

Assessment of Ethics Review Applications submitted in the period b/n June 1995-mid May 2004.

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Introduction

Health research activities in Ethiopia started over a century ago. Moreover, in the last few decades with the establishment and expansion of health higher learning institutions the volume of research works have been increasing. Nevertheless, the research activities have not been in a coordinated manner, until ESTC issued a National Health Science and Technology Policy in 1994. Following the issuance of the policy, a broad-based National Health Science and Technology Council was established 1995 to advise the government on HS&T issues including health research and development. The council in order to discharge its duties effectively, organized itself in to four standing committees; of which the National Ethics Review Committee (NERC) is one. After the establishment of NERC, health research ethics review at national level started as of June 1995. Since then a number of ethics review applications have been submitted and reviewed by the committee. The objectives of this assessment are to describe the major problems identified in the ethics review applications and identify the major beneficiaries (institutions/Pis) of the National Ethics Review System.

Methodology:

Minutes of the National Ethics Review Committee and documents of the reviewed projects have been assessed. The necessary data was then extracted and entered in an EPI-INFO Version 6 statistical package and analyzed in the form of frequency tables and graphs.

Results

Number of applications received: A total of 135 applications have been submitted for national ethics review in the period June 1995 up to mid May 2004. The average number

of applications per year has been 13.5. However, ten of the applications were incomplete and hence were not referred to the NERC. Although there were some irregularities, it can be generally said that the number of applications has been increasing [Fig.1].

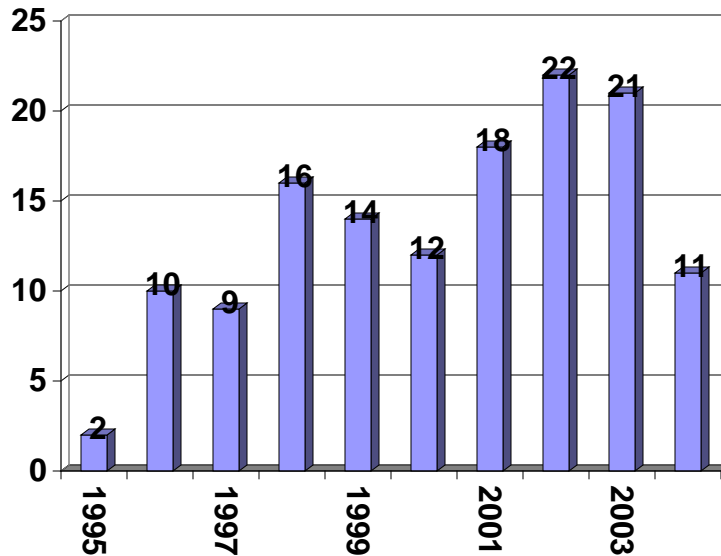


Figure 1. Number of Applications submitted for Ethics Review by Years

Beneficiary host institutions: As described in table 1, AAU, AHRI/ALERT and EHNRI have been the major beneficiary institutions in the last ten years. Other teaching institutions in the country, foreign universities, regional health bureaus, MOH, central referral hospitals, few NGOs, professional societies, the national defense force and others have benefited from the national ethics review system.

Table.1 Number of applications submitted for review by applying institutions (June 1995-mid May, 2004)

<i>Applying Institutions</i>	<i>Number of Applications</i>	<i>Percent</i>
AAU (FM, IPB, RPO, Science F)	35	25.9
AHRI/ALERT	33	24.4
EHNRI	17	12.6
Foreign Universities	9	6.7
GCMS	8	5.9
Regional State HBs	8	5.9
Amanuel Hospital	6	4.4
NGOs	6	4.4
MOH	4	2.9
National Defense Force	4	2.9

Others*	5	3.7
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- Others include: Professional Societies, JIHS, HAPCO, Miz-Hasab.

Project areas/regions: Majority of the applications (40.5%) were for projects intended to be implemented in Addis Ababa followed by projects covering more than one regions (35.9%).[Table 2]

Table 2. Ethical review applications received by project areas.

<i>Project area</i>	<i>Number</i>	<i>%</i>
More than one regions	47	35.9
Tigray	3	2.3
Amhara	10	7.6
Oromyia	8	6.1
SNNPR*	10	7.6
Addis Ababa	53	40.5

* SNNPR: Southern Nation Nationalities Peoples Region

Status and addresses of PIs: Figs 2 & 3 show that most of the PIs of submitted applications were researchers (79) and students (43). Other health professionals working in institutions with no direct mandate to do research works took few shares of the applications (13). Almost 2/3rd of the applications had PIs inside Ethiopia, while the rest from abroad.

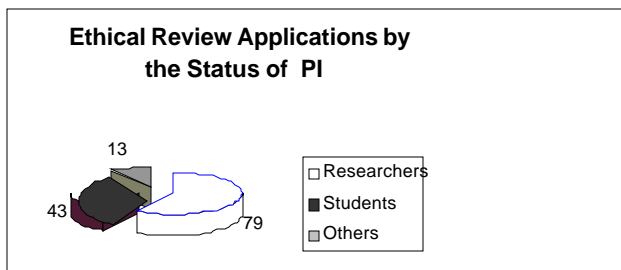


Figure 2. Ethics Review Applications By the status of PIs

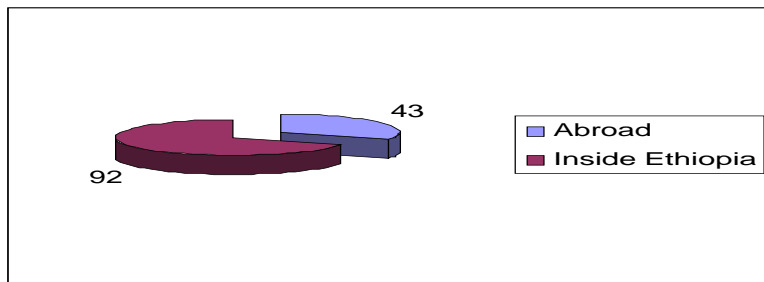


Figure 3. Ethical Review Applications by the addresses of P

First review results: As shown below in fig. 4, 125 applications have been reviewed by NERC in the indicated period; of which 38 (30.4%) were approved, 72 (57.6%) were given conditional approval and the rest 15(12.0%) were not approved.

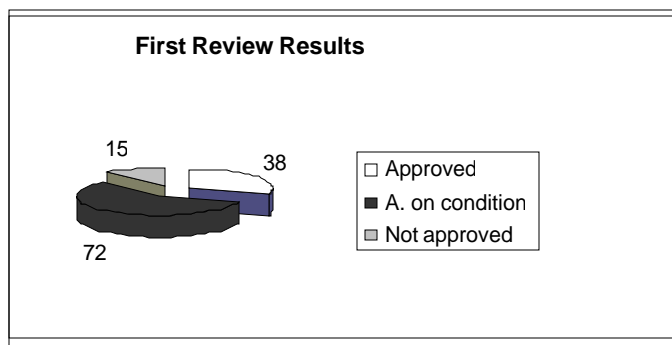


Figure 4. First Review Results

Final status of conditionally approved/ not approved projects: As described in Table 4, out of the 72 applications/projects which were conditionally approved in the first review, 63 have got approval after fulfilling the conditions stated by NERC, while 9 remain on pending status. And from 15 projects which were not approved in the first review, 5 got approval after revising and re-submitting the proposals.

Common conditions/reasons stated by NERC either to approve on condition or not approving the applications:

The most frequently cited reasons/conditions for giving conditional approval or denying the approval by NERC were one or more than one of the following reasons (table 5):

- a) Failure by host institutions/PIs to submit all required documents (55). This reason was not the sole factor to reject the project. Nevertheless, it had been one of the reasons for conditional approvals before the year 2000. After this period, preliminary screening using checklist has been introduced and review applications failing to attach all required documents would not be even referred to NERC.
- b) Inappropriateness of the consent form (lacks the necessary information) (52),
- c) Failure to include provision of standard care (22), and
- d) Not well addressing the provisions to overcome possible risks (if any).

Table 3: Status of applications after the first review by applying institutions.

Applying Inst.	Total applications	Approved	A. on condition	Not approved
AHRI/ALERT	33	12	17	4
FM-AAU	26	7	18	1
EHNRI	17	5	10	-
GCMS	8	1	5	2
Amanuel Hosp	6	2	3	1
SNNPRHB	4	-	2	2
MOH	4	1	3	-
National Defense Force	4	-	2	2
Others	33	11	12	4

Table 4. Final status of conditionally approved/ not approved applications in the first review.

<i>First review result</i>	<i>Final Status</i>			
	<i>Approved</i>	<i>Not approved</i>	<i>Pending</i>	<i>Total</i>
A. on condition	63	0	9	72
Not approved	5	10	-	15

Table 5: Common conditions/reasons stated by NERC either to conditionally approving or to not approving the applications.

<i>Conditions/reasons</i>	<i>Number of Applications</i>
Incomplete documents*	55
Inappropriate consent form	52
Confidentiality not well addressed	29
Provision of standard proven care not described/not acceptable	22
Provision to overcome possible risks (if any) not well addressed	15
Methods not ethically sound	12
Material Transfer Agreement no attached	7

* Specifically applied for conditional approvals before the year 2000.

Conclusion and Recommendation

There is an increasing trend in the number of ethics review applications although with some irregularities across the past years. The proportion of applications, which obtained direct approval, was less than 1/3rd of the total applications. Even the majority of applications received from institutions staffed with relatively qualified personnel did not get direct approval. This shows that a more intensified training on basic ethics principles and awareness creation exercises on the nationally developed health research ethics review guideline and procedures are needed to strengthen ethics review committees at all levels in the country.