት ፕሮቶኮሎችን በመገምገም/ማጽደቅ/በግምገማ/ኡዲት (ፍተሻ) ላይ ያለዎት ልምድ ምን ይመስላል?

3. የክትትል ዓላማ ምንድን ነው?

4. የድህረ ማፅደቅ እና የመስክ ክትትል ሲደረግ የሚያጋጥሙ ተግዳሮቶች ምንድን ናቸው?

5. በእርስዎ አስተያየት፣ ከመጀመሪያው ፈቃድ በኋላ የጥናት ድህረ ማጽደቅ ክትትል/PAM ማን ክትትል ማድረግ አለበት?

6. የድህረ ማፅደቅ እና የጥናት መስክ የመከታተል እድሎች ምን ምን ናቸው ብለው ያምናሉ?

7. ጥናቶችን በመከታተል ረገድ የኮሚቴዎ ሚና ካለ ይግለጹ?

8. ጥናቶች በፕሮቶኮል መሰረት መሄዱን ለማስከበር እንዴት ክትትል ሊደረግባቸው እንደሚገባ አስተያየትዎ ምንድነው?

9. በኮሚቴው ውስጥ በነበሩበት ጊዜ፣ በጥናት ስፖንሰሮች/መርማሪዎች የፕሮቶኮል ጥሰቶች እንዳሉ ያውቃሉ እና አዎ ከሆነ፣ እነዚህ በኮሚቴዎ እንዴት ተስተናግደዋል?

10. REC በጥናት ውስጥ የፕሮቶኮል ጥሰቶችን ማስተዳደር አለበት ወይም ማስተዳደር ይችላል ብለው የሚያስቡት አንዳንድ መንገዶች ምንድን ናቸው?

11. በእርስዎ አስተያየት፣ ከጥናት በኋላ ማፅደቁን በማረጋገጥ ረገድ የ RECs ሚና ምን መሆን አለበት?

12. የተቀዳ የምርምር መረጃዎችን RECs በቀጥታ የማግኘት መብታቸው ላይ ምን አስተያየት አለህ?

13. ጥናቶች ለመስክ ክትትል እንዴት መምረጥ አለባቸው?

14. ከቁጥጥር ኡዲት በኋላ በተደረጉ ጥናቶች የስነምግባር ጥሰቶች ሲታወቁ ምን መሆን አለበት ብለው ያስባሉ?

15. ከተሞክሮዎ ወይም ሊሰጡዋቸው ከሚፈልጉት ምክሮች ለማጋራት የሚፈልጉት ሌላ ነገር አለዎት?

Table 10: Nationally Registered IRERCs by NRERB, MoE, Ethiopia, 2023 GC

So.No.	Name of IRERC	Registration code	Date of Registration	Level
1	Tigray Health Research Institute of Review Board	IRB 002/2019	5-Jun-19	A
2	Mekele University College of Health Sciences	IRB004/2020	31-Jan-20	A
3	Eka Kotebe General Hospital	IRB 005/2021	6/08/2013 E.C	A
4	Arba Minch Health Sciences College	IRB006/2021	31 August 2021	A
5	Akililu Lema Institute of Pathobiology	IRB007/2021	9-Nov-21	B
6	Addis Continental Institute of Public Health(ACIPH)	IRERC004/2022	1-Dec-22	A
7	Dire Dawa University	IRB008/2022	14-Jan-22	B
8	Arba Minch University College of Medicine and Health Sciences	IRB002/2022	20-Feb-22	A
9	Hawassa College of Health Sciences	IRB003/2022	20-Feb-22	B
10	Ethiopian Public Health Institute	IRB004/2022	16-May-22	A
11	Ethiopian Society of Sociologists, Social workers, and Anthropologists (ESSSWA)	IRB003/2022	29-Jun-22	A
12	University of Gondar College of Medicine and Health Science and Specialized hospital	IRERC-001/2022	1-Sep-22	A
13	Ethiopian Midwives Association (EMwA)	IRB005/2019	31-Oct-22	A
14	Ethiopian Association of Anesthetists (EAA)	IRERC003/2022	10/21/2022	B
15	Ethiopian Public Health Association	IRERC001/2017	2-Feb-23	A
16	Addis Ababa University College of Health sciences (AAUCHS)	IRERC004/2023	3/1/2023	A
17	Armauer Hansen Research Institute (AHRI)	IRERC007/2023	4/3/2023	A
18	Hamlin Fistula Ethiopia	IRERC007/2023	4/3/2023	B
19	Ethiopian Medical Association	IRERC00/2022	3/22/2023	B

Table 11 Violations/deviations found by SMV report and corrective actions

Violation themes	Monitoring sites in violation (N =46)	Corrective action/ Measures taken
Informed consent issues	19	➢ Continued GCP training of study recommended ➢ Information was added on the ICF (Phone address of PI and IRB) ➢ Assent form requested Address of the IRB recommended Amendment needed ➢ A copy of signed consent should be given and translation of ICF to local languages was stressed ➢ Explanation asked for with a clear warning against future repetition
Deviation from investigational plan (protocol)	14	➢ Continued GCP training of study recommended ➢ The amendment needed to give compensation appropriately ➢ Adherence to the protocol and if there are any changes, request an amendment from the IRB ➢ Monitoring plan recommended ➢ Quality assurance recommended ➢ Explanation asked for with a clear warning against future repetition
No reporting of SAEs to IEC	2	➢ SAE should be reported within 24 hours ➢ Submission of AE reports ➢ Continued GCP training of study recommended ➢ Explanation asked for with a clear warning against future repetition

Privacy of the study participants and the data confidentiality	9		➢ Files should be locked and confidentiality should be maintained ➢ ODK should be locked in the password
Issues related to the principal investigator	2		➢ Continued GCP training of study recommended
IEC approval status	2		➢ Ethical clearance should be renewed ➢ Submission of protocol report Amendment should be requested before the data collection ➢ Submit protocol deviation to the IRB
Other findings ❖ Safety of data collectors, throat irritation from chemicals use without PPE ❖ Documentation problem No hard copy CRF No hard copy protocol No hard copy investigator file and enrollment log ❖ No GCP training for researchers	3	➢ Each happened once on different sites	➢ A hard copy of CRF should be ➢ Appropriate training should be given including investigational products and the safety of the study team and participants ➢ Continued GCP training of study recommended ➢ Enrollment file, investigator file, and study protocol should be available in hard copy

Codebook

PAM Mixed-method.mx20

5/18/2024

Code System

1 Experiences	0
1.1 Reasons	0
1.1.1 Convienence method (+)	2
1.1.2 Risk based selection	12
1.1.3 Based on decision not by guideline	4
1.1.4 Based on the type of studies	0
1.1.4.1 Multi site studies	1
1.1.4.2 Longitudinal studies	1
1.1.4.3 Interventional studies	3
1.1.4.4 Clinical trials	4
1.1.4.5 New methodology	1
1.1.4.6 Sensitive studies	4
1.1.4.7 Large-scale studies	3
1.1.5 Routine (+)	12
1.1.6 For cause	3
1.1.6.1 Suspicion	2
1.1.6.2 AE	2
1.1.6.3 Whistle-blowers	3
1.1.6.4 SAE (+) (+)	3
1.2 Passive	2
1.2.1 Giving opinion to modifications	6
1.2.2 Ongoing review of the protocol (+)	15
1.2.2.1 No ongoing review	2
1.2.3 Reception of notifications of starting	1
1.2.4 Reviewing progress report	12
1.2.5 Through dissemination of the result	1
1.3 Active monitoring	0
1.3.1 On-site monitoring	10
1.3.1.1 No finding on SM	1
1.3.1.2 No Experience of SM	8
1.3.2 Scheduled visit	7
1.3.3 Surprise visit	7
2 Corrective actions	0

2.1 Feedback or Reccomendation given	0
2.1.1 Direct reccomendation for the PI	4
2.1.2 Actions for minor deviation	1
2.1.3 Explanation with caution	2
2.1.4 Methodological recommendation	1
2.1.5 Reporting	4
2.1.6 Special attention for SAE	1
2.1.7 Training	1
2.1.8 Warnings	2
2.2 Request information	0
2.2.1 Clarification	1
2.2.2 Handling of violatgions	3
2.3 Serious measures	0
2.3.1 Firing the data collectors	2
2.3.2 Legal measures	3
2.3.3 Loss of investement	2
2.3.4 Not voluntary participation on-spot correction	1
2.3.5 Prohibition or termination of the study	16
2.3.6 Removal of the ethical clearance	2
2.3.7 Retraction	1
2.3.8 Strict measures	3
2.3.9 Suspension	4
2.4 Immediate discussion and action	2
3 Gaps	0
3.1 COI	1
3.2 Clearance issue	0
3.2.1 Inappropriate letter	1
3.2.2 Retrospective review	1
3.2.3 Starting before the approval	1
3.3 Compensation	2
3.4 IC process	5
3.5 Not going according to the protocol	0
3.5.1 Participant enrollenment not as planned	4
3.5.2 Protocol deviations	6

3.5.3 Study site changing	1
3.6 Protocol violation	4
3.6.1 Breach of confidentialty and privacy	1
3.6.2 Data collector errors	7
3.6.3 No violations found or heared so far	5
3.6.4 Not deliberate mistakes and could be managed accordingly	1
3.6.5 Rare thing	1
3.6.6 Suspected violation	3
3.7 Reporting gap	0
3.7.1 Amendement	2
3.7.2 Progress report not sent	1
3.7.3 SAE reporting	1
4 Context of the IRB and general characterstics	2
4.1 PAM role	0
4.1.1 IRBs	26
4.1.1.1 The Community representative participation	1
4.1.1.2 Reviewers and the institution	2
4.1.1.3 Secretariat role	6
4.1.2 The role of IRBs regarding PAM	1
4.1.2.1 Addressing problems	1
4.1.2.2 Appropriate attention needed	3
4.1.2.3 Update the SOP	1
4.1.2.4 Notifying the stakeholders	1
4.1.2.4.1 Empowering the participants	1
4.1.2.5 Having the necessary plan	4
4.1.2.6 Finding resources	3
4.1.3 Research advisory committee	1
4.1.4 The healthcare professionals	2
4.1.5 Self-assessment tool for IRBs	2
4.1.6 Shared role	5
4.1.7 Independent reporters or auditors	1
4.1.8 Sponsor	2
4.1.9 Regulatory authorities	2

4.1.9.1 NRERB accreditation	2
4.1.9.2 FDA	1
4.1.9.3 Lack of support	1
4.1.9.4 Monitoring of IRBs itself	2
4.1.10 Data safety monitoring board	1
4.1.11 The study team (+)	5
4.1.11.1 Assigned field supervisors	1
4.1.11.2 Trust based	1
4.1.11.3 Up to the capacity of the study team	1
4.2 Views	0
4.2.1 Access to database	0
4.2.1.1 Time consuming	1
4.2.1.2 Better to be accessed	3
4.2.1.3 Deidentified data access only	2
4.2.1.4 RA access	1
4.2.1.5 Couldnot access the raw data	7
4.2.1.6 Based on purpose	6
4.2.2 No study done on the researchers view	2
4.2.3 Positive (+)	5
4.2.4 Contextual need for PAM (+)	8
4.2.5 Site monitoring should be done	8
4.2.6 Was neglected issue (+) (+)	18
4.3 Structure and functions of IRBs	0
4.3.1 Stablishement of IRBs	1
4.3.2 Mandatory ongoing review	7
4.3.3 Ongoing review not mandatory	1
4.3.4 Coolaborative work	3
4.3.5 Online meeting	1
4.3.6 Emperative of clearance (+)	2
4.3.7 IRB Report	1
4.3.8 Review process	4
4.3.8.1 Less pepers reviewed this days	1
4.3.8.2 Only for the institution	2
4.3.8.3 Time taken	1

4.3.8.3.1 Awareness creation for the process	1
4.3.8.4 Online communication	1
4.3.8.5 Rejected protocols	2
4.3.8.6 Tie breaker	1
4.3.8.7 Independent reviewer	3
4.3.8.8 Looking for the CV	3
4.3.8.9 Requesting the expedite review	1
4.3.8.10 Anonimous members	3
4.3.9 IRB to IRERC	2
4.3.10 Presence of SOP (+)	15
4.3.11 Composition	3
4.3.12 Short term studies or surveys	6
4.3.13 Less clinical trials	4
4.3.14 Periodic report request (+) (+)	6
4.3.15 Monthly sitting allowance	1
4.3.16 Collaborative work	1
4.3.17 Hierarchical follow-up	1
4.3.18 Good institutional support	10
4.4 Objective	0
4.4.1 Protection of the institution	1
4.4.2 Research mis-conduct reduction	2
4.4.3 Building trust	1
4.4.4 Accountability	1
4.4.5 Assuring the benefit deserved	3
4.4.6 Quality assurance	8
4.4.7 Continues support for the researchers	2
4.4.8 Ensuring Compliance	22
4.4.9 Safety and the right protection	21
4.4.10 Teaching and Learning	4
4.4.10.1 Real understanding	7
5 Challenges	0
5.1 Observer effect	3
5.2 Attitude	0
5.2.1 Researchers' view towards the IRBs	0

5.2.1.1 Percieved simplicity	2
5.2.1.2 Lack of awareness about IRBs	5
5.2.1.3 Ignorance	3
5.2.1.4 No role after approval	2
5.2.1.5 Trust issues	1
5.2.1.6 Fear	8
5.2.2 Members view	2
5.2.3 Lack of willingeness	2
5.2.4 Stakeholders view	1
5.2.5 Researchers attitude	1
5.2.6 Big institutions and PIs pressure on the IRB	1
5.3 Lack of system	0
5.3.1 Lack of ethical culture	1
5.3.2 Poor institutional support	6
5.3.3 No clear guidance for on-site monitoring (+)	7
5.3.4 Unclear role (+)	9
5.3.4.1 Lose of trust	2
5.3.5 Lack of a supportive system	3
5.4 High burden	0
5.4.1 Abscence of members	1
5.4.2 Too much paper work	1
5.4.3 Monitoring burden	6
5.4.4 Time	13
5.4.5 Compensation for IRBs	3
5.5 Cotextual challenges	0
5.5.1 Lack of capacity	2
5.5.2 Progress report non submission	4
5.5.3 Dependence on the institution	2
5.5.4 Not accessing the researchers	1
5.5.5 Large scale or multicentered studies related challenges	2
5.5.6 Security	3
5.5.7 War	2
5.6 Resource	17

5.6.1 SOP not uptodate due to budget	1
5.6.2 Competence and training	3
5.6.3 Human power shortage (+)	3
5.6.4 Budget problem (+) (+)	16
6 Suggestions given	0
6.1 Digitalization	0
6.1.1 Recomendation of the digitalization of the PAM	1
6.1.2 The digitalization up to the approval	2
6.1.3 CAPI	1
6.2 Suggestions for the researchers	0
6.2.1 PAM Awareness	13
6.2.2 Planning the PAM by PIs	4
6.2.3 PIs should strive for adherence and reporting	4
6.2.4 Timely renewal	1
6.3 Mechanisms and approaches (+)	0
6.3.1 Clear guidance	2
6.3.2 Scheduled visit is not good	3
6.3.3 The need for mechanism	1
6.3.4 Other independent body	6
6.3.5 Smooth communication with PIs	9
6.3.6 Phone follow up using checklist	2
6.3.7 Publishing the protocol and comparing with the actual work	1
6.3.8 Not like policing	3
6.3.9 Multiple method	2
6.3.10 Surveyors	6
6.3.11 Checklist	2
6.3.12 Proactive management	3
6.3.13 Self-assesement tool	8
6.3.14 Culture creation	3
6.3.15 Charge	2
6.3.15.1 Benefit outweigh the cons	1
6.3.15.2 Challenges of charging	1
6.4 Capacity building	0

6.4.1 The need for PAM	4
6.4.2 More emphasise for PAM	1
6.4.3 Regular PAM training (+)	4
6.4.4 RAs oversight of IRBs (+)	7
6.4.5 Strengethening the functions of IRBs (+) (+) (+) (+) (+) (+)	20
6.4.6 System development	5
7 Opportunities of PAM	0
7.1 Supportive activities	0
7.1.1 Presentation about the progress	1
7.1.2 Stakeholders oversight	1
7.1.3 Self-monitoring	1
7.1.4 Annual forum	1
7.1.5 Summit of stakeholders	1
7.2 Research scale-up	0
7.2.1 New interventions	2
7.2.2 Large-scale studies	1
7.2.3 The methodology	1
7.2.4 Clinical trial	1
7.2.5 The presence of studies	2
7.3 Triggers	0
7.3.1 Context based	1
7.3.2 Whistlebloowers	2
7.3.3 The aim to avoid harm	1
7.3.4 Being obligatory	4
7.3.5 Accreditation	3
7.3.6 Mandatory for Publication	2
7.3.7 Compliant	1
7.4 Capacity	0
7.4.1 Presence of supportive law	1
7.4.2 Credibility	1
7.4.3 Awareness of the healthcare providers	1
7.4.4 Resource	5
7.4.5 Being a full-board	1

7.4.6 Presence of supportive staff in the institution	1
7.4.7 Presence of active follow-up	1
7.4.8 Teaching learning activity	4
7.4.9 The presence of Universities	1
7.4.10 Expertise	2
7.4.11 Training and advocacy	3
7.4.12 Active member	1

1 Experiences

Previous PAM experiences of IRBs

1.1 Experiences >> Reasons

Reasons to conduct PAM

1.1.1 Experiences >> Reasons >> Convienence method (+)

Convienent method for the selection of studies to be monitored, since resources are scarce

1.1.2 Experiences >> Reasons >> Risk based selection

Based on the level of the risk, high risk studies are selected for on-site monitoring.

1.1.3 Experiences >> Reasons >> Based on decision not by guideline

The selection of studies for on-site monitoring is based on the decision of the IRB, not just by the guideline

1.1.4 Experiences >> Reasons >> Based on the type of studies

Based on the study type like, sensitive studies, long-lasting studies, multi-site studies, large scale studies, clinical trials, interventional studies, longitudinal studies, and the use of new methodology

1.1.4.1 Experiences >> Reasons >> Based on the type of studies >> Multi site studies

Prioritize the on-site monitoring of studies if multi-site studies

1.1.4.2 Experiences >> Reasons >> Based on the type of studies >> Longitudinal studies

Longitudinal studies selected for on-site monitoring

1.1.4.3 Experiences >> Reasons >> Based on the type of studies >> Interventional studies

Interventional studies are selected for PAM

1.1.4.4 Experiences >> Reasons >> Based on the type of studies >> Clinical trials

Clinical trials should be selected for on-site monitoring

1.1.4.5 Experiences >> Reasons >> Based on the type of studies >> New methodology

When the study involves a new methodology, it needs on-site monitoring.

1.1.4.6 Experiences >> Reasons >> Based on the type of studies >> Sensitive studies

On-site monitoring should be done for Sensitive studies and involving vulnerable groups

1.1.4.7 Experiences >> Reasons >> Based on the type of studies >> Large-scale studies

Large-scale studies selected for on-site monitoring.

1.1.5 Experiences >> Reasons >> Routine (+)

The conduct of PAM as a routine activity

Initial selection
Created: Girum, 4/29/2024 9:06 AM

When the protocols are reviewed, they are selected based on the recommendation of the reviewers

1.1.6 Experiences >> Reasons >> For cause

The conduct of PAM for specific reasons or causes

1.1.6.1 Experiences >> Reasons >> For cause >> Suspicion

If there is question during the initial review

1.1.6.2 Experiences >> Reasons >> For cause >> AE

When adverse event occurred

1.1.6.3 Experiences >> Reasons >> For cause >> Whistle-blowers

When concerns reached the committee members from other bodies

1.1.6.4 Experiences >> Reasons >> For cause >> SAE (+) (+)

Site visit is being done when a Serious adverse event is occured

SAE
Created: Girum, 4/20/2024 5:32 AM

The finding of SAE during the study

Casuality establishment
Created: Girum, 4/20/2024 5:36 AM

Establishment of a casualty for a SAE

1.2 Experiences >> Passive

Passive means of follow up of studies after initial approval

PAM passive way
Created: Girum, 5/1/2024 8:18 PM

Passive way of monitoring of studies after the approval, no site visit experience

1.2.1 Experiences >> Passive >> Giving opinion to modifications

issuance of opinion to protocol modifications

Looking protocol amendments
Created: Girum, 4/10/2024 1:52 PM

Reception of protocol amendements

1.2.2 Experiences >> Passive >> Ongoing review of the protocol (+)

Ongoing review of the protocols regularly

Ongoing review based on the type of studies
Created: Girum, 5/1/2024 8:09 PM

Ongoing review depend on the type of studies.

Ongoing review
Created: Girum, 5/1/2024 8:15 PM Modified: Girum, 5/3/2024 12:29 PM

The view towards PAM/ongoing review is different and can be seen as going to the site and evaluate the work

Ongoing review
Created: Girum, 4/10/2024 1:52 PM

Ongoing review of protocols

1.2.2.1 Experiences >> Passive >> Ongoing review of the protocol (+) >> No ongoing review

The IRB did not have an experience of on-going review of studies

1.2.3 Experiences >> Passive >> Reception of notifications of starting

Reception of notification that the study has been started

1.2.4 Experiences >> Passive >> Reviewing progress report

Review of the progress report of a study

Reception of progress report
Created: Girum, 5/2/2024 10:55 AM

The admin of IRB will communicate to find the report based on the SOP

1.2.5 Experiences >> Passive >> Through dissemination of the result

The method of follow-up is through dissemination

1.3 Experiences >> Active monitoring

1.3.1 Experiences >> Active monitoring >> On-site monitoring

On-Site monitoring

SM Experience
Created: Girum, 4/28/2024 5:38 PM

On-site visit experience of IRBs

1.3.1.1 Experiences >> Active monitoring >> On-site monitoring >> No finding on SM

When the IRBs got at the site, there were no new things found, and the PIs were working as they planned

1.3.1.2 Experiences >> Active monitoring >> On-site monitoring >> No Experience of SM

No previous experience of on-site monitoring

1.3.2 Experiences >> Active monitoring >> Scheduled visit

The IRB communicates with the PI and appoints the date of the visit

1.3.3 Experiences >> Active monitoring >> Surprise visit

The IRB's surprise visit to the study site without the awareness of the PI

2 Corrective actions

Corrective actions taken for identified gaps

2.1 Corrective actions >> Feedback or Reccomendation given

2.1.1 Corrective actions >> Feedback or Reccomendation given >> Direct reccomendation for the PI

Direct recommendations were given for the PIs to correct the issues

2.1.2 Corrective actions >> Feedback or Reccomendation given >> Actions for minor deviation

If minor deviation, the IRB recommends correcting it accordingly

2.1.3 Corrective actions >> Feedback or Reccomendation given >> Explanation with caution

Explanation and caution given for the researchers

2.1.4 Corrective actions >> Feedback or Reccomendation given >> Methodological recommendation

Methodological recommendation were given for the PI

2.1.5 Corrective actions >> Feedback or Reccomendation given >> Reporting

If there is violation, reporting is the first step

2.1.6 Corrective actions >> Feedback or Reccomendation given >> Special attention for SAE

If SAE occurs frequently, the need for special attention will be suggested for the PI

2.1.7 Corrective actions >> Feedback or Reccomendation given >> Training

Telling the PI to give relevant training

2.1.8 Corrective actions >> Feedback or Reccomendation given >> Warnings

If minor breaches identified, we will give them a warning letter or oral warning

2.2 Corrective actions >> Request information

2.2.1 Corrective actions >> Request information >> Clarification

Clarification was requested to investigate the cause and the event

2.2.2 Corrective actions >> Request information >> Handling of violatgions

The researcher should give the reason for the actions against the protocol and should be decided by mutual agreement

2.3 Corrective actions >> Serious measures

2.3.1 Corrective actions >> Serious measures >> Firing the data collectors

Once serious violations by the data collectors found, they will be fired immediately

2.3.2 Corrective actions >> Serious measures >> Legal measures

Taking the case to the legal body

Legal proceedings
Created: Girum, 5/3/2024 3:08 PM

Taking the issue to the legal proceeding

2.3.3 Corrective actions >> Serious measures >> Loss of investement

Research is an investment, so stopping it is a loss of investment

2.3.4 Corrective actions >> Serious measures >> Not voluntary participation on-spot correction

When the ethics committees aware that the researchers tried to convince the participants with out thier consent, we managed them on-spot

2.3.5 Corrective actions >> Serious measures >> Prohibition or termination of the study

Terminate the study totally

2.3.6 Corrective actions >> Serious measures >> Removal of the ethical clearance

The ethical clearance will no longer be functional if there is a major violation found and if the funder is also violating the ethics

2.3.7 Corrective actions >> Serious measures >> Retraction

There will be a high probability of retraction from the publication

2.3.8 Corrective actions >> Serious measures >> Strict measures

Strict measures will be taken for the protocol violation

2.3.9 Corrective actions >> Serious measures >> Suspension

When protocol violations happen, the study should be stopped temporarily until resolved

2.4 Corrective actions >> Immediate discussion and action

Immediate discussion and ways forward/ Immediate actions for the violation will be given

3 Gaps

Gaps identified during PAM and on-site monitoring

3.1 Gaps >> COI

CoI happened and managed accordingly!

3.2 Gaps >> Clearance issue

Publication of study done on human subjects using ethical clearance from natural sciences. It should not be done as this.

3.2.1 Gaps >> Clearance issue >> Inappropriate letter

Clearance taken from natural sciences without the inclusion of the medical team or without oversight by the IRBs composed of medical team

3.2.2 Gaps >> Clearance issue >> Retrospective review

The retrospective ethical clearance request after the completion of the study

3.2.3 Gaps >> Clearance issue >> Starting before the approval

There was one ongoing study that started the data collection before the approval letter given.

3.3 Gaps >> Compensation

Gaps in actual compensation given for the study participants versus written in the protocol

Lack of clarity regarding the compensation
Created: Girum, 5/2/2024 1:51 PM

The compensation for the study participants were tailored to their distance travelled. We recieved some compliants regarding this difference. This could have been solved at the study site.

3.4 Gaps >> IC process

Any problems identified in informed consent process

Non-voluntary participation
Created: Girum, 5/2/2024 12:57 PM

There were rumors regarding the participation with out the voluntary agreement of the study participant

3.5 Gaps >> Not going according to the protocol

Not going as planned protocol

3.5.1 Gaps >> Not going according to the protocol >> Participant enrollenment not as planned

Enrollment of the study participants other than what mentioned in the protocol

Over enrollement or underenrollement without reporting
Created: Girum, 4/21/2024 8:13 AM

When the sample size changed without reporting

3.5.2 Gaps >> Not going according to the protocol >> Protocol deviations

Minor deviations like methodological changes and selection of study participants

3.5.3 Gaps >> Not going according to the protocol >> Study site changing

Changing the study site which is not mentioned in the protocol

3.6 Gaps >> Protocol violation

Violations of the protocol

3.6.1 Gaps >> Protocol violation >> Breach of confidentialty and privacy

The breach of the privacy and confidentiality identified through site monitoring

3.6.2 Gaps >> Protocol violation >> Data collector errors

Mostly, violations found so far are the faults of the data collectors

Fabrication
Created: Girum, 5/3/2024 9:36 PM

Fabrication of the data found

3.6.3 Gaps >> Protocol violation >> No violations found or heared so far

So far, there have been no violations found by on-site monitoring

3.6.4 Gaps >> Protocol violation >> Not deliberate mistakes and could be managed accordingly

3.6.5 Gaps >> Protocol violation >> Rare thing

Protocol violations are uncommon especially when there is good communication and responsible researchers

3.6.6 Gaps >> Protocol violation >> Suspected violation

Without clear evidence of violation, there may be a suspicion

3.7 Gaps >> Reporting gap

Not reporting the SAE or the progress and the necessary reportings

3.7.1 Gaps >> Reporting gap >> Amendement

Amendment not requested by the researcher due to several reasons like time shortage

3.7.2 Gaps >> Reporting gap >> Progress report not sent

The progress report of the study have not been submitted to IRBs

3.7.3 Gaps >> Reporting gap >> SAE reporting

A gap in the reporting of serious adverse events like not in time or nor generally reporting them

4 Context of the IRB and general characterstics

The biggest IRB in the country next to the NRERB

4.1 Context of the IRB and general characterstics >> PAM role

The role to conduct PAM

4.1.1 Context of the IRB and general characterstics >> PAM role >> IRBs

IRBs have a role to do PAM

4.1.1.1 Context of the IRB and general characterstics >> PAM role >> IRBs >> The Community representative participation

Community representatives should also involve in selected on-site monitoring since there could be feedback from the community and can see it independently

4.1.1.2 Context of the IRB and general characterstics >> PAM role >> IRBs >> Reviewers and the institution

The role of PAM rests on the shoulders of the reviewers and the institution that approves the protocol

4.1.1.3 Context of the IRB and general characterstics >> PAM role >> IRBs >> Secretariat role

The secretariate is composed of one or two members, and responsible to follow the studies

4.1.2 Context of the IRB and general characterstics >> PAM role >> The role of IRBs regarding PAM

What is the role of IRBs in conducting PAM

4.1.2.1 Context of the IRB and general characterstics >> PAM role >> The role of IRBs regarding PAM >> Addressing problems

The responsibility of IRBs in PAM is overlooking the process of the study teams and addressing the problems if occured

4.1.2.2 Context of the IRB and general characterstics >> PAM role >> The role of IRBs regarding PAM >> Appropriate attention needed

The attention given to PAM should be enhanced

4.1.2.3 Context of the IRB and general characterstics >> PAM role >> The role of IRBs regarding PAM >> Update the SOP

The role of the IRB is to update the SOP according to national and international guidelines.

4.1.2.4 Context of the IRB and general characterstics >> PAM role >> The role of IRBs regarding PAM >> Notifying the stakeholders

To prevent the conmduct of research with out ethics oversight, the stakeholders should be notifieed by the IRBs to not let the research go with out the approval

4.1.2.4.1 Context of the IRB and general characterstics >> PAM role >> The role of IRBs regarding PAM >> Notifying the stakeholders >> Empowering the participants

The address of IRBs are present in the consent form, so the study participants should be aware about its presence and contact the IRBs if anything happened

4.1.2.5 Context of the IRB and general characterstics >> PAM role >> The role of IRBs regarding PAM >> Having the necessary plan

The role of the IRBs in conducting PAM is to have the necessary plan and process including getting the budget

4.1.2.6 Context of the IRB and general characterstics >> PAM role >> The role of IRBs regarding PAM >> Finding resources

One of the roles of IRBs is to searching for the resources needed to conduct PAM

4.1.3 Context of the IRB and general characterstics >> PAM role >> Research advisory committee

Since the burden is much on the committee, PAM should also be supported by research advisory committees

4.1.4 Context of the IRB and general characterstics >> PAM role >> The healthcare professionals

The health care providers should also be aware about the studies that are being done on their patients and they should ask the researchers for their identity and the presence of ethical clearance

4.1.5 Context of the IRB and general characterstics >> PAM role >> Self-assessment tool for IRBs

The self-assessment tool will also help to assess the IRBs, their level of transparency

4.1.6 Context of the IRB and general characterstics >> PAM role >> Shared role

Several stakeholders should do PAM activity depending on the type of the study

4.1.7 Context of the IRB and general characterstics >> PAM role >> Independent reporters or auditors

Independent reporters or auditors do follow-up activity

4.1.8 Context of the IRB and general characterstics >> PAM role >> Sponsor

The sponsor has a responsibility to conduct post-approval monitoring in Clinical trials

4.1.9 Context of the IRB and general characterstics >> PAM role >> Regulatory authorities

PAM is the role of regulatory authorities

4.1.9.1 Context of the IRB and general characterstics >> PAM role >> Regulatory authorities >> NRERB accreditation

The NRERB gives accreditation to IRBs.

4.1.9.2 Context of the IRB and general characterstics >> PAM role >> Regulatory authorities >> FDA

Clinical trials should be monitored by regulatory authority, FDA

4.1.9.3 Context of the IRB and general characterstics >> PAM role >> Regulatory authorities >> Lack of support

There is a lack of empowerment of IRBs by the National Board and MoE, they should check the works of IRBs and support them technically

4.1.9.4 Context of the IRB and general characterstics >> PAM role >> Regulatory authorities >> Monitoring of IRBs itself

The current system of monitoring and accreditation of the IRBs is poor and only relies on the report. It is not enough to give accreditation on this way

4.1.10 Context of the IRB and general characterstics >> PAM role >> Data safety monitoring board

Data Safety Monitoring Boards have the right to access recorded research data directly

4.1.11 Context of the IRB and general characterstics >> PAM role >> The study team (+)

It is the study team's role to conduct PAM

PI
Created: Girum, 4/16/2024 1:55 PM

If the study involves several research team, the PI should do PAM

4.1.11.1 Context of the IRB and general characterstics >> PAM role >> The study team (+) >> Assigned field supervisors

The field supervisor should do monitoring, but not sure how properly work

4.1.11.2 Context of the IRB and general characterstics >> PAM role >> The study team (+) >> Trust based

Based on trust in the researchers

4.1.11.3 Context of the IRB and general characterstics >> PAM role >> The study team (+) >> Up to the capacity of the study team

The Study team should follow the study thoroughly and if beyond their level, then reporting to the IRBs

4.2 Context of the IRB and general characterstics >> Views

4.2.1 Context of the IRB and general characterstics >> Views >> Access to database

The view of IRBs towards the access of raw data directly by IRBs

4.2.1.1 Context of the IRB and general characterstics >> Views >> Access to database >> Time consuming

Accessing the data to cross-check is difficult and time-consuming.

4.2.1.2 Context of the IRB and general characterstics >> Views >> Access to database >> Better to be accessed

It could have been better if IRBs accessed the raw data

4.2.1.3 Context of the IRB and general characterstics >> Views >> Access to database >> Deidentified data access only

The IRB should not access the dataset unless the personal identifiers are not available

4.2.1.4 Context of the IRB and general characterstics >> Views >> Access to database >> RA access

Only regulatory bodies should access the database directly. In our situation, the FDA and the NRERB are considered as a RA

4.2.1.5 Context of the IRB and general characterstics >> Views >> Access to database >> Couldnot access the raw data

IRBs could not access the database directly

4.2.1.6 Context of the IRB and general characterstics >> Views >> Access to database >> Based on purpose

Based on the purpose, IRBs can access the raw data directly like when SAE occured

4.2.2 Context of the IRB and general characterstics >> Views >> No study done on the researchers view

There is no study that assess the view of researchers towards IRBs

4.2.3 Context of the IRB and general characterstics >> Views >> Positive (+)

Researchers have a positive view towards IRBs

Stands to protect the researchers
Created: Girum, 5/4/2024 12:22 AM

Positive view of the researchers since it stands to protect them as well

4.2.4 Context of the IRB and general characterstics >> Views >> Contextual need for PAM (+)

The actual challenges on the ground might differ. So, PAM should be done to understand the real context

Advantage of Site monitoring
Created: Girum, 4/11/2024 1:45 AM Modified: Girum, 5/8/2024 11:16 PM

How a study selected for on-site monitoring

Reason for on-site monitoring
Created: Girum, 4/11/2024 1:42 AM

The compliance and the actual contextual implementation of the study is being able to be assessed by on-site monitoring.

4.2.5 Context of the IRB and general characterstics >> Views >> Site monitoring should be done

On-site monitoring should be done and experience sharing with the researcher

4.2.6 Context of the IRB and general characterstics >> Views >> Was neglected issue (+) (+)

4.3 Context of the IRB and general characterstics >> Structure and functions of IRBs

4.3.1 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Stablishement of IRBs

4.3.2 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Mandatory ongoing review

Ongoing review of the protocol is mandatory

4.3.3 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Ongoing review not mandatory

Ongoing review of the study after approval is not mandatory

4.3.4 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Coolaborative work

Since there is no special support for on-site monitoring, the usual work of the IRBs is done by collaborating with other institutions.

4.3.5 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Online meeting

Planning to conduct online meeting via zoom, since most members are absent during in-person meeting

4.3.6 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Emperative of clearance (+)

Studies involving human subjects need to be reviewed by the IRB

Expertise review
Created: Girum, 5/3/2024 3:14 PM

IRBs should adhere to their responsibility in giving clearance paper only to their level of expertise and scope

4.3.7 Context of the IRB and general characterstics >> Structure and functions of IRBs >> IRB Report

Reports will be prepared bi-annually and also annually summarizing the yearly work

4.3.8 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process

4.3.8.1 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Less pepers reviewed this days

4.3.8.2 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Only for the institution

The review is done for the institution only since difficult to follow after approval.

4.3.8.3 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Time taken

Mostly the review process takes time

4.3.8.3.1 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Time taken >> Awareness creation for the process

To shorten the back and forth, all the necessary things should be provided and it is depend on the awareness of the researcher

4.3.8.4 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Online communication

Mostly soft copy submission is prefered by the researchers

4.3.8.5 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Rejected protocols

During initial review, there is a history of rejection, after giving a major comment and idf delayed response or non response of the comments

4.3.8.6 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Tie breaker

If the verdict of the reviewers is different, the chairperson interferes with the decision to come to the middle ground.

4.3.8.7 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Independent reviewer

The reviewer should be independent to minimize COI

4.3.8.8 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Looking for the CV

When reviewin the protocol, CV of the PIs is neededd to assess the competence

4.3.8.9 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Requesting the expedite review

The PIs request the expedite review since the time is short

4.3.8.10 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Review process >> Anonimous members

The names of the members and the reviewers will not be disclosed to the researchers

4.3.9 Context of the IRB and general characterstics >> Structure and functions of IRBs >> IRB to IRERC

The name changed from IRB to IRERC and the level become A

4.3.10 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Presence of SOP (+)

Availability of written SOP for the conduct of PAM and SM in respective institutions

Presence of clear SOP about PAM
Created: Girum, 4/20/2024 8:32 AM

SOP availability in the institution to conduct Post-approval monitoring

4.3.11 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Composition

The composition of the IRBs is from different backgrounds.

4.3.12 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Short term studies or surveys

Studies conducted in short duration for master's thesis or PhD projects

4.3.13 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Less clinical trials

Small numbers of clinical trils reviewd so far and those should be reviewed by the NRERB

4.3.14 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Periodic report request (+) (+)

Requesting the report of the study depending on the time taken for the completion of the study

Email reminder
Created: Girum, 4/22/2024 10:53 AM

Remind the request for the final report via email

Phone reminder
Created: Girum, 4/22/2024 10:52 AM Modified: Girum, 4/29/2024 4:01 PM

Requesting the final report through phone calls

4.3.15 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Monthly sitting allowance

There is a sitting allowance monthly for the meeting, but no special payments for the site-monitoring

4.3.16 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Collaborative work

Collaborative work is common and should also follow the protocol of the other institution's protocol violation management

4.3.17 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Hierarchical follow-up

The field supervisor follow the data collectors, and they are being followed by the researchers and the researchers will be followed by IRB.

4.3.18 Context of the IRB and general characterstics >> Structure and functions of IRBs >> Good institutional support

The presence of good institutional support for PAM activities, including office and logistics

4.4 Context of the IRB and general characterstics >> Objective

The objectives of PAM

4.4.1 Context of the IRB and general characterstics >> Objective >> Protection of the institution

The purpose of IRBs could be the protection of the institution indirectly.

4.4.2 Context of the IRB and general characterstics >> Objective >> Research mis-conduct reduction

PAM could decrease the research mis-conducts like fabrication

4.4.3 Context of the IRB and general characterstics >> Objective >> Building trust

The participant could think things are going good and in accordance to the protocol

4.4.4 Context of the IRB and general characterstics >> Objective >> Accountability

PAM is the accountability of the IRBs

4.4.5 Context of the IRB and general characterstics >> Objective >> Assuring the benefit deserved

The benefit that could be gained as a resultb of the study will be ensured

4.4.6 Context of the IRB and general characterstics >> Objective >> Quality assurance

The researcher and sponsor could be benefited as a means of quality assurance

4.4.7 Context of the IRB and general characterstics >> Objective >> Continues support for the researchers

IRBs usually give continuous support at different stages of the research including the implementation

4.4.8 Context of the IRB and general characterstics >> Objective >> Ensuring Compliance

Ensuring that the actual work of the research is in line with the approved protocol

4.4.9 Context of the IRB and general characterstics >> Objective >> Safety and the right protection

Protection of the safety of study subjects

4.4.10 Context of the IRB and general characterstics >> Objective >> Teaching and Learning

Teaching and learning process between the Pis and IRBs

4.4.10.1 Context of the IRB and general characterstics >> Objective >> Teaching and Learning >> Real understanding

Real understanding of the context is able to find using on-site visit.

5 Challenges

Potential or faced Challenges in PAM and SM

5.1 Challenges >> Observer effect

There may be observer effect on the researchers when they know that they are being observed. So, they may change their behaviour, may not reflect the actual practice.

5.2 Challenges >> Attitude

5.2.1 Challenges >> Attitude >> Researchers' view towards the IRBs

The view of the researchers towards the IRBS

5.2.1.1 Challenges >> Attitude >> Researchers' view towards the IRBs >> Percieved simplicity

The main challenge here is that challenge related to the perception of researchers toward getting ethical clearance as a simple step.

5.2.1.2 Challenges >> Attitude >> Researchers' view towards the IRBs >> Lack of awareness about IRBs

There is lack of awareness about the function of IRBs. It is not about the procedure, but about science, adds value to the science

5.2.1.3 Challenges >> Attitude >> Researchers' view towards the IRBs >> Ignorance

The researchers might say the IRBs are bureucratic

5.2.1.4 Challenges >> Attitude >> Researchers' view towards the IRBs >> No role after approval

The trend is that researchers view that the IRBs have no role after the initial approval

5.2.1.5 Challenges >> Attitude >> Researchers' view towards the IRBs >> Trust issues

When the researchers are monitored by IRBs, the may think they are not trusted for their work.

5.2.1.6 Challenges >> Attitude >> Researchers' view towards the IRBs >> Fear

5.2.2 Challenges >> Attitude >> Members view

IRB members view the PAM activity as a role of chair member and secretariat

5.2.3 Challenges >> Attitude >> Lack of willingeness

Researchers unwillingness towards the conduct of on-site monitoring

5.2.4 Challenges >> Attitude >> Stakeholders view

Stakeholders view towards the IRB role after the approval is not as significant activity

5.2.5 Challenges >> Attitude >> Researchers attitude

Researchers may not be willing to be evaluated in Ethiopia

5.2.6 Challenges >> Attitude >> Big institutions and PIs pressure on the IRB

After securing funds and if the study is supported by the MoH, there may be a tendency to influence the decisions of the IRBs.

5.3 Challenges >> Lack of system

5.3.1 Challenges >> Lack of system >> Lack of ethical culture

The main challenge is lack of ethics culture in the institution even by higher officials

5.3.2 Challenges >> Lack of system >> Poor institutional support

Lack of support from the institute to the conduct of PAM

5.3.3 Challenges >> Lack of system >> No clear guidance for on-site monitoring (+)

There is no clear guideline to conduct on-site monitoring

No clear SOP for the on-site vist
Created: Girum, 5/2/2024 12:42 PM

There is lack of clear SOP or guideline to conduct the on-site monitoring

5.3.4 Challenges >> Lack of system >> Unclear role (+)

The role IRBs in conducting PAM is unclear

Unclear role regarding budget
Created: Girum, 5/3/2024 2:46 PM

It is unclear who should support the budget for monitoring

5.3.4.1 Challenges >> Lack of system >> Unclear role (+) >> Lose of trust

5.3.5 Challenges >> Lack of system >> Lack of a supportive system

Lack of supportive system to conduct PAM and SM

5.4 Challenges >> High burden

The challenges related to high burden for IRBs

5.4.1 Challenges >> High burden >> Abscence of members

The absence of members during the meeting

5.4.2 Challenges >> High burden >> Too much paper work

Challenges for the committees after the approval may be too much paperwork

5.4.3 Challenges >> High burden >> Monitoring burden

The burden is high on IRBs to monitor all studies

5.4.4 Challenges >> High burden >> Time

Lack of time

5.4.5 Challenges >> High burden >> Compensation for IRBs

IRBs have not been compensated for the activity and they worked as a responsibility of their profession.

5.5 Challenges >> Cotextual challenges

Challenges related to the context

5.5.1 Challenges >> Cotextual challenges >> Lack of capacity

The SOP is just adopted from other universities and could not reflect our view and since we could not able to prepare by ourselves. The adopted SOP dectates us to do a scheduled visit, but it could have been better if it is done surprizingly

5.5.2 Challenges >> Cotextual challenges >> Progress report non submission

PIs did not submit the progress report accordingly

5.5.3 Challenges >> Cotextual challenges >> Dependence on the institution

Being under the umbrella of the instition creates dependency on the willingeness of the institution

5.5.4 Challenges >> Cotextual challenges >> Not accessing the researchers

During the site visit, the researchers could be inaccessible

5.5.5 Challenges >> Cotextual challenges >> Large scale or multicentered studies related challenges

When a study is large scale or multi-centered, there may be special challenges related to the context, there is a need to balance the challenges as they may appear different from site to site.

5.5.6 Challenges >> Cotextual challenges >> Security

The current security issue may pose challenge to go to the field visit

5.5.7 Challenges >> Cotextual challenges >> War

During the time of the Ethio-Tigray war, we were in the survival mode and not worried about the function and we lost the connection of the NRERB

5.6 Challenges >> Resource

Lack of logistics to conduct PAM and SM

5.6.1 Challenges >> Resource >> SOP not uptodate due to budget

It has been 12 years since the SOP updated

5.6.2 Challenges >> Resource >> Competence and training

Lack of expertise and training related to PAM and SM

5.6.3 Challenges >> Resource >> Human power shortage (+)

One of the reasons that the IRB could not do on-site monitoring is shortage of human power

Not a dedicated staff member for the IRB
Created: Girum, 5/2/2024 12:34 PM

The IRBs are not the exclusive member of the IRB

5.6.4 Challenges >> Resource >> Budget problem (+) (+)

Research project inability to support for PAM despite request
Created: Girum, 4/16/2024 2:05 AM

Research projects usually ask for support for the IRB's PAM activity but are usually not able to give logistic support

Tried but failed
Created: Girum, 5/5/2024 3:24 PM

Support from other stakeholders sought but not be gained

6 Suggestions given

Suggested recommendation regarding the conduct of PAM

6.1 Suggestions given >> Digitalization

6.1.1 Suggestions given >> Digitalization >> Recomendation of the digitalization of the PAM

Monitoring should be digitalized, and even it could be better than going to the site

6.1.2 Suggestions given >> Digitalization >> The digitalization up to the approval

The digital way of process up to the approval

6.1.3 Suggestions given >> Digitalization >> CAPI

The use of electronic-based data collection tools may enhance the monitoring activity since there will be enough evidence online and GPS could be checked

6.2 Suggestions given >> Suggestions for the researchers

6.2.1 Suggestions given >> Suggestions for the researchers >> PAM Awareness

Awareness creation will help the researchers follow the approved criteria. They will be conscious of their actions if they are aware of the presence of ongoing monitoring.

6.2.2 Suggestions given >> Suggestions for the researchers >> Planning the PAM by PIs

The researchers should know about the post-approval monitoring of the study so they should plan to support financially and ready to support IRBs

6.2.3 Suggestions given >> Suggestions for the researchers >> PIs should strive for adherence and reporting

PIs should strive for requesting amendment before changing the protocol and asking renewal

6.2.4 Suggestions given >> Suggestions for the researchers >> Timely renewal

Researchers should renew the protocol as planned

6.3 Suggestions given >> Mechanisms and approaches (+)

6.3.1 Suggestions given >> Mechanisms and approaches (+) >> Clear guidance

6.3.2 Suggestions given >> Mechanisms and approaches (+) >> Scheduled visit is not good

The SOP dectates us to notify the PIs in advance to go to the site. But, this could not achieve the objective since the PIs may change the behaviours during that time and may pretend

6.3.3 Suggestions given >> Mechanisms and approaches (+) >> The need for mechanism

There could be a COI by sponsors and there should be a mechanism to handle this by PAM

6.3.4 Suggestions given >> Mechanisms and approaches (+) >> Other independent body

Other than IRBs, other independent bodies like NGOs could do monitoring activities

6.3.5 Suggestions given >> Mechanisms and approaches (+) >> Smooth communication with PIs

The approach with researchers should not be like a police to find thieves

6.3.6 Suggestions given >> Mechanisms and approaches (+) >> Phone follow up using checklist

Following the study using a phone call to check their report with checklist

6.3.7 Suggestions given >> Mechanisms and approaches (+) >> Publishing the protocol and comparing with the actual work

The actual work of the study after implementation will be compared with the published protocol

6.3.8 Suggestions given >> Mechanisms and approaches (+) >> Not like policing

The site-monitoring should not be just fault finding or policing

6.3.9 Suggestions given >> Mechanisms and approaches (+) >> Multiple method

Using multiple methods and based on the intensity of the risk, the frequency will be determined. As well as, using self-assessment tool to be filled out by the researchers regularly

6.3.10 Suggestions given >> Mechanisms and approaches (+) >> Surveyors

Surveyors should be trained to conduct PAM

6.3.11 Suggestions given >> Mechanisms and approaches (+) >> Checklist

Checklists could be used to assess the compliance and continuous report should be accepted and feedback should be given

6.3.12 Suggestions given >> Mechanisms and approaches (+) >> Proactive management

The IRBs proactively assess the potential challenges before the actual data collection

6.3.13 Suggestions given >> Mechanisms and approaches (+) >> Self-assesement tool

Researchers will fill out the self-assessment tool regularly. This could help the IRBs identify the protocol violations and the progress of the study

6.3.14 Suggestions given >> Mechanisms and approaches (+) >> Culture creation

The first thing should be the creation of ethics culture to enhance the adherence of the researchers to the ethical practices by themselves

6.3.15 Suggestions given >> Mechanisms and approaches (+) >> Charge

A plan to charge 1% of the research fund to the IRBs, out of which half to the initial review and half for PAM

6.3.15.1 Suggestions given >> Mechanisms and approaches (+) >> Charge >> Benefit outweigh the cons

At least having enough budget could enable us to send the right person to do monitoring in the field. So, the benefits outweigh the cons of charging 1%

6.3.15.2 Suggestions given >> Mechanisms and approaches (+) >> Charge >> Challenges of charging

There could be a view towards the IRBs as a profit motive committee

6.4 Suggestions given >> Capacity building

6.4.1 Suggestions given >> Capacity building >> The need for PAM

Through PAM, the gaps could be identified

6.4.2 Suggestions given >> Capacity building >> More emphasise for PAM

More emphasis should be given for PAM than initial review

6.4.3 Suggestions given >> Capacity building >> Regular PAM training (+)

Regular training for the IRBs

Training need for IRBs
Created: Girum, 4/29/2024 4:17 PM

IRBs should not be arranged without ethics training

6.4.4 Suggestions given >> Capacity building >> RAs oversight of IRBs (+)

IRBs should be checked for their function by appropriate regulatory authorities like the MoE and should be accredated

Accreditation
Created: Girum, 4/10/2024 1:52 PM

The IRBs should strive for accreditation

6.4.5 Suggestions given >> Capacity building >> Strengethening the functions of IRBs (+) (+) (+) (+) (+) (+)

Capacity building should be done

Increasing the number of IRBs
Created: Girum, 5/6/2024 5:25 PM

The number of IRBs should be increased to decrease the burden

Strengethening
Created: Girum, 5/3/2024 7:03 PM

Potential stakeholders like MoE and other NGOs should support the IRB

Inclusion of lawyer
Created: Girum, 5/2/2024 1:58 PM

The member should be supported by the lawyer to allow them discuss to legal cases

SOP should be strengethen
Created: Girum, 4/10/2024 1:52 PM Modified: Girum, 5/3/2024 6:57 PM

The SOP should be updated

Strong supervision
Created: Girum, 5/3/2024 1:24 AM

If the conduct of supervision enanced, it could lead to the overall strengethening of the IRBs

6.4.6 Suggestions given >> Capacity building >> System development

A system for PAM should be implemented

7 Opportunities of PAM

Opportunities of post-approval monitoring

7.1 Opportunities of PAM >> Supportive activities

7.1.1 Opportunities of PAM >> Supportive activities >> Presentation about the progress

It would have been better if the researcher present the report every three mont to the IRB in person

7.1.2 Opportunities of PAM >> Supportive activities >> Stakeholders oversight

When stakeholders of the research observe the research

7.1.3 Opportunities of PAM >> Supportive activities >> Self-monitoring

Since the burden is high on IRB, self monitoring by the study team would be an opportunity

7.1.4 Opportunities of PAM >> Supportive activities >> Annual forum

An annual forum should be established to discuss and share experiences to not repeat the same mistake

7.1.5 Opportunities of PAM >> Supportive activities >> Summit of stakeholders

There should be a summit among the stakeholders to discuss and accept the work of the research if and only if the signed IRB approval is available

7.2 Opportunities of PAM >> Research scale-up

7.2.1 Opportunities of PAM >> Research scale-up >> New interventions

The implementation of new drugs or interventions like medical devices could draw our attention. Or Interventional studies

7.2.2 Opportunities of PAM >> Research scale-up >> Large-scale studies

One of the opportunities of PAM is the presence of large scale studiees

7.2.3 Opportunities of PAM >> Research scale-up >> The methodology

The design and the methodology of the study may be an opportunity to do PAM.

7.2.4 Opportunities of PAM >> Research scale-up >> Clinical trial

When clinical trials are done

7.2.5 Opportunities of PAM >> Research scale-up >> The presence of studies

The availability of the research to be done is an opportunity

7.3 Opportunities of PAM >> Triggers

7.3.1 Opportunities of PAM >> Triggers >> Context based

The opportunities of PAM is relative and context based

7.3.2 Opportunities of PAM >> Triggers >> Whistlebloowers

One of the opportunities to do PAM is when the participants or others report any issues to the IRB

7.3.3 Opportunities of PAM >> Triggers >> The aim to avoid harm

The study should not inflict harm to the society even if it could not benefit

7.3.4 Opportunities of PAM >> Triggers >> Being obligatory

The institution has an obligation to follow the study

7.3.5 Opportunities of PAM >> Triggers >> Accreditation

Even if the NRERB control of IRBs is not enough especially for local IRBs, the presence of it and the accreditation system can be seen as an opportunity

7.3.6 Opportunities of PAM >> Triggers >> Mandatory for Publication

Previously was not seen it as essential, but now a days, there is awareness regarding the need of the IRB letter for publication

7.3.7 Opportunities of PAM >> Triggers >> Compliant

The presence of compliant from the participant could be seen as an opportunity to do monitoring

7.4 Opportunities of PAM >> Capacity

7.4.1 Opportunities of PAM >> Capacity >> Presence of supportive law

7.4.2 Opportunities of PAM >> Capacity >> Credibility

The participants could feel sence of responsibility if they know the IRBs are there for the safety of them, and create good environment between the participant and the researchers

7.4.3 Opportunities of PAM >> Capacity >> Awareness of the healthcare providers

Awareness of the healthcare providers towards the IRBs and the IRB clearance letter so that they can ask the researcher before the commencement of the data collection

7.4.4 Opportunities of PAM >> Capacity >> Resource

The presence of resources to conduct SM and PAM

7.4.5 Opportunities of PAM >> Capacity >> Being a full-board

Being a full board is one of the opportunities to conduct PAM and should be prioritized

7.4.6 Opportunities of PAM >> Capacity >> Presence of supportive staff in the institution

The staff of the institution is supportive

7.4.7 Opportunities of PAM >> Capacity >> Presence of active follow-up

If the researchers aware that their work will be assessed, they will follow their protocol accordingly

7.4.8 Opportunities of PAM >> Capacity >> Teaching learning activity

One of the opportunities of PAM is teaching learning between the IRBs and the researchers and experience sharing

7.4.9 Opportunities of PAM >> Capacity >> The presence of Universities

When we see it in the Ethiopia level, the presence of many Universities and many research centers

7.4.10 Opportunities of PAM >> Capacity >> Expertise

The presence of expertise is also an opportunity to do PAM

7.4.11 Opportunities of PAM >> Capacity >> Training and advocacy

Training and advocacy should be available and there should be resource to do that

7.4.12 Opportunities of PAM >> Capacity >> Active member

The presence of active members who can go to the on-site visit