



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL HEALTH RESEARCH ETHICS COUNCIL ASSESSMENT/EVALUATION QUANTITATIVE REPORT



Proposed REC Assessment Data Analysis Plan

Study objectives

- (a) Assess compliance level of registered RECs with DOH health research ethics national guidelines with regards to composition.
- (b) Determine RECs compliance with DOH national research ethics guidelines requirements related to procedures.

TABLE 1

	1 - 3	4 - 6	7 - 9	10 and more
Stakeholders served	14	4	1	3

Summary: Table 1 indicates that most (64%) RECs serve at most three stakeholders. Some of the stakeholders include the institution where the REC is based, students and staff affiliated to the institution and private research companies. Only 14% (3 of 22) of RECs provide their services to at least 10 different stakeholders. The REC services include health research protocol evaluation. Eighteen percent (4 of 22) of RECs serve at least 4 stakeholders.

TABLE 2

Duration of RECs	<1 yr	1 – 3 yrs	4 – 6 yrs	7 – 10 yrs	>11 yrs
	0	5	6	3	8

Summary: According to table 2 at the time of REC evaluation (2009) the Human Research Ethics Committee (Medical) based at Witwatersrand University was the oldest REC which had been existing for 43 years. While the for the same time period, the Ekurhuleni Health District Research Ethics Panel based at Ekurhuleni Metropolitan Municipality and HPCA Research Ethics Committee based at Hospice Palliative Care Association of South Africa had been operating for about 02 years. Health and Wellness

Sciences Research Ethics Committee based at Cape Peninsula University of Technology had been in operation for 03 years. Thirty-six percent (08 of 22) of RECs had been operating for at least 11 years. On the other hand 50% (11 of 22) of RECs had been in operations for at most 06 years. Half of (5 of 12) of this category were between 1 – 3 years old. This implies that 23% (5 of 22) of the RECs registered with NHREC are relative new (<3 years).

TABLE 3

RECs	Total# of research proposals in past 12 months	Approved	Declined	Not processed	Total # of meetings in past 12 months
A333000100	400	250	0	150	12
A333001100	322	322	0	0	12
A333001200	400	250	0	150	12
A333001300	0	0	0	0	4
A333001400	5	5	0	0	5
A333001500	60	58	2	0	10
A333001600	50	48	1	1	12
A333001700	50	50	0	0	12
A333001800	180	180	0	0	12
A33300190	15	11	2	2	15
A444000100*	21	18	0	3	3
A444000200	12	11	1	0	10
A444000300	153	140	13	0	9
A444000400	756	605	6	145	11
A444000500	5	3	0	2	2
A444000600	117	114	2	1	6
A444000700	500	488	2	10	11
A444000800	200	185	0	15	24
A444000900	250	250	0	0	11

A33300190	15	11	2	2	15
A55500200	120	50	12	58	4
A555002100	36	0	0	36	11
A555002200	30	30	0	0	10
TOTAL	3682	3068	41	573	217

Summary: Based on table 3 above, the 22 RECs registered with NHREC met 217 times and received 3682 research protocols for approval in a period of 12 months. On average RECs met 09 times in twelve months with a range of 02 - 22. Six RECs processed 100% of submitted health research protocols. Eighty-three percent of submitted health research protocols were evaluated. While only 1% was not approved, it is concerning that 16% of submitted protocols were not processed. In some cases for example TUT Research Ethics Committee, 100% of submitted health research protocols were not processed. Six RECs ranged from 19% to 48% for not processing submitted health research protocols.

The high percentage of none processed health research protocols could highlight a few challenges. For instance, the challenges could include limited capacity by RECs, work overload and limited access to RECs. This could suggest the need to strengthen some RECs or REC capacities and to increase access to RECs. It could further suggest an increase in the number of RECs. According to section 73 (1) of the National Health Act No. 61 of 2003 (NHA) institutions conducting health research are encouraged to access RECs or establish one. On the basis of NHA, the environment to increase health research work is prepared.

TABLE 4

Provinces	RECs
Gauteng	9
Western Cape	6
Limpopo	2
Mpumalanga	0
Free State	1
North West	0
Northern Cape	0
Kwa-Zulu Natal	3
Eastern Cape	1
TOTAL	22

Table 4 shows that of the 22 RECs assessed by NHREC and DOH, the majority (09) of RECs are based in Gauteng province followed by Western Cape with 06 RECs. In Kwa-Zulu Natal 03 RECs were assessed and 02 in Limpopo province. Free State and Eastern Cape provinces each had 01 REC assessed. While in Mpumalanga, Northern Cape and North West provinces there was none. More work by NHREC and DOH is needed to identify, register and audit the remaining known and newly established RECs as mandated by the National Health Act No. 61 of 2003.

TABLE 5

# REC members who received training								
RECs	Trained N =	%	Not trained	%	Require training 3 months	Require training 6 months	Not sure	Province
A333001300	5	83	1	17	Yes			GP
A333001400	2	15	11	85			X	WC
A333001500	16	100	0	0			X	GP
A333001600	9	100	0	0			X	GP
A333001700	14	93	1	7			X	KZN
A333001800	16	100	0	0			X	GP
A33300190	4	50	4	50			X	GP
A333000100	10	56	8	45			X	WC
A333001100	17	100	0	0				FS
A333001200	12	56	8	44			X	WC
A333001300	5	83	1	17	Yes			GP
A333001400	2	15	11	85			X	WC
A444000100*	6	100	0	0				GP
A444000200	13	87	2	13			X	KZN
A444000300	6	24	18	76			X	LP
A444000400	14	40	21	60			X	GP
A444000500	12	100	0	0				WC
A444000600	14	64	8	36			X	LP
A444000700	11	37	19	63		Yes		WC
A444000800	4	40	6	60			X	GP

A444000900	06	62	10	38			X	KZN
A55500200	12	86	4	14			X	EC
A555002100	14	82	3	18		Yes		GP
A555002200	7	58	5	42			X	WC
TOTAL	224	64%	129	36%				

Sum

mary: Table 5 give a break down of the number of REC members who received training. At the time of REC assessment, membership to RECs was estimated at 353. Sixty four percent of members had training in health research ethics and the balance (36%) still need such training. Medical and Research Ethics Committee based at the SA National Blood Service indicated that one of its 06 members will be trained within 03 months period after the REC assessment. While Tshwane University of Technology (TUT) Research Ethics Committee and Faculty of Health Sciences Research Ethics Committee based at University of Cape Town motioned that some of the members of their RECs will receive training within 06 months of the assessment visit. Continuous training of new REC members will increase the capacity of RECs to evaluate health research protocols.

TABLE 6

Presence/absence of working procedures for:	YES	NO
Frequency of meetings	20	2
Preparations of agendas and minutes	20	2
Distribution of papers prior to meetings	20	2
Consideration and review of research proposals	20	2
Methods of decision making	20	2
Prompt notification of decisions	19	3
Reporting of adverse effects	18	4
Safety monitoring	18	4
Active monitoring of adherence to conditions of approval	12	10
Handling of complaints	15	7
Suspension and discontinuation of research proposal	16	6

Fees, if any, to be charged	14	8
Confidentiality of the content of protocols proceedings	18	4
Committee proceedings	20	2
Research ethics training of members	12	10
Continuous review and annual recertification	18	4
Procedures to address conflict of interest for members	14	8
Procedures to address conflict of interest for researchers	15	7
Introduction/orientation of new REC members	14	8
Do you have Standard Operating Procedures	18	4

Summary: Table 6 indicates that, 80% to 90% of (20 to 21) of the 22 assessed RECs carry out 12 of the 20 (60%) working procedures according to the DOH nation health research ethics guideline. On the other hand 55% to 63% (12 to 14) of RECs assessed by NHREC and DOH carry out 05 of 20 (2.5%) work procedures according to DOH national health research guidelines. The five work procedures include active monitoring of adherence to conditions of approval, Fees, if any, to be charged, research ethics training of members, Procedures to address conflict of interest for members and introduction/orientation of new REC members.

It is particularly concerning that 55% (12) of RECs perform active monitoring of adherence to conditions of research protocol approval. This implies that 45% of RECs are not sure whether researchers adhere to conditions of approved research protocols. It implies that there are high chances of violation of rights of participants in those approved research studies where active monitoring is none existent.

Characteristics of RECs

Table 7

RECs	No. Members	Males	Females	REC chairpersons	Professional Scientists	Lay representatives	Leg representatives
A333000100	18	11	7	Yes	Yes	Yes	No
A333001100	17	9	8	Yes	Yes	Yes	Yes
A333001200	20	11	9	Yes	Yes	Yes	Yes
A333001300	6	3	3	Yes	Yes	No	Yes
A333001400	13	7	6	Yes	Yes	Yes	Yes
A333001500	16	11	5	Yes	Yes	Yes	Yes
A333001600	9	3	6	Yes	Yes	Yes	Yes
A333001700	15	6	9	Yes	Yes	No	No
A333001800	16	8	8	Yes	Yes	Yes	Yes
A33300190	8	6	2	Yes	Yes	Yes	Yes
A444000100*	6	3	3	Yes	Yes	No	No
A444000200	15	4	11	Yes	Yes	Yes	Yes
A444000300	24	10	14	Yes	Yes	Yes	Yes
A444000400	35	19	16	Yes	Yes	Yes	Yes
A444000500	12	3	9	Yes	Yes	Yes	Yes
A444000600	22	16	6	Yes	Yes	No	No
A444000700	30	15	15	Yes	Yes	Yes	Yes
A444000800	10	4	6	Yes	Yes	Yes	Yes
A444000900	16	12	4	Yes	Yes	Yes	Yes
A55500200	16	9	7	Yes	Yes	Yes	Yes
A555002100	17	14	3	Yes	Yes	No	Yes
A555002200	12	6	6	Yes	Yes	Yes	Yes
TOTAL	353	190	163	22	22	17	18

According to table 7, all RECs had a chairperson, men and women, and members from the health care professional science fields. The total number of members of the 22 RECs registered with the National Health Research Ethics Council was estimated at 353 and REC members were male (54%) dominated. Women had a 46% representation with a slight percentage difference (6%) from men. The percentage difference on gender of REC membership is viewed to be minimal considering the requirement of not more than 70% of either male or female by the DOH guidelines.

77% (17 of 22) of RECs had a representation of lay persons. It is concerning that 23% (5 of 22) of RECs did not have lay persons. The further apprehension is that the interest of the community might be overlooked in RECs where there is no lay person. On the other hand 82% (18 of 22) of RECs had members who were legally trained. While the remaining 18% (4 of 22) RECs are lagging behind. Generally, registered RECs partially complied with DOH national health research ethics guidelines but have some limitations which need the attention of the NHREC. Most of these shortcomings will be addressed if the NHREC implements the suggested recommendations contained in this report.

Institution type where RECs are based

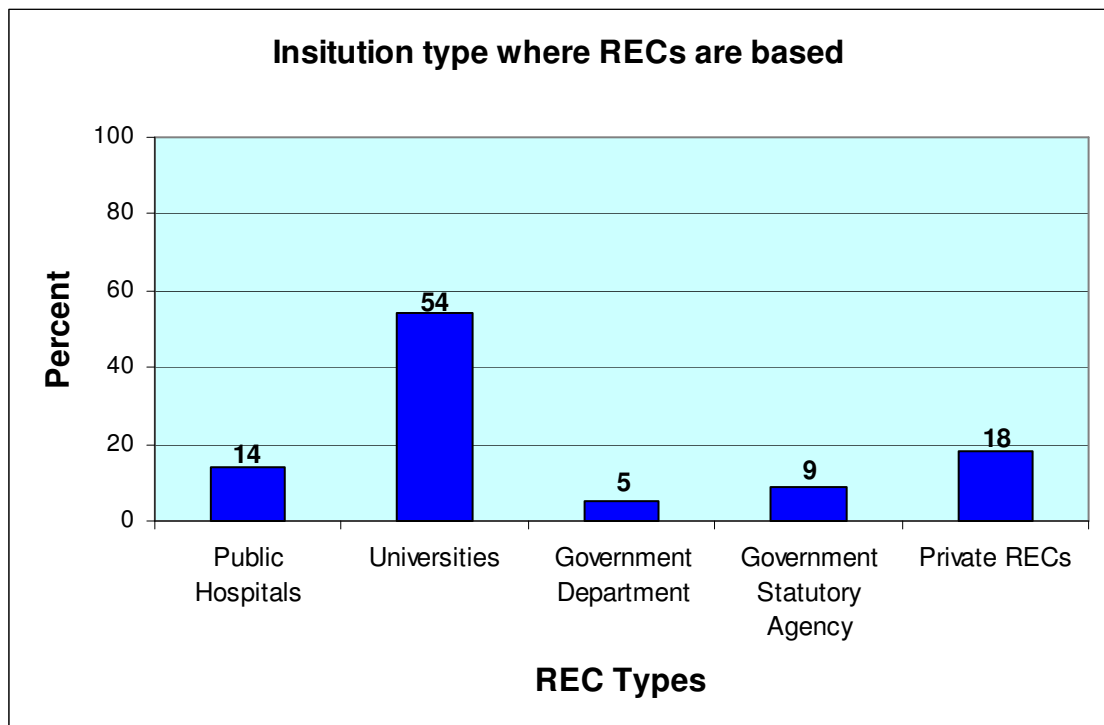


Figure 1.

Figure 1 indicates that majority (54%) of RECs registered with NHREC are based at universities and 18% (4 of 22) operate from private institutions. Nine percent (02 of 22) of the RECs are based at government statutory agencies such as Medical Research Council (MRC) and Human Sciences Research Council (HSRC). Of the remaining 14% are based at public hospitals, namely 1 Military hospital, Polokwane Mankweng hospital complex and McCord hospital as well as 5% (01 of 22) based at Ekurhuleni Metropolitan Municipality, a local government administration.

TABLE 8

Levels

Level 1	%	Level 2	%
6	28	16	72

The DOH national Health research ethics guidelines distinguish between two levels of RECs. They are levels 1 and 2. According to the national guidelines level 1 RECs are those deemed to “have capacity to assess straightforward research designs that involve minimal risk to human participants. They include health research proposals that do not involve drug research, biomedical research involving human tissues, high-budget research (more than R 250 000 per annum), and high technology research”. While level 2 RECs refer to those “may review all types of health research proposals”.

According to table 8, seventy two percent of RECs assessed by NHREC and DOH are registered at level 2 and the remaining are registered at level 1. Since level 1 RECs evaluate research protocols with less risk such as behavioural studies, the NHREC should guide them to distinguish which DOH work procedures (national research ethics guidelines) to comply with.

Recommendations

- More RECs are needed to provide their services of evaluating health research protocols to more institutions to generate more research since there are institutions struggling to access RECs which majority of RECs (10 < RECs) serve only up to three stakeholders.
- Relatively new (<3 years old) RECs will need constant support and guidance from the NHREC.

- The NHREC should carefully evaluate whether all RECs ensure that researchers adhere to conditions of approved research protocols, and develop strategies to encourage active monitoring of adherence to conditions of approved research protocols.
- The NHREC needs to encourage training of new REC members to strengthen the capacity of RECs.
- The NHREC should distinguish between REC levels and indicate which set of requirements should level 1 RECs comply with.
- The NHREC to encourage all RECs to have lay and legal representatives.
- The NHREC to identify unregistered RECs and persuade them to register particularly those based at hospitals, government departments and private organizations.