Republic of Sudan
Federal Ministry of Health
National Henlth Research Louncil
Directorate of Research

Accreditation Guidelines for Research Ethics Committees In Sudan

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Acknowledgment

The Directorate of Health Research at the FMOH, acknowledges the great endeavors undertaken by state ministries of health and research institutes in establishing ethical review bodies and is honored to present to the Research Ethics Committees (RECs) the Guidelines for Accreditation of Research Ethics Committees.

The guidelines will help RECs to improve the review process at their level and prepare for accreditation that will be undertaken by the NHREC and independent assessors.

The Directorate of Health Research acknowledges the great contributions of different partners, made to develop these guidelines.

In particular, appreciation goes to the members of NHREC, who conceptualized the idea of developing the guidelines for accreditation of ethics committees. As well, our appreciation goes to the members of the national council of health research and all stakeholders who provided remarkable technical inputs throughout the process of developing the guidelines, whether through individual interviews, consultation meetings or by emails. Without the guidance and technical contributions of the task force who assisted the national consultant to produce these guidelines, we would not have been able to bring it in this shape. In particular we thank Dr Elfatih Malik, Dr Samia Habbani, Dr Mai Abdelrhman, Dr Shahd Osman and Dr Maisa Alfadhul

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Septemper, 2017

Preamble

The transitional constitution of the Republic of Sudan (2005) has encouraged the promotion of scientific research, conditioned with protection and promotion of the lives of research participants. The Public Health Act 2008 & the presidential decree of 2011, have charged the federal ministry of health, to protect and promote the lives of Sudanese people, among them are those who participate in health-related research.

The National Council of Health Research and the national health research ethics committee (NHREC), , has developed several guidelines, tools and training courses, both for research ethics governing bodies (research ethics committees) and for the researchers to ensure that research participants are well protected and treated with dignity ولقد كرمنا بني آدم : الآية(كما قال الله تعالى من الإسراء) 70

This document: Guidelines for Accreditation of Research Ethics Committees, is one of the series of these tools meant to ensure that conduction of research in Sudan, is adherent to the national and international commitments and guidelines.

We hope that this document will help the research ethics committees at all levels to revise their research review systems, prepare and voluntarily request for registration and accreditation. Accreditation will provide sub-national and institutional research ethics committee's greater opportunities to approve research protocols and facilitate access to more funds and publications.

During the course of using these guidelines, the Secretariat of the National Council of Health Research, will be pleased to receive any comments and/ or queries in relation to this document.

Dr. IsamEldin Mohammed Abdalla

Undersecretary, FOMH

President, National Health Research Council

Septemper, 2017

List of abbreviations

CIOMS	Council of International Organizations of Medical Sciences
FMOH	Federal Ministry of Health
GDP	Gross Domestic Product
GNP	Gross National Product
IDP	Internally Displaced Peoples
IOMS	Islamic Organization of Medical Sciences
MERETI	Middle East Research Ethics Training Initiative
MSF	Medicines Sans Frontieres
NCHR	National Council of Health Research
NGO	None-governmental Organization
NHREC	National Health Research Ethics Committee
PHA	Public Health Act
PI	Principal Investigator
PRD	Product Research & Development
SOPs	Standard Operating Procedures
TDR	Tropical Disease Research
UK	United Kingdom
UN	United Nations
USD	United States Dollar
WHO	World Health Organization
WMA	World Medical Association

1. Introduction

The National Council of Health Research that was defined by the Public Health Act of July 2008 and re-constituted by the Ministerial Decree 2/2012 signed on 18th January 2012, is the federal body governing the conduct of quality health research in the country and the Directorate of Health Research (DoR), at the Federal Ministry of Health (FMOH) is the secretariat and the house of the NCHR [1].

This has been preceded by a six years of extensive endeavors by the FMOH and partners in establishing oversight committees and developing guidelines, tools and training programmes; all were to ensure ethical conduct of research and to protect the human subjects participating in health research. These guidelines and tools were based on the international standards of research ethics stipulated in Nuremberg code 1947, Declaration of Helsinki 1964, Belmont report 1979, CIOMS and WHO guidelines[2][3][4][5][6].

A national health research ethics committee (NHREC), established in 2002 by a ministerial decree, is the authoritative federal oversight committee responsible of advancing research ethics in Sudan in collaboration and coordination with states' ministries of health (SMOH) , health sciences and health related research institutes including academic and specialized research institutes.

In 2007, a breakthrough took place with the ministerial decree[7], that enhanced the decentralization of the research ethics review process at states, hospitals and research institutes, through state Research Ethics Committees (RECs) and Institutional Review Boards (IRBs). In this document, the reference to REC or an IRB is not pertaining to any difference in the functions and responsibilities towards protection of the life and dignity of health research participants. Therefore to standardize the terms and avoid any conceptual confusion, we will use the term "REC" that also includes IRBs or any other name given by any entity to its "research review body/system".

Now, around 15 RECs were established and have communicated this to the

secretariat of the NCHR; however, it's not clear whether they adhere to the national standards or not (Data sheet, DoR/FMOH, 2015).

To ensure the quality of the research review by REC, the secretariat of the NCHR is developing these guidelines, to accredit and register RECs.

This document provides a glance at the current situation of the research ethics review at international and national levels, highlights national gaps and defines the main standards to be assessed as a perquisite for the accreditation. It provides a systematic and friendly steps to assess and accredit RECs, against a set of core standards, rather than to discuss ethical issues . The SOPs that enhance the ethical review of health research are well explained in the national guidelines of health research ethics, developed and widely disseminated by the FMOH in 2008.

The document is supplemented by friendly user guides to summarize the accreditation process in a stepwise approach both for RECs and assessors/ accreditors (annexes 2 & 3)

2. Methodology for developing the accreditation guidelines

To define standards and accreditation guidelines for the conduct of health research that is ethical, the following process was followed:

1. Establishment of a technical advisory committee of stakeholders to ensure a participatory process.
2. Desk review of the national and international standards commonly used in the review of health research including the establishment of and tools used to assess the review made by RECs.
3. Identification of the gaps related to the quality of review in Sudan.
4. Consultations with key stakeholders and review of laws and legislations supporting ethical review processes in the country.
5. Review the models used internationally and in similar countries to accredit national RECs.
6. Develop outlines for the proposed accreditation for Sudan.
7. Circulation and presentation of the products to the advisory committee seeking further guidance and concurrence.

8. Update and present the final product to a larger national forum of stakeholders for endorsement of the document.
9. Submit the final endorsed document to the FMOH and WHO.

1. Chapter One: Situational Analysis

1.1. Sudan

Sudan is in the northeast Africa. It neighbors Chad and Central African Republic on the west, Egypt and Libya on the north, Ethiopia and Eretria on the east and South Sudan, Kenya, Uganda and Democratic Republic of the Congo on the south. It covers an area of 1,886,068 $km^{2.}$ It's the third largest country in the African continent. The total population of Sudan is estimated at 35,482,233 with a growth rate of 2%); infant mortality rate of 52.86/1000 live births; life expectancy: 63.32 and density per sq mi: 42.4. Half of population is (50.4%) males. The Literacy rate is 72% (2011 estimates.) and GNP per capita is estimated at USD 2,600. Sudan ranks the 187th of countries regarding the human development Index (2014 estimates for 2013)[8].

Sudan is a multi-cultural country. Majority of population are Muslims. The mother tongue and official langue is Arabic; however Sudanese (more than 300 tribes including those who now belongs to South Sudan) tribes, speak more than 100 tribal languages, many of which are spoken by large numbers of people[9]. According to UN estimates, 6.9 million people are in need of humanitarian assistance in Sudan. Latest estimates suggest that by the end of 2015, there could be up to 460,000 refugees and asylum-seekers in the country[10]. The conflicts and natural disasters, mainly drought that have hit different parts of Sudan during the last few decades, have resulted in an influx of displacement. AS per the latest estimates of 5th January 2015 by the Internal Displacement Monitoring Center there were 3,100,000 IDPs[11]. This situation creates a burden on the already scarce health services and necessitates the provision of services by national and mainly international NGOs, mostly anticipated to be engaged in international research. For instance MSF Holand, an international NGO, has published at global level,

253 research papers in 2013 only[12].

With this background, is that the protection of Sudanese people whether they are settling or IDPs as well as that of the refugees is compromised without ensuring competent systems for medical practice and biomedical research. A special attention should be paid for ethical review of research in humanitarian settings.

1.2. Definition of Health Research

Health is the center of development and public health programmes, are the key interventions towards achieving health in developing countries. These programmes/interventions should be based on scientific evidence, that's research, which must be guided by the fundamental principles of human dignity and ethics in its planning and execution[13].

Research in health, whether purely medical (directly imply therapeutic or clinical methods) or behavioral, usually involves human subjects in its different aspects. Research involving human subjects is defined by WHO as "Any social science, biomedical, behavioral, or epidemiological act that entails systematic collection or analysis of data with the intent to generate new knowledge in which human beings are involved" .

Research is also defined as the "development of knowledge with aim of understanding health challenges and mounting response to them"[14]. As defined by CIOMS guidelines, in the context of ethics, research includes medical and behavioral studies. Research involving human subjects may employ either observations, physical, chemical or psychological intervention; it may also either generate records or make use of existing records containing biomedical or other information about individuals who may or may not be identifiable from the records or information[5].

In the context of the social determinants of health, the conduct of health research is not limited to medical scientists or health professionals. Health research or "Research for Health" is increasingly becoming the business and concern of many stakeholders and health partners; all need to grasp the scientific methods and ensure the ethical conduct of research.

Special attention must address researches carried out by sectors other than health and that affects directly or indirectly the health of research participants

1.3. History of Health Research in Sudan

The history of health research in Sudan goes back to 1903, with the establishment of Wellcome Tropical Research Laboratories, donated by Mr H.S. Wellcome and directed by Dr Andrew Balfour to study the pattern of different tropical diseases in Sudan as collaborative research with British institutes and to serve the Sudan Medical Service (SMS) through capacity building and trainings. Later , Stack Laboratories, attached to Kitchener's school of medicine, became the arm of medical research in Sudan 1935 as an integral part of the SMS along with carrying routine investigations. This was followed by experimental researches with the objective to establish vaccine institute in Khartoum[15]. Obviously, this was far before the global inception of the culture of research ethics.

The bulk of research in Sudan has grown between 1949-1970 under the leadership of Sudanese researchers: M A Haseeb and Satti, who were awarded the Shousha Foundation Prize for outstanding contribution to medical education and research in the Sudan in 1963 and 1970, respectively[15].

In 1970, the National Council for Research was established with five specialized councils including the Medical Research Council (MRC). The MRC, then, established the Institute of Tropical Medicine and a hospital for tropical medicine in Omdurman 1972. It was a collaboration between MRC, MOH and Faculty of Medicine [15].

The period after, starting as of 1991, research centers and councils witnessed continued shifting between ministries and renaming with the continuous change in the leadership of national research in the country. The Institute of Tropical Medicine continued as it was. In 1998 a DoR was established at the FMOH, guided by a multidisciplinary national council, all under the auspices of the Undersectary of Health[16].

1.4. Ethics in Research involving Human Subjects: Global perspectives

Islam, has very early emphasized the ethics as a basis for human conduct, whether towards a human to human or a human to animals in many and various aspects, both in Holly Quran and Sonnate . Islam has encouraged the development of science[17].

«وقل ربى زدنى علماً» سورة طه الاية (114)

This includes the search for evidence , whether that is to discover nature leading to deep believe in the power of God or to implement scientific methods for solving problems without harming people or changing the nature without strong justification. The freedom in scientific research in Islam forbids issues that are forbidden by Islam such as changing genomics, etc.. [18].

Islam has already emphasized the three principles of ethics: respect to persons, beneficence & none-maleficence and justice as a core practice for a Muslim in all his/her norms and behaviors and not limited to research as will be elaborated.

The international guidelines of biomedical research involving human subjects, developed by the CIOMS, IOMS and WHO, 2004, has as well confirmed the adherence of Islam to the international three ethical principles that were emphasized hundreds of years later in Nuremberg code[19].

1) Respect to person:

قال الله تعالى (:ولقد كرمنا بني آدم), الآية 70 من الإسراء

The respect to person was further confirmed and elaborated in the principles of Figh:

“ the belongings of a person should not be used by others without permission/ consent and the person’s rights cannot be denied by others without his consent ”. It has also clearly stated that incompetent persons should be protected through guardians and if not from the family, or relatives, the estate takes care of that.

وعلى ذلك نصت القواعد الفقهية العامة أن « من لايصح تصرفه لاقول له « . وأقامت له ولياً أو وصياً يلى تدبير

أموره ورعاية شؤونه على النحو الذى يحقق مصلحته ، ويوفر الحفاظ عليها ، ويحميه من سوء استغلال الغير له [19].

2) Maleficence and none beneficence :

وهو تحقيق المنفعة، ونفي الإيذاء أو إلحاق الضرر المتعمد بالغير:

Maleficence and none beneficence is one of the core principle in Figh and that it's a duty of any Muslim to avoid harm. قال الله تعالى:."ولا تلقوا بايديكم إلى التهلكة وأحسنوا إن الله يحب المحسنين ", سورة البقرة الاية 195) وقول الرسول صلى الله عليه وسلم (لا ضرر ولا ضرار , رواه أحمد وابن ماجة)[19] .

Islam principles, go further to confirm that if there is a harm, we have to minimize it to the minimum possible and that if the harm is inevitable we should chose the less harmful decision, as has been elaborated by El Emam Ibn Taymmia

بقولـه:(إن الشريعة جاءت بتحصيل المصالح وتكميلها ، وتعطيل المفاسد وتقليلها بحسب الإمكان ، ومطلوبها ترجيح خير الخيرين إذا لم يمكن أن يجتمعا جميعا ، و دفع شر الشرين إذا لم يندفعا جميعا) .

3) Justice

Justice as a core principle of dealing with people at all and every level, has been as well, emphasized in Quran and Sonnate.

كما فى قوله تعالى (" إن الله يأمر بالعدل والإحسان" , الآية 90 من سورة النحل) فيه تأكيد تحقيق العدالة مع الإحسان للناس حيث أن العدل هو التسوية والإنصاف . والاحسان " إما جلب مصلحة أو درء مفسده ."

The guidelines has elaborated in many sub-areas under the major three principles as a reference, but has concerns in issues in biomedical research such as genomics including different types of conception, cloning, research on early stages of conception and on embryonic tissues etc... As well, the use of placebo in clinical trials has created a lot of debate but as well, there was no specific mention to it.

The Nuremberg code of 1947 [1&20], the Universal Declaration of Human Rights

1948, Belmont report 1979 [4&21] , CIOMS guidelines & the Declaration of Helsinki adopted by the WMA in 1964, lately amended in 2008 [3,5,22nd] ; all have stipulated the basis upon which countries have founded the ethical conduct of research through the establishment of national governing bodies to ensure the maximum possible level of protection of human subjects involved in research. To give the Human Rights Declaration a legal as well as moral force, the UN General Assembly adopted in 1966 the International Covenant on Civil and Political Rights. Article 7 of the Covenant states "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation"[5]. Be it a code , international declaration, a call for commitment or SOPs, all have either in part or in total, confirmed and detailed or summarized the ethical principles that almost all review bodies (RECs) and researchers follow to ensure an ethical conduct of research.

These principles can be summarized as follows, however each of which can as well be detailed as will be presented later under the accreditation standards :

1. Scientific design of the research, it's not ethical to conduct a study that is of a weak or none relevant design. Thus the technical review is an essential part of the ethical review.
2. Respect for person:

a. Ensuring an informed consent by competent and incompetent persons

b. Confidentiality

c. Voluntary participation in research

3. None-maleficence and beneficence

a. Weighing risk-benefit ratio

b. Reducing harm by avoiding unnecessary risks and providing maximum care when it is inevitable/possible

c. Ensuring benefits of participating persons and communities in which

the research is taking place.

4. Justice

a. Appropriate selection of persons

b. Equal distribution of risk and benefit between participating persons

c. Addressing issues of vulnerability of research participants.

d. Equal distribution of risk and benefit between participating communities through community participation in planning and monitoring the research.

1.5. Establishing Review Systems

Each country must establish an oversight system to govern and improve the different country's review system such as RECs hand in hand with development of RECs[23].

Ethical review committees may function at the institutional, local, regional, or national level, and in some cases at the international level[5]. It depends very much on joint collaborative research, the bulk of research a t local level and scarcity of resource persons.

In accordance with the international guidelines mentioned before, many countries have succeeded in establishing review systems; no matter to what extent these systems adhere to each and every step of the ethical review process. WHO, as a leading agency responsible of promoting health of the people and research development for health, has a major role to play in safeguarding the research subjects. In this regards, WHO developed different tools and guidelines to ensure the protection of human subjects involved in health and health related research as early as 1990s. These guidelines included the Operational Guidelines for Ethics Committees that review biomedical research 2000, which were widely disseminated and used by many countries.

In 2011, WHO has disseminated its latest standards & operational guidance for Ethics Review of Health-Related Research with Human Participants. The operational standards are in fact, are summarizes of an international accumulated experiences and can be relevant to different local contexts[24].

The WHO standards & operational guidance for Ethics Review, cover main

five areas, 10 standards including sub-areas. These standards as mentioned before, are adopted by many countries under similar or different names. They serve both as guidance for quality review as well as criteria to be examined for accreditation.

Below is a summary for these standards.

1. Standards for research ethics review system (RERS)

Standard 1: The responsibility for establishing the RERS.

2. Standards and Guidance for entities that establish RECs

Standard 2: Composition of RECs

Standard 3: Resources for RECs

Standard 4: Independence of RECs

Standard 5: Training the REC members

Standard 6: Transparency, accountability and quality of the performance of RECs

3. Standards and Guidance for members of the RECs

Standard 7: Ethical basis for decision making in RECs

i. Scientific design and conduct of the study

ii. Risks and potential benefits

iii. Selection of study population and recruitment of research participants.

iv. Inducement, financial benefits and financial costs

v. Protection of research's participants' privacy and confidentiality.

vi. Informed consent process

vii. Community consideration

Standard 8: Decision making procedures for REC

4. Standards and Guidance for the secretariat, staff & administration of the RECs

Standard 9: Written Policies & procedures

i. Membership of the REC

ii. Committee governance

iii. Independent consultants

iv. Submissions, documents required for review, review procedures and decision making.

v. Communicating a decisions

vi. Follow up reviews and monitoring of proposed research.

vii. Documentation and archiving.

5. Standards and Guidance for researchers

Standard 10: Researchers' responsibilities

i. Submitting an application for review

ii. Conduct of research

iii. Safety reporting

iv. On-going reporting and follow up

v. Information on research participants.

1.6. Assessment and Accreditation of Research Ethics Committees: Global Perspectives

Countries are increasingly devoting significant resources to creating or strengthening research ethics committees, but it's not yet clear whether these committees are actually improving the protection of human research participants. Auditing and accreditation programs can improve the quality of ethics review by encouraging the development of standardized policies and procedures, promoting a common base of knowledge, and enhancing the status of research ethics committees within their own institutions[25]. Governmental and private audit and accreditation initiatives have been put in place to formally assess RECs. Examples are: the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), the Association of Accreditation for the Human Research Protection Programme (AAHRPP)[26]. Surveying and evaluating ethical review practices is another tool developed in 2002 and advocated for, by the TDR Programme of WHO to complement earlier documents of operational guidelines for REC [27]. Other institutions and programmes concerned with research ethics such as MERETI have

developed and tested self-assessment tools to assist RECs identify capacity gaps and therefore seek quality improvement[26]. As well, some African developing countries have paid attention to the need for assessing and accrediting their REC, examples are evaluation of REC, Botswana [28] and An assessment of RECs in three countries: Egypt, India and South Africa using a self-assessment tool, showed that the RECs in these countries have achieved a maximum score of ~70%; the mean scores were significantly associated with budget allocation for REC, but not with duration of establishment, presence of national guidelines or frequency of meetings. As a group the investigated RECs achieved more than 80% in the domains of: submission processes and documents received, criteria for ethical review, criteria for informed consent and recording meetings minutes. However RECs scored less than 80% in the domains of: institutional commitments, policies and procedure of the REC, membership and training, policies and procedures for protocol review, elements of a decision letter and criteria for continuous review. This study shows that assessment and setting standards for assessment (accreditation) is important to highlight areas for improvement in ethical review[26].

1.7. Governing Health Research Ethics in Sudan

The first medical ethics committee in Sudan was established in 1968 to govern medical ethical practice, followed by the Act of Medical Ethics in 1969. Ten years later (1979) , that a committee for research ethics was formed at the National Laboratories and Health Research as an initiative of few scientists. One year later (1980), a research ethics committee was established at the faculty of medicine, University of Khartoum[30].

Through 1996 to 2002, great achievements were gained in terms of strengthening national governing bodies (refer to history of research in Sudan).

In November 2002, the composition of the former national research council was revised and a National Health Research Council (NHRC) under the leadership of the FMOH , was established by a ministerial decree No.11/2002,

of His Excellency, the Federal Minister of Health. Under that decree, the establishment of the national advisory technical (NAT) and national health research ethics committees was stipulated. However; they were not actually formed until 2004, by a circular of the Undersecretary of Health.

1.7.1. Composition of the National Health Research Ethics Committee (NHREC)

The NHREC, is composed of around (25) different stakeholders concerned with research enterprise in the country. The chairperson and members are selected by the Federal Minister of Health. The term of membership ends by resignation, termination, completion of three years (cycle) or death[31].

Composition of the NHREC.

1. A chair-man (from outside the FMOH); selected by the Undersecretary of Health (who is the chair of the council of health research)
1. A rapporteur who is the secretary general of the council of health research executive secretariat (the DoR at the FMOH)

Members

2. Attorney of the FMOH
3. Six representatives of universities, academic institutions and research institutes
4. Representative of the Sudan Medical Council
5. Representative of the Sudan Veterinary Council
6. Representative of the National Health Laboratory
7. Representative of the Sudan Pharmaceutics & Poisonings Council
8. Representative of the Sudan Health Professionals Council
9. Representative of the Sudan Medical Specialization Board
10. Representative of the Journalism & Publishing Council
11. Two representatives of national NGOs working in research
12. Two representatives of Islamic and Christian religious leaders.
13. Two representatives of Community leaders

14. Two expert freelancers researchers.
15. Representative of the Government of South Sudan (abolished by the referendum)

1.1.2. Functions of the NHREC:

The following are the functions of the NHREC:

1. Selection of deputy chairperson
2. Developing guidelines for ethical review of research
3. Ethical review of research conducted at national level, in more than one state or researches in which international partners are engaged and researches submitted for international funding.
4. Ethical review of clinical trials
5. Monitor the progress of research projects through progress reports by investigators and site visits.
6. Establishment, supervision and accreditation of Institutional Review Board (IRBs) and state ethics committees

The NHREC established in 2002, continued under the re-defined National Council of Health Research (NCHR) 2012.

In 2007, a breakthrough took place with the Ministerial Decree that enhanced the decentralization of the research ethics review process by encouraging states, research institutes and hospitals to establish Research Ethics Committees (RECs), or Institutional Review Boards (IRBs) that are similar to the composition of the NHREC and to follow the national standards for ethical review.

Currently, a sub-committee of nine members of the NHREC is responsible of both technical and ethical review of the research protocols; however the composition is not adherent to the standards set for ethical review, as it does not include community members, NGOs, nor representatives to other professional councils.

1.1.3. National legislations Supporting Research Ethics in Sudan

1.1.3.1. The Law of National Research Center 1991

In Article 7 Para : The center, under which different sectoral research centers were established, shall be responsible of ensuring ethical conduct of research in accordance with religion, culture and national norms.

1.1.3.2. Other sectoral laws

Between 1995-1996, some sectors such as animal resources, agriculture, atomic power, science & technology, have issued laws that encourage the promotion of scientific and collaborative research; however laws, have not clearly stated the ethical aspects, when human participants are involved in in these sectoral researches. It's anticipated that industrial , agricultural etc might directly or indirectly involve human participants. The NHREC as an arm to the NCHR as well as the FMOH being responsible of the protection and promotion of the lives of people should work with relevant sectors to emphasize the ethical review of such researches.

1.7.3.3 : Interim Constitution of the Republic of Sudan 2005

Promotion of scientific research and protection of humans involved in research were explicitly stated in the Interim Constitution of the Republic of Sudan 2005, under Articles 13 & 28

1.7.3.4. The Public Health Act 2008:

The Public Health Act of 27th July 2008, superseding the one in 1975, have stipulated in its second chapter, Article 5-G (5و .) the establishment of a national public health coordination council (NPHCC) chaired by His Highness, the Vice President of the Republic of Sudan or whom he delegates and that the NPHCC is responsible of " supervising the medical research involving human subjects in coordination with concerned bodies to ensure that it is aligned with medical ethics and professionalism in the context of Sudanese norms, culture, traditions and heritage" . The Act under chapter six, Article 29-1, stipulates the establishment of a " National Council of Health Research" , the composition of which shall be called by the federal minister of health and chaired by the Under-secretary of Health. The composition of the NCHR shall include representatives of health authorities, health institutes and related sectors and that the DoR shall act as a permanent secretariat and

shall house the NCHR.

The NCHR along with other functions, is responsible of governing the quality and ethical conduct of research in health. Under Article 30, the NCHR is responsible of setting policies to deal with new health and medical technologies and advancement such as cloning, genomics, organs' transplantations and others in coordination with concerned parties. It is responsible of establishing specialized committees to assist in undertaking different responsibilities and roles to that end as will be deemed appropriate by the council[1].

1.7.3.5. The Presidential Decree (39) of 2011

Under Act 29-1, the Presidential Decree has redefined the terms of references for the FMOH including:

1. Developing national policies and legislations that protect and promote the health of Sudanese people.
2. Development, monitoring and evaluation of the national strategies for health .
3. Development of the levels & standards of the promotive, preventive, curative and rehabilitative health services, in collaboration with related sectors

Under the same Act, the Presidential Decree has assigned the FMOH the role of supervision on biomedical research and the responsibility of ethical conduct of research within the local context and undertaking national health studies. As well, it was assigned the development of national data base in health, conduction of national health surveys and generation of data for health planning and monitoring.

1.7. The Ethical Review Process in Sudan

1.1.7. Tools in Use

Since its establishment, the NHREC, has developed different tools and guidelines to govern the ethical conduct of research. Of these, are the national guidelines for ethical review of research involving human subjects that was disseminated at all levels by 2008.

As well, a template for protocol submission was also developed and

disseminated. This template addresses the different aspect of ethical conduct of research such as the technical credibility & benefits of the research to the community, autonomy of the study participants, beneficence and none maleficence and justice to ensure that investigators will cater for the ethical issues during planning and implementing research . Each of these aspects was addressed in details. Along with the protocol template, a check list was also developed to assist RECs during the process of reviewing protocols.

1.1.1. Flowchart of the Ethical Clearance Process

1.1.2. Experiences of Eight RECs

To be enlightened while developing the accreditation guidelines, by the current practice and under the request of the stakeholder group, who contributed to this endeavor, a purposeful sample of 11 RECs was selected. They represent private academic institutes, professional training and research and training, hospitals, and states. Although the objective was not to assess/ evaluate these RECs, but rather to learn from their experiences, so that the proposed accreditation is aligned with actual gaps; however one REC was very reluctant to contribute, one denied having a REC, despite the name was documented in the list of RECs at DoR and in one key informant was not available.

In-depth interviews with either chairs or rapporteurs of RECs showed the following general findings:

1. Policies and guidelines:

a. Membership , appointing and termination policies are hardly available

b. Policy addressing disclosure and management of conflict of interest is missing

c. Majority of RECs adopted the national guidelines

2. REC composition:

a. Prior research experience was the main criteria for selection of REC

members

b. Membership of lay man and nonscientists was overlooked though it's known to respondents. When included it was not appropriate. This is an area that needs deliberations and agreement on who represents the none scientists and laymen.

c. Most of REC don't fulfill criteria of IRB (independent, multi-disciplinarily composition of members

1. Training of REC in Research ethics :

a. Training in ethics is not perceived as important as research expertise criteria. One of the respondents said ''Having two sessions in ethics within the training on research methodology is enough to be acquainted with ethical reviews''.

2. Misconceptions:

a. It was commonly perceived by respondents that IRB function is different from the REC and that IRBs are more concerned with the technical review of the research proposals rather than ethical review and that students' researches shouldn't go through a rigorous review process. One of the respondents said ''just make sure that research investigators have a consent form, that stated the rights for withdrawal and emphasized on assurance of confidentiality and privacy''

b. Only research on randomized clinical trials (RCT) that requires rigorous ethical review.

3. Review process:

a. Review checklist / format available have adequately addressed study , design whereas ethical review elements were totally overlooked

b. Quorum is required for a full board review however requirement of attendance of certain members (like outside REC institute, or lay man , or non-scientist) is not addressed within the quorum.

c. Informed consent templates deficient (does not comply with all elements of the international standard of I.C)

d. Decisions are made by consensus

e. Continuous follow and review of approved studies are reported mainly among REC that have RCTs (2/8)

4. Poor documentation system:

a. Information about REC processes were difficult to retrieve and meeting minutes were hardly obtained.

b. Meeting minutes obtained documented the main elements frequently reported (date, attendees, research title & decisions made.

c. They were quite deficient with regards to documentation of the review process including deliberations around the different ethical aspects.

The above were few areas concerned with the review, finally respondents were asked about their views towards establishing an accreditation system. Most thought that it will lead to improvement of the performance of RECs .

Chapter 2: Accreditation of Health Research Ethics Committees & Institutional Review Boards

2.1. The definition of Accreditation

Accreditation is the act of granting credit or recognition, especially to an educational institution that maintains suitable standards. Accreditation is necessary to any person or institution in education that needs to prove that they meet a general standard of quality[32].

In health a standard is a "desired and achievable level of performance against which actual performance is measured" [33].

The organization and standardization of RECs is an important aspect to protect subjects participating in clinical research. There is a healthy trend worldwide to register and/or accredit research RECs reviewing clinical health research. The method/s of accreditation requires identification and definition of a number of minimal requirements relating to the standards that REC should follow.

The national bioethics committee of Kenya, defines accreditation of a REC, for operational purposes, as " giving approval and delegated authority, to an ethics committee to conduct ethics reviews on behalf of the NBC" [29].

Certification refers to the confirmation of certain characteristics of an object,

person, or organization. This confirmation is often, but not always, provided by some form of external review, education, assessment, or audit. Accreditation is a specific organization's process of certification[34].

In this document, accreditation means "delegating authority by the NHREC to a research ethic committee / institutional review board or any other name given to such type of committees that review any type of research involving human subjects, following a competent and quality assessment of that committee/body etc..".

2.2. Objectives of the Accreditation RECs

The real value of accreditation is not the "Control", but the initiation of formative processes which result on quality improvements on the institution's own facilities[35].

The overall objective is to define competent REC, who can serve as advocates for , and safeguards of the welfare of research subjects and community at large by ensuring a conduct of ethical research. REC function is not limited to protect research subjects but also to ensure that resources are spent on good research that will benefit the community and the country.

Specific objectives are to:

Standardize the ethical review procedures across the country

1. Identify gaps in the ethical review aspects and assist REC to address these gaps .
2. Build community, national and international trust and promote collaborative research.
3. Set an example to be followed by investigators.

2.3. Which REC is Eligible for Accreditation ?

All types of RECs, no matter what name it holds or to what entity does it belong, shall be subject to accreditation.

A REC, is defined as a " Group of people appointed to review research proposals/protocols, to assess formally if the research is ethical". This means the research should conform to recognized ethical standards, which includes: accepting the dignity , rights , safety and well-being of the people

who take part in [36].

As mentioned before, a REC can be at national, sub-national, regional, or at institutional level. Research committees that belong to sectors other than the health sector, but are involving human subjects in research, should be subject to assessment and accreditation by these guidelines. The NCHR is authorized by the Presidential Decree to protect people, should work with its members from other sectors to identify such type of researches and coordinate means and strategies to ensure that sectoral research committees are following the standards that protects human research participants.

It's not advisable in the context of scarce expertise, that every and each institute establishes a REC, rather stakeholders in research are advised to join efforts and establish a single competent and accredited REC at the state level. In some countries, stakeholders establish Regional RECs. Decisions might depend on access to each other, connectivity, as well on the bulk of health-related research carried.

REC can review any type of research when it's accredited. This includes but not limited to: epidemiological research, social science research, research on records /personal information or research on stored samples; however the review of the clinical trials and international collaborative research will be at the discretion of the NHREC. With regards to inter-state research reference should be to the RECs in each of the collaborating states or the NHREC as deemed easier for investigators.

The NHREC is to advocate at all levels for the registration and accreditation of RECs. It will work closely with RECs to advocate for voluntarily application for accreditation; however the NHREC or a hub- review committee at an institutional level, can assess any committee under its governance, even if it has not applied for accreditation, so as to ensure quality and competency in the ethical review process.

RECs should understand that accreditation is for quality control and improvement and not for imposing rules.

The NHREC in collaboration with its partners such as WHO, TDR programme

and donors supporting research will establish a national registry and will share the names of accredited RECs to be included in the WHO registry. Donors will also be posted about the accredited RECs. This is expected to build international trust and generate more resources to RECs

Periodicity of accreditation

A REC will be eligible for the first accreditation after being registered and has satisfied requirements for accreditation as per the guidance in this document. . Registration here refers to the fact that a REC communicate to the NHREC, the dates it was established, shares the ethical guidelines and SOPs that it follows and request to be included in the data base of NHREC.

Accredited RECs are subject to renewal of accreditation within three years of the former accreditation. Renewal should be requested at least six months before expiry of former accreditation. If a REC pass accreditation dates, its responsibility of review should be withheld by the NHREC until it is renewed. A continuous quality checks should be performed through routine annual reporting and supervision.

2.4. Who is responsible of the accreditation?

The NCHR is responsible of the overall protection of research participants and supervising biomedical research; therefore it is mandated by accrediting and re-accrediting the NHREC. To do that the NCHR can commission independent local or international experts to assess and accredit the NHREC. The NHREC is mandated to monitor and strengthen the role of REC with the aim of protecting the life, dignity and benefits of a research participant, groups and the community at large. To ensure independent review of the RECs as perquisite for the accreditation, the NHREC shall commission independent national reviewers to a join a team of the NHREC members to accredit RECs.

It's the responsibility of NHREC to nominate the accreditation team . The nomination proposal, shall be endorsed by the chairperson of the NCHR.

2.5. Steps of Accreditation Process

2.5.1. Preparation of the accreditation (six weeks)

The following steps are not necessarily achieved in the sequence, they are written.

2.5.1.1. Preferably receipt of a written request/application for accreditation by the chair of the REC or the head of the institute to which that REC belongs (example in annex 1). However as mentioned before, NHREC has the duty to follow up and map RECs in the country and carry assessments as part of the accreditation even if REC did not apply.

2.5.1.2. Provision of evidence that the REC was established enough time that allow it for readiness for the planned accreditation or has been accredited three years ago (for renewal). Decree, circular or a letter of establishment to be attached with the application.

2.5.1.3. Sharing SOPs/guidelines or tools used by the REC to review research protocols (examples of documents are in annex 2) .

2.5.1.4. Use Standardized Assessment Tools

As part of setting the accreditation system, the NHREC in consultation with stakeholders, prepares an standardized framework/ tool for assessing the review process of RECs . Several international tools are available for assessing the RECs before accreditation [24, 27, 37]. They can be used in total, or adapted to the local context according to the national ethical standards set for the review. To standardize the process and for the sake of comparability over time, the NHREC should use the same framework for all assessments unless new national SOPs are developed. Assessment of the different thematic areas can be done using weighed criteria. The objective is not to specifically score an individual REC, but giving weight to key areas will help in decisions regarding accreditation and certification. As well, it serves as a bench mark for the RECs and for the NHRECs to monitor its own quality of work overtime. While the overall findings will definitely be shared with REC, scoring certain areas should only be shared with REC if requested and should be kept confidentially within the NHRECs. The NHREC can publish overall scored assessments without identifiers. .

2.5.1.5. Develop a plan for accreditation

The plan includes activities to be carried at federal level and at the REC's level. The plan includes nomination of the accreditation team, identification of financial resources and all required logistics. Careful and early planning will ensure better outcomes and will spare the time allocated for the whole process.

2.5.1.6. Identify and establish the review/assessment team.

The team should be a multi-disciplinary, of an adequate number (3-5), highly committed and versant in the subject of health research ethics (HRE) and on evaluations/assessments, preferably with experience in education. This number can be reduced or increased according to the number of applications /planned assessments at a time. The team should include more members independent of the NHREC in addition to fewer of NHREC members. The team leader should be senior expert.

Due to scarce expertise in research ethics, it is common that experts serve in more than a REC. Conflict of interest shall be strictly ruled out when assigning the assessment team. Conflict of interest might

include employment whether full or part-time with the institute to which a REC belongs, engagement in joint research or in any other financial relation or known disputes. Assessors should sign a declaration of interest. The team should develop a detailed work plan for tasks under its assignment.

2.5.1.7. Train the assessment team on the tools

Share the assessment framework and data collection tools with assessors, ahead of the training. Hold a one day training for the assessors to go through the different tools at least two weeks before the beginning of the process.

Establish early and frequent contacts with target REC

The purpose is to prepare for accreditation, including dates, preparation of reports, documents to be reviewed and lists of REC members and senior

management staff to be interviewed during the site visits .

Dates should be carefully planned to ensure availability of at least 60% of the members of the targeted REC and availability of at least two senior management staff of the institute during the site visit. The objective is to firstly assess the supportive environment at institutional level and that the feedback to the senior management will ensure implementation of any corrective measures if required. The process should be cooperative, supportive and educative to the REC.

2.5.1.8. Share with REC the list of documents to be reviewed before the site visit

REC should share with the accreditation team some key documents before conducting a site visit. Sharing the documents in advance will help the accreditation team identifying specific gaps where they can provide more technical guidance when visiting the REC. Assessors should always keep in mind that the main objective is to ensure the competency of the REC rather than a quick check process.

The key documents to be shared in advance are reflected in annex 2 of this document. It's presented as check list for REC to ensure that it will be prepared and submitted along with the application form. The same applies to RECs that will be assessed in case they didn't apply.

The assessor team should examine the SOP and check tools used by the REC for the review of research protocols ahead of the site visits . This is meant to provide constructive feedback to REC on required amendments. Feedback can be shared with targeted REC even before the site visit of assessor team.

2.5.1.9. Advocate for the process

Encourage the targeted REC to hold internal orientation meeting/s about the process ahead of time.

The objective of these meetings is to prepare relevant staff of the entity to which REC belongs to facilitate the process, own the results of assessment

and proactively contribute to recommended improvements.

2.5.1.10. Conduct a site visit to REC (at least 2 full working days for a single REC)

The site visit is complementary to the desk review carried out earlier. The purpose of this visit is to assess the supportive environment available for the REC at institutional level, advocate for the ethical review process and to check organizational areas of the work of the REC such as availability of a secretarial support, offices available for the REC meetings, storing and archiving system for the reports, random check of meetings' minutes other than those shared, a sample of research protocols etc ..

Proposed Meetings of the assessor team : (Refer to the Guiding Note for Assessors)

2.5.1.10.1. Meeting with Senior Management of REC's Entity.

The purpose of the meeting is to introduce the assessor team to and brief the senior management under which the REC is established about the process of the accreditation, the specific objective and expected outcomes of the visit. Some senior management (especially if are recently appointed) might not be aware or closely following the performance of the REC. This meeting is an opportunity to advocate for the ethical review and the support expected by senior management to REC.

In this meeting, assessor/s in particular ask about policies, standards, organizational aspects including if reports of REC are shared with senior management and whether they are asked for .

2.5.1.10.2. Meeting the Chair of REC, Acting chair and Rapporteur

In this meeting, the assessors go through the whole assessment/survey tool already designed and endorsed by NHREC and its stakeholders. The tool must cover all aspects of policy, organization, technical/SOPs, reporting etc.. Assessors discuss the issues that face the REC if any.

2.5.1.10.3. Meeting with REC members

Assessors check the number of members, their affiliations and trainings on research ethics, periodicity and types of meetings (regular meetings,

adhoc meetings etc..) , enquire about the review process as per the SOPs. Assessors discuss the issues that face the REC if any.

2.5.1.10.4. Meet key investigators and stakeholders

Assessors try to meet some investigators identified during checking the protocols. If meetings are not possible, other means can be used such as telephone conferences, emails etc.. Other potential stakeholders can be met. Decisions on whom to meet should be decided and planned before the site visit. Stakeholders will differ according to the scope of work the REC.

2.5.1.10.5. Check, review and discuss available documents

These include: SOPs of REC (shared earlier before site visit)

2.5.1.10.6. Hold a debriefing meeting

The senior management and REC members should be notified ahead of time, that a debriefing meeting will be held at the end of the site visit. The objective is to share the preliminary findings and discuss areas for improvements and how each of the institute, NHREC and other stakeholders will contribute to that. The REC should be encouraged to prepare a plan of action for interventions required including developing a quality check and monitoring system by which it can periodically assess and improve its performance. The plan is to be shared with NHREC within 4-6 weeks following the visit at the latest. Implementation of the plan is the prime responsibility of the REC's entity. Stakeholders might be motivated to contribute to the improvement' plans. Prior and continuous advocacy for accreditation will ensure the engagement and motivation of stakeholders.

2.5.1.11. Analyze data and write the assessment report

The assessment report shall contain all the information gathered during the accreditation process. It highlights the findings from all thematic areas (areas for assessment should be the headings and sub-headings of the report) . As well, it includes the proposed decision of the accreditation status. The assessment's report is discussed by the NHREC . The accreditation status proposed by assessors shall firstly be endorsed by the NHREC's quorum and shall be signed by the chair before being shared with the

assessed REC.

Decisions on accreditation status of the assessed REC:

The following decision's pathways should be followed:

1. REC is accredited and will immediately be added in a national registry and information will be shared with international partners.
2. Minor improvements are to be made. The NHREC will follow up with REC until gaps are bridged. The REC's chair or rapporteur should present to the NHREC a report confirming that corrective measures were taken (along with evidence), lately three months after assessment. Upon satisfaction of NHREC, the applicant REC can be accredited & registered. In case of failure to do that within three months, the function of the REC will be suspended and will be treated as per decision three below..
3. Major gaps were identified

NHREC, notify the REC entity and withhold the function of REC until required interventions are implemented lately six months after assessment. A complete reassessment will be carried out including the site visit. The NHREC should provide technical assistance to REC to ensure that improvements were made. RECs are encouraged to use these guidelines for self-assessment before applying for accreditation.

Benefits of accreditation

The NCHR should in particular widely disseminate the accreditation registry, especially with donors and international partners, advocate for resource mobilization and allocation of resources to accredited RECs.

Punitive Actions

The NCHR has the legitimate liability of withholding any REC that intentionally or inadvertently fails to comply to repeated assessment's recommendations.

In case the REC/IRB did not take corrective measures within the timelines and continued to work, the following actions should be followed in sequence:

1. Notify the REC's identity in writing

2. Notify the scientific research governing body at the Ministry of higher Education, so that REC will not be considered in any grants or other consideration.
3. The REC will be subjected to Judiciary provisions as per the NCHR/ NHREC regulations.

Finally, it is very critical to use the information generated through an assessment process to stimulate practical improvements. This requires a commitment from accrediting authority here the NCHR, NHREC and stakeholders to the process of continuous quality improvement and accreditation.

2. 6. Steps in accreditation process

The accreditation is not a target in its self as repeatedly mentioned before. It's a means to ensure that research participants' rights are protected, the community is assured and trusts researchers and that researchers are protected against being sued for any serious violations. Thus putting an accreditation system for research ethics committees in place will require strengthening the overall research governance system.

This will include but not limited to:

A) Immediate actions

1. The NCHR reviews the performance of the NHREC as soon as possible before assessing other RECs.
2. The NCHR strengthen its secretariat to undertake its responsibility in developing the capacities of RECs.
3. Commitment to allocation of financial and human resources to the secretariat is paramount for secretariat to undertake its responsibilities. This includes and not limited to, full time staffing, building strong administrative systems such as databases, electronic and hard archiving, online system for submitting applications, complaints, requests, periodic reports, systems ensuring confidentialities etc...
4. The NHREC, revise the SOPs if required and present them in brochures and user friendly formats, shares them widely and work closely with RECs to strengthen their technical capacity with focus on implementation of the

national SOPs, monitoring and quality improvement. .

5. Develop and implement advocacy and capacity building plans on health research ethics including the training of RECs.
6. Map the RECs and develop a phased plan for accreditations with focus on guiding RECs in establishing internal quality improvement systems.
7. Assist growing institutes to start with regional/zonal RECs.

B) Intermediate Actions

8. Operationalize the Public Health Act

a. Advocate among stakeholders for the regulative and authoritative role of the NCHR from one hand and the FMOH on another hand.

b. Develop regulating laws, that clearly impose punitive actions in case of violations of professional codes for conduct of research

9. Implement the national health research strategy (endorsed two years ago) .

Chapter Four: References

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Chapter Four: Annexes

Annex 1: Application form for Accreditation

1. Title of REC & entity: (institute, hospital, state, etc)
2. ……Date of application:……
2. Date of establishment of the REC/IRB:……
3. Number of research protocols reviewed by REC during the last three years
3. 1st Yr……./ 2nd Yr……3rd Yr:…….Number of reports shared with the NHRECs during the last three years
4. 1st Yr……./ 2nd Yr……3rd Yr:……..
4. Last date of accreditation of REC:…….
5. Not applicable
5. Type of accreditation requested: Primary Renewal if renewal: # of previous accreditations :……..
6. Proposed Dates of assessment/accreditation in weeks:……
7. Completion of the check list of requested documents in annex 2:

Y N:

Name & signature of chair of the REC:……

Name & signature of head of the institute :……Stamp:

Annex 2: A check List of Documents attached to Application Form
(To be completed by the applicant authority)

In the context of this assessment, yes "Y" means that the document/ information required is available and has been attached to the application form, while no "N" means it was not attached, even if it is available at REC level. You have to complete this check list along with reading the guiding notes for it. When it's not required to attach a document, usually you are asked to indicate that in the summary report, purposely prepared for this accreditation. In the case you mentioned that, tick Yes.

Check the documents attached by type:

A) Governance & Policy aspects:

1. Circular/letter of the decision of establishment of the REC:

Y ☐ N: ☐

2. Circular/letter of the date of establishment of the REC:

Y ☐ N: ☐

3. Circular/letter specifying the first & second level authority under which REC works:

Y ☐ N: ☐

4. Circular/letter specifying the terms of reference of the REC:

Y ☐ N: ☐

5. How the chair is appointed is specified in a document of REC:

Y ☐ N: ☐

6. How each member was appointed :

Y ☐ N: ☐

7. The conditions upon which membership is terminated

Y ☐ N: ☐

8. List of members of the REC: (A table can attached indicating all the information required on the REC's members)..

Y ☐ N: ☐

9. Title of each member within the REC was specified (professional, lay man, religious, etc) :

Y ☐ N: ☐

10. Professional expertise of each member (e.g physician, attorney, surgeon, teacher etc..):

Y ☐ N: ☐

11. Gender of each member was specified:

Y ☐ N: ☐

12. Date of appointment of each member of the REC is specified

Y ☐ N: ☐

13. Training of each member on research ethics :

Y ☐ N: ☐

14. Regularity on attending meetings

Y ☐ N: ☐

15. Copy of a letter/circular etc specifying approved budget for the REC (one for each year):

Y ☐ N: ☐

B) Technical Aspects upon which REC Performs

16. Sample of the research protocol application form

Y ☐ N: ☐

17. Copy of the SOPs used by the REC in reviewing a research protocol:

Y ☐ N: ☐

18. Copies of meetings' minutes held by REC:

Y ☐ N: ☐

19. Copies of feedback letters to the PI/s including the decisions by REC on the protocol

Y ☐ N: ☐

20. Copies of progress reports by PI/s on approved researches

Y ☐ N: ☐

21. Copies of final reports by PI/s on approved researches

Y ☐ N: ☐

22. Copies of monitoring reports by REC

Y ☐ N: ☐

23. Copies of annual reports of the REC :

Y ☐ N: ☐

24. A compiled summary status by REC

Y ☐ N: ☐

Annex 3: Guidance Note for REC on the Documents to be Attached with Application

*Note: This guidance note has to be read in reference to the serials of documents mentioned under the check list. The number of documents to be attached here is meant for REC applying or being accredited for the first time.

**Application here refers to application for accreditation or accreditation decided by authoritative body (NHREC/NCHR).

*** If this is the first or a renewed accreditation for REC, a summary report has to be prepared on the status of REC work. The guiding notes here below can serve to be points for preparing the summary report along with other information that REC deems relevant to share with assessor before the site visit.

S.N	Document	guidance
1	Decision on the establishment of the REC	Decree/ordinance circular/ by a high level official entity stipulates the establishment of the REC. The same document might have included answers/specification of the subsequent areas below
2-4	Date of establishment, governing entity (affiliation), remittance, TOR of REC	Date of establishment or renewal of REC. - These policies /decisions might have been issued separately or included in the decree, ordinance or circular etc… If they were issued separately, attach smaples.

5-6	Appointment of the chair and members	-Criteria for appointing the chair and members Might have been described in a national, international or institutional guidelines followed by an institute or the authority under assessment. - If by national or international guidelines you have to mention so, in the summary report and attach only the letter/circular in which the chair/members were nominated . - If the issuing authority under this assessment has issued its own criteria for appointing the chair and members attach the document. -Nomination of the chair/members might have been included in the document under S,N 1, or in the TORs, you don't need to attach another one .
7	Criteria for termination of chairmanship or membership	Attach copy of the document in which the conditions for termination of chairmanship or membership is specified.
8-14	Information about REC's members	Attach a table including the names, date of appointment, professional background (pediatrician, obstetrician, public health, surgeon, pharmacists, microbiologist, scientist researcher, statistician, etc..) , title within the REC (professional, nonscientist, community representative, legal representative, religious person/s), Gender, status of training on ethics (yes/ no). Regularity on attending meetings: check (against TORs of REC) the number of meetings conducted since nomination of the member up to date of application. If a member attended at least 60% of the meetings, s/he is regularly attending.
15	Financial resources for REC	Attach a document reflecting how the REC is financed and what resources have been allocated to it. The document might be: a letter, circular, a plan reflecting the source of funding and an approved request for funding, or approved budgeted plan/s, or an announcement by the chair/ rapporteur documented in a meeting's minutes.

16	Sample of the research protocol application form (RPAF)	A REC must have a RPAF. It might have been developed by REC or by the NHREC or another entity. If it is other than the national, it has to be attached, otherwise refer to in the summary report prepared for accreditation. When you do so, you check yes in the check list. -Attach adverse events forms if any. -Amendment forms if any.
17	Sample of the SOPs used by the REC	A REC might have developed its own SOPs or is using the national SOPs . Attach copy of the SOPs, including standards templates used by REC.
18	Samples of meetings' minutes	Attach at least three samples of the meetings' minutes carried in the last two years
19	Samples of feedback letters to the PI	Attach sample of feedback letters issued by REC chair to the PIs. At least three per each of the last two years.
20	Progress reports by PI/s	PIs should share progress reports with REC on approved researches. Attach at least one copy of a report for the last two years if any.
21	Final reports by PI	PIs should share final reports with REC on approved researches. Attach at least one copy of a report for the last two years, if any.
22	Monitoring reports by REC	REC usually monitors researches under progress through reports of PIs (above) or site visits if required. If site visits were carried attach copy of the REC's report on the visit (reference is to the last two years) .
23	Annual reports by REC	Attach at least one sample of the annual reports of the REC of each of previous two years
24	Compiled summary status report	For the purpose of the accreditation, the REC should prepare a summary cumulative report on its policies, standards and activities carried since the establishment of the REC. It has to be prepared before application for accreditation.