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ORIGINALARTICLE

REVIEW PAPER ON RESEARCH ETHICS IN ETHIOPIA: EXPERIENCES AND LESSONS LEARNT FROM ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES 2007-2012

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ABSTRACT

Health research in Ethiopia is increasing both in volume and type, accompanied with expansion of higher education and research since the past few years. This calls for a proportional competence in the governance of medical research ethics in Ethiopia in the respective research and higher learning institutes.

The paper highlights the evolution and progress of the ethics review at Addis Ababa University- College of Health Sciences (AAU-CHS) in the given context of health research review system in Ethiopia. Reflections are made on the key lessons to be drawn from the formative experiences of the Institutional Review Board (IRB) and their implications to the Ethiopian health research review system. This article is a review paper based on review of published and un published documents on research ethics in Ethiopia and the AAU-CHS (2007-2012). Thematic summaries of review findings are presented in thematic areas - formation of ethics review and key factors in the evolution of ethics review and implications.

The IRB at AAU-CHS has been pivotal in providing review and follow-up for important clinical studies in Ethiopia. It has been one of the first IRBs to get WHO/SIDCER recognition from Africa and Ethiopia. Important factors in the successes of the IRB among others included leadership commitment, its placement in institutional structure, and continued capacity building. Financial challenges and sustainability issues need to be addressed for the sustained gains registered so far. Similar factors are considered important for the new and younger IRBs within the emergent Universities and research centers in the country.

Keywords: Institution Review Board, ethics committee, Research ethics, Addis Ababa University, CHS

INTRODUCTION

As is stipulated in international research governance guidelines, competency in ethics review for medical research is an important factor for the growth and quality of medical research in any given setting. In Ethiopia the past decade has documented unprecedented number and type of medical research conducted by different cadre of medical professionals inside and outside the country [1]. This has been further augmented by the unprecedented expansion of tertiary education and postgraduate programs in all science disciplines including medical science and public health [2]. The growth in number and type of conducted researches need to have equality growing, competent and up to the standard ethics review system. This calls for consideration of equally and in-parallel growing ethics review system capable of

handling ethics reviews and follow-ups of the volume of research conducted.

With the current trend of expansion of higher institution greater academic freedom and openness for external and international research partnerships one can easily imagine that there will be a greater need in the years to come for a competent national system and institutional capacity. In this whole effort academic institutions play a pivotal role of teaching and leading in medical research including the ethics aspect of it. In Ethiopia, even though the history of modern medical research is not so old, the role played by institutes such as the Addis Ababa University College of Health Sciences in setting exemplary standards for ethics review are to be underlined with key lessons having continual implications for other similar institutions in Ethiopia.

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The objective of this paper is to map out trajectories in the development and reflect on the evolution of health research ethics at AAU-CHS; to provide analysis of key lessons learnt from AAU-CHS's Institutional Review Board (IRB); and to argue for a model of institutional capacity building in order to meet the increasing need for research ethics review in Ethiopia and the way forward.

MATERIALS AND METHODS

We reviewed published and unpublished documents on research ethics in Ethiopia and the evolution and development of research ethics review at AAU-CHS from 2007 to 2012. Key terms used for both online and manual search were; research ethics, medical ethics, IRB, ethics review, Ethiopia, Addis Ababa University. Synonyms and Boolean combination were used as required. Thematic summaries of review findings are presented in the areas of the formation of ethics review and key factors in the evolution of ethics review and their implications. In 2012 the authors were involved in an assessment conducted to evaluate IRBs at AAU/CHS and other seven universities in Ethiopia which are under the Medical Education Partnership Initiative (MEPI) consortium. The same findings were used to illustrate the status of the IRB in 2012.

The paper first introduces the development of bioethics and research ethics in Ethiopia including historical landmarks. This is followed by presentation of the evolution of AAU-CHS IRB with critical reflections on key lessons, challenges and implications.

RESULTS

Evolution of Institutional Research Ethics Board (IRB) at Addis Ababa University CHS: Established in 1950, Addis Ababa University is the oldest and largest higher education institution in Ethiopia, which has made a remarkable contribution to the country through provision of trained manpower, research and community services [3]. The university has contributed as spear-head in higher education and research in Ethiopia and beyond. One of the main campuses of AAU is the College of Health Sciences, which for many years used to be the Medical Faculty having the country's oldest and biggest specialized teaching hospital Tikur Anbessa Specialized

Hospital. The College is a merger of School of Medicine, School of Public Health, School of Allied Sciences and School of Pharmacy. It aspires to be a regional center of excellence in health sciences teaching, research and services enhancing the health and productivity of human and animal populations [4].

The College has recently celebrated its Golden Jubilee, in its historical journey of half a century, AAU-CHS has been considered an important national actor and leader in the area of medical care provision, health workforce training, medical and public health training and research and health system strengthening. This encompassed in addition a role to lead in the area of medical research development, governance and ethics review. Research has been an integral part of the medical education at AAU. It also helped in the establishment of national system for biomedical research ethical review under the Ministry of Science and Technology. Most of the national steering and standing committee members were and are from the Medical Faculty of Addis Ababa University. The then Faculty of Medicine and current College of Health Sciences run an IRB, which is one the first African IRBs to receive Strategic Initiative for Developing Capacity in Ethical Review recognition from WHO [5]. The IRB also serves in capacity building for the national research ethics review in collaboration with partners i.e. professional associations and donors.

Even before the formation of a Research Ethics Committee (REC) and subsequently an IRB, for many years the College, under the then faculty of medicine had a faculty research and publication committee (FRPC) which was mandated to review and approve research projects and other academic documents and publish guidelines and modules as were required. The FRPC later on evolved to FRPC-1 (for academic staff) and FRPC-2 (for postgraduate research including Masters and PhD projects). Later on the faculty AC decided to rearrange FRPC into Faculty Institutional Review Board (FIRB). The current IRB evolved out of this earlier structure. In 2007 the current IRB was established under the faculty of medicine [6].

Over the years the IRB functioned as independent structure within the Faculty of Medicine and later the College of Health Sciences. During its establishment a document with Terms of Reference (TOR) was developed which clearly stipulated the mandates and operational and structural provisions for its independent function and entity. In addition Standard Operating Procedures (SOPs) were developed and

approved for implementation (2007 later revised in 2009) [6]. The composition of members for the first IRB was representation from different units and departments in the faculty with balanced professional mix and experience in research taken in to due consideration.

As mentioned earlier, the IRB is one of the first IRBs to have received an international accreditation. The IRB got recognition through FERCAP/SIDCER [20]. It also had certification from US Federal Wide Assurance and the Ethiopian Science and Technology Ministry. Apart from reviewing research proposals from academic staff and post graduate research students, the IRB provided basic and advanced trainings in research ethics for its members and other academic staff. To mention few, two rounds of training as part of the Medical Education Partnership Initiative (MEPI) in collaboration with CDC, E- based training on research Ethics in collaboration with University of Oslo, An International course on Surveying and Evaluating Ethical Review Practices in collaboration with SIDCER and AHRI were given in various occasions.

From 2008 until 2012, the IRB reported to have revised about 548 proposals. Most research projects are related to higher degrees including Masters and PhD degrees and Clinical Trials. Based on the IRB assessment conducted in 2012, we discuss some of the key observations which were determinant for the success of the IRB compared to IRBs in other universities under the MEPI consortium. The factors include (i) Human Capacity (members, composition and training), (ii) Availability and adherence to Guidelines and SOPs, (iii) Documentation and Archiving, and (iv) Infrastructure (Office-space, Office-equipments, communication facilities and budget).

Human Capacity (Professional and Administrative): The number and composition of members of the IRB were governed by its SOP with numbers ranging between 11 and 13, composed from various mixes of professionals with reasonably adequate overall composition in terms of professional mix. The IRB in addition to its regular members, had independent consultants in different areas of expertise [6]. While one of the main problems for most IRBs was unavailability of community representatives and lack of motivations and incentives for the community representatives and also for the other IRB members, AAU CHS always had a community representative in its membership. The IRB in addition had permanent office staff; a secretary and an office assistant. The secretary plays administrative roles without any pro-

fessional involvement, on top of routine secretarial activities and archiving.

Regarding conducting trainings for IRB members, except for AAU-CHS no other institution was providing research ethics trainings for its members and other staff. The trainings given included basics on research ethics and practical sessions on proposal review. Training is an important pillar for quality and standards of IRB activities. This is one of the areas that require investment and strategic plan to build capacities of available staff and in thinking through the next generation of members.

Standardized Review Guidelines and Accreditation:

While other institutions had overall guidelines at their best, AAU-CHS was one of the few having detailed operational Standard Operating Procedures Manual (SOPs), Guidelines for Research Applicants and Research Review Procedures manual. These helped in guiding the review and application process in a structured manner with significant degree of consistency. Most do follow the guidelines set by the national research ethics guideline of the Ethiopian Science and Technology Commission [7]. According to local and international guidelines, every REC and IRB is required to have its own guidelines on application procedures and standard operation procedures or TORs [7,8].

Existence of SOPs clarifies and facilitates the decision making procedures and processes in ethical review. Among other things, SOPs shall address points on how reviews are conducted, meetings are held and decisions are passed and communicated. Written policies and procedures specify the membership, committee governance; review procedures, decision-making, communications, follow-up, monitoring, documentation and archiving, training, quality assurance, and procedures for coordination with other RECs. AAU-CHS developed SOP as per requirements of FERCAP/SIDCER for accreditation [5,6]. Subsequently the IRB had international accreditations from WHO/SIDCER (November 22-26, 2009) (Figure 1) at FERCAP Conference in Phillipines. IRB of College of Health Sciences, Addis Ababa University registered in USA, and obtained Renewal of IORG-IRBs and Renewal Registration of Federal Wide Assurance (FWA), USA.

The professional mix of reviewers allowed for proper review of not only the ethics and consent forms of the research projects but also the science. When needed consultants were contact to do reviews in their areas of expertise. Apart from the ethical con-

siderations and the consent documents and procedures, thorough reviews were done on the technical rigor and the methodological plausibility of submitted research projects. The IRB followed the principle "Bad science is bad ethics" and that there is a need for relevant review of scientific methods as part of ethical appraisal [9].

AAU-CHS also had mechanisms in place for the follow-up of approved proposals. However the follow-ups were not satisfactory due to lack of budget and poor compliance from researchers. Follow-up of approved proposals is one of the core functions of IRBs. Approval of an ethically sound research proposal is just the first stage in ensuring 'protection human subjects' in research undertakings. Lack of follow-up is due to lack of capacity to do it as there are no provisions in place to make proper follow-up on studies.

Documentation and Archiving: In 2012 the IRB was one of the only few institutional boards that provided a well structured application format for ethics review process. This was accompanied by both hard-copy and electronic archiving system. Archiving and documentation is very important attribute in proving and assuring that standards for IRB requirements are met. This holds true for most international accreditations including WHO/SIDCER and others [5].

The IRB secretariat especially the administrator and secretary had the prime responsibility for this. As discussed earlier, having a dedicated office and office staff was very important for proper documentation and archiving.

Infrastructure: Since its establishment, the IRB had a dedicated office space. Presence of an adequate office space was important for running board meetings, to keep the archives and documents related to ethical review and for secretarial functions. Some committees meet in the offices of their chair person or one of its members. This could create sense of insecurity and absence of a focal point where the institutional records and memories are properly stored. Having a dedicated office space is one of the important administrative provisions required for ensuring long term sustained functions.

The IRB did not have a dedicated budget of its own, however, it was reported that it can request for materials like stationary whenever needed from institutional supplies. While there is no any payment scheme in the AAU IRB, few other IRBs try to compensate their members for transportation costs by providing them nominal amount of money from their institutional budget. Most IRB members are already over loaded and busy professionals who are executing their IRB duties on top of all this.

Picture 1 , Recognition Plaque/Shield by WHO/SIDCER– First IRB from Africa and Ethiopia. FERCAP conference on November 22-26, 2009, Philippines



DISCUSSION

Like many other developing countries, bioethics is a young and new topic in Ethiopia and is mainly focused on medical research ethics, with some components of medical professional ethics. In Ethiopia, the agenda of health research ethics was initiated by the then health department of the Ethiopian Science and Technology Commission (ESTC) when in 1994, the commission officially launched a national health science and technology policy and established a broad based body at a level of a council with a function to advise the federal government on health science research and development. The first national health research ethics guideline was developed by the commission in 1995 and has been revised twice, in 1997 and 2004 respectively [10]. All regional and institutional committees need to be registered at the secretariat of National Research Ethics Committee, to be renewed every two years. It has been emphasized that there is a need to further strengthen the local capacity of ethical review of health related research in the country and various efforts have taken place in different points in time since then [11,12].

Important factors of bioethics and research ethics in Ethiopia include sectors in the government such as the Ministry of Science and Technology ; Federal Ministry of Health, Ethiopian Food, Medicines and Health Care Administration and Control Authority (EFMHACA); prominent research centers such as Ethiopian Public Health Institute (EPHI) [13] and Armauer Hansen Research Institute (AHRI) [14]; professional associations such as Ethiopian Medical Association (EMA) and Ethiopian Public Health Association (EPHA), Nurses, Midwives and Medical Laboratory technologist associations; and Universities hosting training programs in the fields of Medicine and other health sciences.

Health Research in Ethiopia is dated to more than a century old. The first medical publication from Ethiopia was on “Abyssinya and its Sanitary and Medical Aspects” in *The Lancet (1868)* [15]. However output in terms of quality and quantity remains low as the total number of publications are still fewer in number. Despite development of medical research in Ethiopia over the past decades it lacks detailed laws and regulations [1]. With the rapid expansion of post-graduate programs in the major public universities and the increased the availability of findings, the number of research projects with human subjects is

progressively increasing. These have put increasing demand on the current research governance system to be more effective and efficient [2]. There are various challenges in the research governance systems and capacity at various levels [16]. Community’s awareness about research and research ethics elements in Ethiopia, are not well developed compared to communities in developed countries. A study on consent form standards, suggested that the standards of ethical review and informed consent need to be improved [17]. So far, there are not independent academic courses in research ethics. This is rather addressed under research methods trainings for post-graduate students. Professional associations such as EMA, ETBIN and other partners provide various trainings on ‘research ethics’. But not very structured as such [18].

Some contextual challenges for bioethics and research ethics in Ethiopia include decision-making in medical care and health research at an individual level is determined by ethno-cultural factors existent in the country. Health professionals and researchers therefore need to take time to understand and pay attention to such paradigms which could take different shape across ethnic differences in this multicultural country [19]. In addition, consent and decision-making mechanism are influenced by a number of cultural and social issues such as stigma and discrimination [20-22]. Vulnerability of study subjects is considered a challenge especially during decision making in the informed consent processes [23-24].

For the proper functions of an IRB, well established ethical review system in place with the required standards for application, review and approval procedures is vital. This further needs to be standardized and possibly accredited for the same purpose. Review system encompasses of an established system for proper review of research proposals with involvement of relevant authorities to ensure that ethics review of health-related research is supported by an adequate legal framework that is consistent with the standards; that research ethics committees capable of providing independent review of all health-related research exist at each level; and that an appropriate and sustainable system is in place to monitor the quality and effectiveness of research ethics review.

The core of an IRB and its functions lies in the composition and expertise of its members. Composition has to be multidisciplinary and should be able to reflect the social and cultural diversity of the communities from which the research participants are likely to be drawn. This includes lay people and other

members whose primary background is not in health research and they should be available in reasonably adequate number [8]. Having a community representative is a very key international requirement in establishing IRBs. No full board IRB meeting should be conducted if the community representative is not in attendance of the meeting.

Even though the core of ethics committee and its functions lie on its members, it needs adequate support staff with adequate training for properly executing its technical and administrative responsibilities [8]. To this effect IRBs do need IRB administrators or at least full time secretaries to run the office and secretarial works as well as deal with routine administrative issues [25]. An IRB administrator or its equivalent is responsible for the oversight, administration, implementation, and management of all IRB business, including policies and procedures related to the protection of the rights and welfare of human subjects and the institutions compliance with all the continually updated regulations, local laws and institutional policies that are applicable [26].

Ethics is a dynamic subject – refresher trainings also needed on regular interval for all IRB members on service. There are various ways of providing trainings such as short courses, long-term courses, on-line courses and refresher seminars. Members need to have trainings on the ethical aspects of health-related research with human participants, how ethical considerations apply to different types of research, and how the REC conducts its review of research, is provided to REC members when they join the committee and periodically during their committee service [8]. Tracking records of IRB members is another important attribute to determine whether an IRB meets required standards. This also helps to regularly audit the capacities of IRBs which needs to be provided for internal auditors and surveyors as this is one criterion for IRB recognition.

As per the existing standards, the archiving and record keeping should always be very confidential and this needs to be insured by keeping the records in safe location and follow standard procedures. There should also be clear procedures on who should access documents, and how [8]. Even if this is claimed by some of the IRBs, it is difficult to verify without SOPs. One advantage of using information technologies (IT) for ethical review and documentations is an electronic data base [25].

According to the current international guidelines, research ethics committees do need adequate re-

sources for their members and staff to fulfill the assigned functions. These resources include, but not limited to, office space and equipments such as computers, stationary, telephone, copy machines etc [8]. An adequate office space is needed not just for holding committee meetings. It is required for all the other important activities beyond the meetings such as routine administrative activities, keeping store of committee files and for keeping records related to review in a secure and confidential manner. [8] An office space is vital for an IRB to create a stable environment for its functions, for proper documentation and archiving and for sustainability of IRB roles.

Most IRB members are already over loaded and busy professionals who are executing their IRB duties on top of all this. Whether IRBs generate their own income or no, it is important to compensate the members for their time and extra efforts on IRBs. Adequate financial resources need to be there to permit the committee to produce high-quality work [8]. If IRBs are not adequately funded, they will be unable to run their mandates successfully. One option for financing IRBs could be charging for ethical review services. There are no uniform practices regarding IRB fees. Some institutes ask for payments for proposal review services and accordingly researchers make budget plan for the IRB services [25].

Depending on ‘IRB costs’ and how expensive it is to run IRBs, there is argument that the IRB services should be charged. The Ethiopian National Guideline also has stated of review fees for projects at national level [7]. However, one potential problem associated with IRB fees could be potential conflict of interest that could results. However, different IRBs follow their own mechanism in ensuring that potential conflict of interest is avoided when implementing IRB fee policy. The bottom line is availing budget for smoothly running the IRB activities. Charging an IRB review fee for commercially sponsored research is a common way for an IRB to supplement the operating budget provided by institutions. Most sponsors would not object to paying reasonable fee. Adequately resourced IRBs benefit both the sponsor as well as the institution, and, most importantly, subjects who participate in research [25].

Limitations: This review process in focused only on the period from 2007 to 2012, and is mainly based on documents reviews and formative reflections of establishing members of the IRB with possibility of subjective reflexivity. In addition, the current assessment was limited to assessing IRB/REC systems based on the reports from focal persons without triangulation.

Conclusions and Recommendations: The AAU CHS IRB has made a remarkable progress in the years which followed its establishment in 2007. These formative years can be considered learning experiences for other IRBs in Ethiopia and other countries in similar settings. Important factors in its successfully evolving to this included leadership commitment, its placement in institutional structure, and continued capacity building of its members. Some of the gaps observed on the formative years were questions of sustainability and staff motivation. The lesson learnt and the achievements registered needed to be maintained through continuous monitoring and evaluation in place accompanied with supportive supervision and reaccreditation. There needed to focus on institutional capacity building on ethics review beyond engaging in routines in review process.

It is important that IRBs provide continuous training for current members on research ethics and training of trainers in certain intervals and encourage the respective IRBs/RECs to run their own local trainings. Motivation of IRB member is a key determinant. There needs to be a mechanism to motivate IRB members and to compensate for the extra services they render. The incentives need to be proportionately adequate and regular.

Further assessment is required on how best to network the existing IRBs with each other and with others in the country and beyond. This includes confidential exchange of electronic information and resources as well as web based links. Also conduct further assessment on how best to address the identified gaps in the future and based on this a strategic plan on how building the capacities of IRBs in the assessed institutions and beyond incorporating the key functions and expectations should be worked out. There should be proper monitoring and evaluation of IRB activities-follow-up studies of similar status on yearly or two yearly bases.

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