Republic of Sudan

Federal Ministry of Health

National Health Research Council

Directorate of Health Research

ASSESSMENT OF THE NEEDS FOR PROMOTING THE CULUTRE AND PRACTICE OF HEALTH RESEARCH ETHICS

IN NORTHERN STATES in SUDAN

2010

Final report

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Acknowledgement

The Directorate of Health Research at the Federal Ministry of health has the pleasure to convey its acknowledgements to many individuals whose efforts and expertise made it possible to produce this report. Without the first step of the proposal writing, this work couldn't see the light. Thanks to the effort of the technical committee namely: Dr. Mustafa Elniemiri from ElNielin University, Dr. Somaia AlFadil from WHO ,Dr. Samira Hamid and Dr. Mohammed ElHassan from University of Gezira, Dr.Howida AbuSalih from KSMOH.

We also appreciate the assistance of universities, research institutes and the states ministries of health who participated in this study as respondents or as administrators. Sincere thanks to them for facilitating the data collection and field work of the research team. The latter are the unknown soldiers, who worked day and night with patience and enthusiasm to collect, edit and process the data. Many thanks to them.

We also acknowledge Mrs. Asia Abdalla – social researcher who has analyzed the qualitative part of the data, Mrs. Nahid Abdulgadir and Mrs. Siham Yagoub for analyzing the quantitative part of the data to come up with the final results of the study.

Last but not the least we would like to thank Dr. Mustafa Elniemiri for his kind assistance to the team all through the study processes till the final step of writing the report. Many thanks for his continuous support to the directorate.

Finally, saying thank you very much is the least to say to the WHO office in Sudan for all the technical and financial support provided in order to put this product in its final shape.

Dr. Iman Abdalla Mustafa

Director, health Research Directorate

Acronyms

CIOMS	**Council of international Organizations of Medical Sciences**
WHO	**World Health Organization**
ICHT	**International Conference of Harmonization of Technical Requirements for Registration of Pharmaceuticals for human use**
RECs	**Research ethics committees**
UNICEF	**United Nation Fund for children**
UNFPA	**United Nation Fund for Population Activities**
UNAIDS	**United Nation AIDS Program**
NGOs	**Non-governmental organizations**
SPSS	**Statistical Package of Social Sciences**
IRB	**Institutional review board**
KSMOH	**Khartoum State Ministry of Health**

Executive summary

The ethical and scientific standards for carrying out biomedical research on human subjects have been developed and established in international guidelines, including the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the WHO and ICH Guidelines for Good Clinical Practice. Compliance with these guidelines helps to ensure that the dignity, rights, safety, and well-being of research participants are promoted and that the results of the investigations are credible

The history of medical research in Sudan goes back to 1903 , with the establishment of Welcome Research Laboratories in Khartoum as a part of the Gordon Memorial College . Policies to conduct research at that time played an important role in the development of new or improved prevention strategies, diagnostic methods, and protocols using the information gained from research

It is very difficult to trace any documentation to the history of research ethics in Sudan before 1979, where a national committee for ethics in research involving human subjects was established by few physicians and scientists to focus on the studies lead by the National Laboratory (Khartoum).

There is worldwide concern and conviction that there is a need for protecting the rights and welfare of research participants and, especially so of vulnerable groups or individuals. Ethical concerns are particularly important in Africa where the rights of participants in clinical trials may be easily exploited because of the high rates of disease, illiteracy and ignorance, extensive abuse of human rights and weak or lack of regulatory bodies and health research ethics committees. In this regard Sudan is not different from African and other developing countries.

The study aim is to investigate the situation of Health Research Ethics at both federal and state level with regard to institutional management capacity curricula, awareness and practice of researchers and communities.

The survey was conducted in **6** Northern states namely:

1. Khartoum
2. River Nile
3. White Nile
4. Gedarif

5. North Kordofan
6. Gazera

The institutions targeted within the 6 states included:

- Medical, public health, medical laboratories and nursing schools.
- Health research institutes within the universities.
- The state Ministries of Health, Federal hospitals and specialized medical centers

The survey quantitative and qualitative data were collected using the following instruments:

- A standardized administered questionnaire for the state ministries of health, hospitals and national centers
- A standardized administered questionnaires for health research institutes, medical, public health, medical laboratories and nursing schools within the targeted universities.
- An in-depth interview targeting Members of the legislative council, representatives National Union of Youth, representatives Local committees, representatives of Humanitarian Aid.
- Focus group discussions targeting the researchers and academicians at the institutional level. 12 focus group discussions were conducted and the total number of the participants mounted to 63.

The quantitative collected data was entered and analyzed using SPSS while the collected qualitative data was analyzed manually using mater sheets.
About 40% of the sampled institutes are medical and health colleges while about 24% of them are research centers and institutes. For these two categories of the sampled institutes conduct of research involving human subjects is mandatory. The implemented institutional activities relevant to research ethics in 60% of the institutions that included research ethics within their policies/ plans are confined to training and establishment of the research ethics committees.
44.7 of the sampled institutes had trained cadres on research ethics which is indicative for the marked shortage of trained human resources on research ethics at the institutional level. For 39% of the institutes with trained cadres, the type of training

on research ethics showed to be short course of 1-2 weeks while about 32% of them had cadres subjected to orientation course less than a week.

The results of the focus group discussions showed that the knowledge of the participants are confined to basic knowledge about research ethics i.e. definition while the majority of them attitudinize the importance of research ethics. However the majority of the participants do not know much about the national and international codes of research ethics involving human subjects.

The interviews with the members of the legislative council, representatives National Union of Youth, representatives Local committees, representatives of Humanitarian Aid showed that mostly they don't have any knowledge about the conducted researches in the health sector or health related sector.

Most of the participants stated that there are no available sources of knowledge about health research ethics, and they don't know where these sources in Sudan are to be accessed.

The research ethics especially in the sampled academic institutes are not well streamlined as training programs but rather the research ethics are included within the elements of the other training programs such as research methodology.

The institutional review boards are established in 65% of the sampled institutes while about 35% of them have not yet established such boards. About 48% of the institutes with established IRBs have their own institutional guidelines available while about 33% of them have the national guidelines available to be used by the IRBs

The vast majority of the participants in the focus group discussions affirmed that there are ethical considerations to be addressed and included in the research proposals. In reality these considerations do not tally fairly with the universally accepted principles of health research ethics.

Despite the vast majority of the IRBs in the sampled institutes used to practice technical and ethical review but the extent and quality of the practiced ethical review are questionable with marked institutional capacity on research ethics. Most of the IRBs are lacking appropriately functioning standard reporting and archive systems.

About 74% of the sampled institutes stated that they have incorporated research methodology within their curricula while about 26% of them have not yet incorporated such contents within their curricula. 50% of the sampled institutes have allotted limited working hours for the research methodology contents. Some institutes

even they allotted extra time for the research methodology but still the allotted time is limited for the incorporated research ethics within the institutional curricula.

The important recommendations include:

- Finalization and dissemination of the national policy document on health research ethics is strongly recommended to strengthen political commitment.
- Capacity building of the human resources at the institutional level is needed through formulation of comprehensive strategic plan
- Scaling up of the quality of training on research ethics through establishment of effective partnerships and collaboration with national, regional and international institutes with expertise on training on research ethics.
- Activation of the IRBs functioning to provide advocacy for research ethics among the community members and the laymen with inclusion of community members and laymen within the membership of the IRBs
- Upgrading of the review process by the IRBs through establishment and dissemination of the national guidelines and the standard operational procedures with continuous training of the IRBs members.
- . Strengthening of the curricula of research ethics with allotting extra working hours to improve the competency of both the under-graduate and post-graduate students on research ethics
- Establishment of the Sudanese Network on Research Ethics including all the partners and the academic institutes to strengthen the ethical standards and practices across the country.

1. Introduction

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trails, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners(1).

The codes consist of rules, some general, others specific that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted (1).

The ethical and scientific standards for carrying out biomedical research on human subjects have been developed and established in international guidelines, including the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the WHO and ICH Guidelines for Good Clinical Practice. Compliance with these guidelines helps to ensure that the dignity, rights, safety, and well-being of research participants are promoted and that the results of the investigations are credible (2).

Countries, institutions, and communities should strive to develop RECs and ethical review systems that ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical research. States should promote, as appropriate, the establishment of RECs at the national, institutional, and local levels that are independent, multi-disciplinary, multi- sectors, and pluralistic in nature. ECs require administrative and financial support (2)

1.1. History of Health Research in Sudan:

The history of medical research in Sudan goes back to 1903 , with the establishment of Welcome Research Laboratories in Khartoum as a part of the Gordon Memorial College . Policies to conduct research at that time played an important role in the development of new or improved prevention strategies, diagnostic methods, and

protocols using the information gained from research (3). Institutionalization of research started with the inception of the National Research Council under the ministry of Higher Education. Health research was part of the responsibility of this council (4).

The following stakeholders are currently involved in health research in the Sudan: (3)

1. The government:

   Under the auspices of the government many ministries i.e. Federal Ministry of Health and States Ministries of Health, Ministry of Science and Technology, Ministry of higher Education, Ministry of Agriculture, Ministry of Animal Recourses are involved in conducting health and health related research.

2. The Universities:

Most of the faculties of medicine, pharmacy, dentistry, laboratory technology, and paramedical colleges, nursing and imaging technology schools are considered as stakeholders and involved in health research. Faculty staff, post and under graduates are major players in health research

3. The private sector:

   In recent years the private sector was attracted by certain research centers in universities to contribute to health research either by giving financial support or by participating in the governing boards or both.

4. The United Nations (UN) Agencies:

   Such as WHO, UNICEF, UNFPA, UNAIDS and others provide technical or financial support to the health research through existing health programmes

5. The European Union (EU)

   Although the contribution of EU to health research is yet not significant it is expected that EU would give support to institutions involved in health research. Such support will be realized by submitting sound research proposals.

6. National and International NGOs:

   Few national and international NGOs are actors in the area of health research.

7. The community

   The local communities do participate in health research; however, their contribution is limited mostly to concurrence at and coordination between researchers and members of community at study area level.

1.2. Research Ethics in Sudan:

It is very difficult to trace any documentation to the history of research ethics in Sudan before 1979, where a national committee for ethics in research involving human subjects was established by few physicians and scientists to focus on the studies lead by the national laboratory (Khartoum), with the following objectives:

1. To address current issues, anticipate potential future problems and facilitate productive communication.

2. To protect the research subjects.

3. To protect physicians and scientists.

4. To protect the State and its citizens from research of low priority and external research.

5. To drive the research towards health priorities.

6. To review all research proposals.

This committee died at its infancy due to lack of political commitment, institutional support, technical capacities in the field of ethics and lack of coordination between different potential stakeholders.

Later in 1999 a National Health Research Council was formulated by a ministerial decree followed by formulation of two sub-committees; technical and ethical under the council in 2002. Members of these committees are representing the different stakeholders in research in the country (3).

1.3. Rationale

There is worldwide concern and conviction that there is a need for protecting the rights and welfare of research participants and, especially so of vulnerable groups or individuals. Ethical concerns are particularly important in Africa where the rights of participants in clinical trials may be easily exploited because of the high rates of

disease, illiteracy and ignorance, extensive abuse of human rights and weak or lack of regulatory bodies and health research ethics committees. In this regard Sudan is not different from African and other developing countries.

In Sudan, there are more than 30 medical and health sciences schools, many of them are involved in research as part of the academic requirements for the fulfillment of postgraduate studies or staff promotion. Few of them have affiliated specialized research institutes. More over there is a limited number of private research institutes that are recently growing up. With the epidemiological background of Sudan coupled by the inadequate service delivery and public health interventions, the academic and research institutes are being more sensitized to conduct a lot of health research to identify interventions required to overcome top priority public health problems. However we are lacking knowledge as to what extent these institutes are also concerned about application of HRE in the course of conduction of their researches. Assessment of the institutional capacities, the understanding of researchers and communities to the concepts and practice of health research ethics and their adherence to its application as well as critical analysis of the teaching of HRE within universities undergraduate and post graduate curricula, are critical perquisites to any future endeavors on promotion of the awareness and practice of health research ethics among all stakeholders in Sudan. Conduct of the assessment under question in itself is an advocacy to these endeavors.

2. Aim of the study

The study aim is to investigate the situation of Health Research Ethics at both federal and state level with regard to institutional management capacity curricula, awareness and practice of researchers and communities.

2.1. Specific Objectives:

1. To identify the number and categories of institutes involved in health research and health research ethics in Sudan.
2. To assess the capacity and supportive environment available for institutionalization and strengthening of health research ethics in identified institutes.
3. To analyze the existing procedures of research protocols review at the institutional level and identify the strengths and weaknesses related to research ethics.
4. To assess the current level of knowledge about research ethics among the researchers, academicians and parliamentarians and identify to what extent they comply with ethical principles in health research.
5. To revise the teaching curricula of universities and other research institutes in respect to the teaching of health research ethics within research methodology and assess the potentialities for introduction of health research ethics into those curricula for under graduates and postgraduates.

3. Research Methodology

3.1. Study design

Descriptive cross sectional study used both qualitative and quantitative methods to cover the study population within the selected study areas according to certain inclusion criteria.

3.2. Study area

The survey was conducted in 6 northern States namely:

1. Khartoum
2. River Nile
3. White Nile
4. Gedarif
5. North Kordofan
6. Gazera

The institutions targeted within the 6 states included:

- Medical, public health, medical laboratories and nursing schools.
- Health research institutes within the universities.
- The state Ministries of Health, Federal hospitals and specialized medical centers.

3.3. Study population

The study population is composed of:

- The medical, public health, nursing and laboratory sciences schools
- Members of the State's legislative councils, representatives of Union of Youth, Local committees, Women Union and representatives of Humanitarian Aid at the States level.
- Academicians and researchers from different institutes.

3.4. Data collection methods:

Data was collected through interviewing the survey participants using two forms of standardized administered questionnaires to collect the quantitative part of the survey.

The qualitative part was collected by conducting focus group discussions and in depth interviews.

3.4.1. The list of variables

1. Establishment of research governing bodies (units, directorates, programmes, committees etc.
2. Availability of legislations, guidelines, acts, decrees or circulars in support of application of research ethics Presence of research committee at the institutional level.
3. Functions (Terms of Reference) of the research committee.
4. Inclusion of the research ethics within the functions of the research committee.
5. Availability of standard operating procedures that regulates IRB/committees activities e.g. chairmanship, membership, meetings etc...
6. The approaches and mechanisms for approval of research proposals at the institutional.
7. Level of Knowledge about research ethics and recognition of the importance of health research ethics.
8. Recognition of the international and national codes on research ethics involving human subjects and research ethics within the human rights context.
9. Existing curricula of HRE (objectives, content, teaching and students` assessment methods and tools.
10. Status of training of the researchers on research ethics.
11. Sources of knowledge about the health research ethics.
12. Availability and accessibility to sources of health research ethics.
13. Types of research conducted in the last 3 years.
14. The degree of involvement of human subjects in research.
15. How many research subjects were involved?
16. Ever thought of ethical principles (to be mentioned) during the proposal development.
17. How the ethical aspects of the research were considered by the researcher.
18. Knowledge about and use of Informed Consent and its importance.
19. Ever obtained informed consent.
20. Mechanism for obtaining informed consent.

Placement of teaching research methodology within the institute academic program.
Total credit hours for teaching research methodology in relation to the whole teaching program.
Whether HRE is included in the teaching program of research (theoretical and practical)

3.4.2. The study instruments

3.4.2.1. Brief description of the survey instruments

The survey quantitative and qualitative data were collected using the following instruments:

a. *A standardized administered questionnaire for the state ministries of health, hospitals and national centers (Annex 1)*

   The questionnaire is composed of three sections namely:
   Institutional commitment to research, the ethical standards and guidelines for review of the research proposals and future directions. The questionnaire is composed of 38 closed- ended questions covering the variables relevant to the three sections.

b. *A standardized administered questionnaires for health research institutes, medical, public health, medical laboratories and nursing schools within the targeted universities*.

   The questionnaire is composed of two parts:
   Part (1) which is similar to the questionnaire for the ministries of health, hospitals and national centers while part (2) is designed specifically to cover the curricular issues of research methodology and ethics. The questions were mostly close-ended and mounted to 60 questions in the twp parts.

c. *An in-depth interview* targeting Members of the legislative council, representatives National Union of Youth, representatives Local committees, representatives of Humanitarian Aid. An interview guidance was used which is composed of open-ended questions covering the following aspects:

- Knowledge of the interviewees about the research conducted on human subjects

- The role of the legislative councils in research and studies conducted at the state level.
- Awareness about the international, national and local regulations/legislation for conduct of research involving human subjects.
- Basic ethical principles for conduct of research involving human subjects.
- The existence of research ethics committee and their functions at the state level

The total number of the interviewees mounted to 28 in the 6 states

d. *Focus group discussions* targeting the researchers and academicians at the institutional level. 12 focus group discussions were conducted and the total number of the participants mounted to 63. The following themes were discussed:

- The knowledge about research ethics and recognition of the importance of health research ethics.
- Recognition of the international and national codes on research ethics involving human subjects and research ethics within the human rights context.
- Sources of knowledge about the health research ethics. Availability and accessibility to sources of health research ethics.
- Status of training of the researchers on research ethics. Training availability and training needs assessment.
- Types and number of research conducted in the last three years, The degree of involvement of human subjects in the research,
- Ever thought of ethical principles (to be mentioned) during the proposal development.
- The review process of the proposal and by whom, and their opinion in the IRBs.
- To what extent is the application of the principles of ethics in health research in the conduction of your research
- Knowledge about and use of informed consent and its importance.

3.4.2.2. Pre-testing of the instruments

The survey instruments were pre-tested prior to the field work as follows:

- Four instruments were administered to similar participants in international University of Africa-Faculty of Medicine and El Rabat Teaching Hospital in order to ensure validity of the instruments.
- The necessary modifications and corrections were incorporated and the final instruments were finalized.

3.4.2.3. Selection and training of the data collectors

Nine data collectors were selected based on their previous experience in conduct of surveys and data collection.

The data collectors were trained (one-day workshop) on the following aspects:

- Research ethics.
- Survey methods
- Details of the data collection instruments
- Discussion and finalization of the field work plan and data collection map

3.5. Sample size and sampling technique

3.5.1. The sample size for medical, public health, medical laboratories and nursing schools

The strategy used for the estimation of the sample size is total coverage and thus the number included mounted to 41

***3.5.2. The sample size for the health research centers*:**

The strategy used for the estimation the sample size was total coverage and thus the number included mounted to 24

3.5.3. The sample size for the state Ministries of Health, hospitals and national centers.

The strategy used for the estimation of the sample size was total coverage and thus the number included mounted to 38.

3.6. Ethical considerations

The survey protocol was submitted to the National Health Ethics Committee for approval and ethical clearance. The following points were considered:
Waiving of informed consent was requested from the National Health Research Ethics Committee as the anticipated risk is very minimal.
Consent of high management of the institutes was obtained prior to the implementation phase of the survey.
Set up for conduct of the interviews was prepared to ensure privacy.
Anonymity of the form for assessment of knowledge on health research ethics.

3.7. Data analysis

The quantitative collected data was entered and analyzed using SPSS while the collected qualitative data was analyzed manually using mater sheets.

4. Results

Tables showing the quantitative results

Table (1): Categories of the sampled institutions

Categorization of the sampled institutions	Frequency	Percentage
Research Centers& Institutes	**24**	**23.3%**
Medical and Health Collages	**41**	**39.8%**
States Ministries of Health	**6**	**5.8%**
Federal Hospitals and specialized medical centers	**32**	**31.1%**
Total	**103**	**100%**

Table (2): Availability of institutional policy directed towards health research

Availability of institutional policy	Frequency	Percentage
Yes	**73**	**70.9%**
No	**30**	**29.1%**
Total	**103**	**100%**

Table (3): Types of the available institutional policy

Type of the institutional policy	Frequency	Percentage
National policy	**30**	**41.1%**
Special institutional policy	**37**	**50.7%**
Both	**6**	**8.2%**
Total	**73**	**100%**

Table (4): Inclusion status of the research ethics within the institutional policy

Inclusion status of the research ethics	Frequency	Total	Percentage
Research policies not including research ethics	**7**	**73**	**10%**
Research policies including research ethics	**60**	**73**	**82%**
Guidelines directed towards research ethics	**10**	**73**	**14%**
Legislation/Acts supportive for the research ethics	**19**	**73**	**26%**
Others	**4**	**73**	**5%**

Table (5): Availability of institutional plan supportive for the health research

Availability of institutional plan supportive for the health research	Frequency	Percentage
Yes	**69**	**67.0%**
No	**34**	**33.0%**
Total	**103**	**100%**

Table (6): Inclusion of the research ethics within the institutional research plan

Inclusion of research ethics within the institutional research	Frequency	Percentage
Yes	**58**	**84.0%**
No	**11**	**16.0%**
Total	**69**	**100%**

Table (7): The basic health research ethics activities within the institutional plan

The activity	Yes	Percentage	No	Percentage	Total	Percentage
Training	**36**	**64%**	**22**	**36%**	**58**	**100%**
Advocacy	**18**	**33%**	**40**	**77%**	**58**	**100%**
Development of guidelines on research ethics	**17**	**29%**	**41**	**71%**	**58**	**100%**
Establishment of health research ethics committee	**36**	**62%**	**22**	**28%**	**58**	**100%**
Others	**8**	**14%**	**49**	**86%**	**58**	**100%**

Table (8): Availability of institutional research unit/committee

Availability of institutional research unit/committee	Frequency	Percentage
Yes	**78**	**75.7%**
No	**25**	**24.3%**
Total	**103**	**100%**

Table (9): Trained cadres on research ethics

Trained cadres on research ethics	Frequency	Percentage
Yes	**46**	**44.7%**
No	**57**	**55.3%**
Total	**103**	**100%**

Table (10): Distribution of the sampled institutions by number of trained cadres on research ethics

Number of trained cadres on research ethics	Frequency	Percentage
Less than 10	**41**	**89.1%**
10 – 19	**3**	**6.5%**
20+	**2**	**4.3%**
Total	**46**	**100**%

Table (11): Distribution of the sampled institutions by type of training on research ethics

Type of the training on research ethics	Frequency	Percentage
Orientation course less than a week	**15**	**32.6%**
Training course of 1-2 weeks duration	**18**	**39.1%**
Training course more than two weeks	**8**	**17.4%**
Advanced training	**3**	**6.5%**
Others	**2**	**4.4%**
Total	**46**	**100%**

Table (12): Reasons for non-availability of trained cadres on research ethics at the institutional level:

The reason	Frequency	Percentage
Non-availability of financial resources at the institutional level	**12**	**21.1%**
Non-availability of qualified human resources for training at the institutional level	**6**	**10.5%**
Both non-availability of the financial and human resources	**4**	**7%**
No response	**9**	**15.8%**
Others	**26**	**45.6%**
Total	**57**	**100%**

Table (13): Availability of intuitional review board (IRB):

Availability of IRB	Frequency	Percentage
Yes	**67**	**65%**
NO	**36**	**35%**
Total	**103**	**100%**

Table (14): Type of the review usually practiced at the institutional level:

Type of the review	Frequency	Percentage
Technical review	**11**	**16.4**
Ethical review	**2**	**3**
Technical and ethical review	**54**	**80.6**
Total	**67**	**100%**

Table (15): Check of the review tools *availability* for the institutional review boards

Review tools	Yes	%	No	%	total	%
Proposal review tool	**22**	**32.8**	**45**	**67.2**	**67**	**100**
Special forms for proposal submission	**15**	**22.4**	**52**	**77.6**	**67**	**100**
Monitoring reports of the clinical trials	**10**	**15.0**	**57**	**85.0**	**67**	**100**
National guidelines	**22**	**32.8**	**45**	**67.2**	**67**	**100**
Institutional guidelines	**32**	**47.8**	**35**	**52.2**	**67**	**100**

Table (16): Check of the review tools *usage* by the institutional review boards

Review tools	Yes	%	No	%	Total	%
Proposal review tool	**17**	**77.3**	**5**	**22.7**	22	**100**
Special forms for proposal submission	**14**	**93.3**	**1**	**6.7**	**15**	**100**
Monitoring reports of the clinical trials	**7**	**70**	**3**	**30**	**10**	**100**

National guidelines	**19**	**86.4**	**3**	**13.6**	**22**	**100**
Institutional guidelines	**30**	**93.7**	**2**	**6.7**	**32**	**100**

Table (17): Regularity and periodicity of the meetings of the institutional review boards

Regularity of the IRB meetings	Frequency	Percentage
Yes	**53**	**79.1**%
No	**14**	**20.9 %**
Total	**67**	**100%**
Periodicity of the IRB meetings		
Monthly	**11**	**20.7%**
Quarterly	**18**	**33.9%**
Bi-annually	**4**	**7.5%**
Ad hoc	**20**	**37.9%**
Total	**53**	**100%**
Quorum of the meetings		
Yes	**38**	**71.7%**
No	**15**	**28.3%**
Total	**53**	**100%**

Table (18): The submitted and rejected proposals to the IRB/council per year

The submitted proposals to the IRB/council	Frequency	Percentage
Less than 10	**20**	**30%**
10-30	**17**	**25%**
31-50	**3**	**4%**
More than 50	**14**	**21%**
Don't Know the No. of the Submitted Proposals	**13**	**19%**
Total	**67**	**100%**

The rejected proposals by the IRBs/council per year		
None	**34**	**51%**
1	**8**	**12%**
2	**8**	**12%**
3	**2**	**3%**
5	**2**	**3%**
Don't Know the No. of the rejected proposals	**13**	**19%**
Total	**67**	**100%**

Table (19): The reasons for submission of the research proposals for ethical review

The reasons for submission of research proposals for review	Yes		No		Total
	Count	**%**	Count	**%**	
Fund raising/TDR	**25**	**24.3**	**78**	**75.7**	**103**
For publications of the research findings	**36**	**35**	**67**	**65**	**103**
For facilitation of data collection process from health facilities	**31**	**30.1**	**72**	**69.9**	**103**
Others	**28**	**27.2**	**75**	**72.8**	**103**
All options	**17**	**16.5**	**86**	**83.5**	**103**

Table (20): Issuing of regular reports by the IRB/council:

Issuing regular reports by the IRB/council	Frequency	Percentage
Yes	**38**	**56.7%**
No	**29**	**43.3%**
Total	**67**	**100%**

Table (21): Availability and type of archive system for the IRB/council report

Availability of archive system	Frequency	Percentage
Yes	**38**	**100%**
No	**0**	**0.0**
Total	**38**	**100%**

Type of archive system		
Hard recording system	**12**	**31.6%**
Electronic soft system	**10**	**26.3%**
Both	**16**	**42.1%**
Total	**38**	**100%**

Table (22): The submission of the reports to the concerned bodies

The submission of reports	Frequency	Percentage
Yes	**27**	**71.1**
No	**11**	**28.9**
Total	**38**	**100**
The concerned bodies receiving the reports		
The national research ethics committee	**2**	**7**
The Federal Ministry of Health	**8**	**30**
Others	**17**	**63**
Total	**27**	**100**

Table (23): The incorporation of the research methodology within the institutional curricula

The incorporation of research methodology within the institutional curricula	Frequency	Percentage
Yes	**48**	**73.8%**
No	**17**	**26.2%**
Total	**65**	**100%**

Table (24): Availability of institutional research methodology curriculum document

Availability of curriculum document	Frequency	Percentage
Yes	**36**	**75%**

No	**12**	**25%**
Total	**48**	**100%**

Table (25): The allotted time (hours) of the institutional research methodology curriculum

The allotted time (hours)	Frequency	Percentage
1 – 19 hrs	**28**	**58.3%**
20 – 29 hrs	**2**	**4.1%**
30 – 39 hrs	**6**	**12.6%**
40 + hrs	**8**	**16.7%**
No response	**4**	**8.3%**
Total	**48**	**100%**

Table (26): The inclusion of research ethics within the institutional research methodology curricula

The inclusion of research ethics	Frequency	Percentage
Yes	**36**	**75%**
No	**12**	**25%**
Total	**48**	**100%**

Table (27): The allotted time (hours) for the research ethics within the institutional research methodology curriculum

The allotted time (hours)	Frequency	Percentage
1 – 19 hrs	**24**	**66.6%**
20 – 29 hrs	**2**	**5.6%**
30 – 39 hrs	**1**	**2.8%**
40 + hrs	**3**	**8.3%**
No response	**6**	**16.7%**
Total	**36**	**100**

Table (28): Availability of institutional *research ethics* curriculum document

Availability of institutional research ethics curriculum document	Frequency	Percentage
Yes	**25**	**69.4%**
No	**11**	**30.6%**
Total	**36**	**100%**

Table (29): The component contents of the research ethics curriculum

Component	Yes	%	No	%	Total	%
Introduction to research ethics	**25**	**69.4**	**11**	**30.6**	**36**	**100**
Principles of ethical review of the research proposal	**15**	**41.6**	**21**	**58.4**	**36**	**100**
Human rights and rights of the vulnerable groups	**17**	**47.2**	**19**	**52.8**	**36**	**100**
Others	**3**	**8.3**	**33**	**96.7**	**36**	**100**

Table (30): Availability of references for research ethics at the institutional level

Availability of references	Frequency	Percentage
Yes	**16**	**44.4%**
No	**20**	**55.6%**

Total	**36**	**100%**

Table (31): Types of references for research ethics at the institutional level

Types of references	Yes	%	No	%	Total	%
Textbooks	**11**	**68.8**	**5**	**31.2**	**16**	**100**
References	**5**	**31.2**	**11**	**68.8**	**16**	**100**
Encyclopedias	**3**	**18.8**	**13**	**81.2**	**16**	**100**
Video tapes	**2**	**12.5**	**14**	**87.5**	**16**	**100**
CDs	**5**	**31.2**	**11**	**68.8**	**16**	**100**
Internet (websites)	**9**	**56.3**	**7**	**43.7**	**16**	**100**

Table (32): inclusion of the research ethics within the students' research assessment

Research Ethics Assessment for under-graduate students	Frequency	Percentage
Yes	**19**	**52.8%**
No	**17**	**47.2%**
Total	**36**	**100%**
Research Ethics Assessment for post-graduate students		
Yes	**14**	**39%**
No	**22**	**61%**
Total	**36**	**100%**

Table No. (33): Conduct of research by university students as graduation requirements

Conduct of research by university students as graduation requirements	Freq	**%**
Yes	**42**	**87.5**

No	**6**	**12.5**
Total	**48**	**100**

Table No. (34): University student's research approval method

Approval method	Frequency	Percentage
Accredited committee	**26**	**61.9%**
Supervisor	**15**	**35.7%**
Both	**1**	**2.4%**
Total	**42**	**100%**

Table No. (35): Conduct of research by post graduate students as graduation requirements

Conduction of researches by post graduate students as graduation requirements	Frequency	**%**
Yes	**31**	**64.6%**
No	**17**	**35.4%**
Total	**48**	**100%**

Table No. (36): Post graduate student's research approval method

Approval methods	Frequency	Percentage
Accredited committee	**25**	**80.6%**
Supervisor	**6**	**19.4%**
Total	**31**	**100%**

RESULTS OF THE FOCUS GROUP DISCUSSIONS:

1. **The knowledge about research ethics and recognition of the importance of health research ethics.**

- Most of the participants mentioned that the health research ethics, and according to their reasoning, it means;
- Respect for humanitarian respondent
  - It is the guidelines for keeping human rights
  - The consent of the respondent to give the data
  - Preserve the secrets of the patient (confidentiality)
  - It is regulations, principles, rules and values.
- Minority of the participants mentioned that their knowledge about research ethics is not based on scientific bases because there are no enough prints or training courses in this area.
- The importance of health research ethics:
- The participants agreed on the importance of health research ethics because it:
  - Make the researcher committed to legal controls
  - Limit the errors in human rights as a result of research conduct.

2. **Recognition of the international and national codes on research ethics involving human subjects and research ethics within the human rights context.**

- The majority of the participants stated that they did not know about the international and the national codes on research ethics involving human subjects.
- They also mentioned that there is no local or national low except the recent ministerial decree; which is not a code, and it is issuing the development of research committees.
- Minority of the participants mentioned that they are aware of the international codes because they have received training courses outside Sudan in countries like Malaysia and England.

3. **Sources of knowledge about the health research ethics. Availability and accessibility to**

sources of health research ethics.

- Most of the participants stated that there are no available sources of knowledge about health research ethics, and they don't know where these sources in Sudan are.
- Minority of them mentioned that, even the sources of knowledge they knew are the outcome of individual efforts or they acquired it from external courses. According to them to these sources are;
    - Periodic
    - The internet
- Some of them mentioned the post graduate and higher studies programs as a source of knowledge about health research ethics, (research methodology). In addition to some references like, how to conduct ethical research and the research methodology manual (Federal Ministry of Health Manual).

4. Status of training of the researchers on research ethics. Training availability and training needs assessment.

- All of the participants agreed upon that the training of the researchers on research ethics is just provided by the Federal Ministry of Health, although this training is weak and the opportunities are available for all researchers. They also elaborated on the curriculum of ethics within the post graduate program in the universities is a summery like.
- The importance of the training of the researchers on the research ethics:
- The participants, all of them; stressed on the importance and urgent need of the training of researchers on research ethics due to the following reasons;
    - Assuring the researchers rights
    - Grantee the participants rights
    - Prevent the harm that might happen as a result of the research
    - Commitment to legal controls that keep the human right

5. Types and number of research conducted in the last three years, The degree of involvement of human subjects in the research,

- Most of the participants stated that the researches' conducted in the last three years are involving human subjects, and they varied in number from one to two research at the personal level and from 6-21 research at the level of the universities and research institutes.
- Types of researches involving human subjects:
    - Prevention of Schistosomiasis at White Nile State
    - The indicators of bilharsiasis Infection at White Nile State
    - Psychometrics and trends in psychological orientation
    - Psychological diseases that afflict the White Nile citizens
    - Nursing care for the unconscious patient at River Nile State
    - Risk factors of hypertension at River Nile state
    - Prevalence of sexually transmitted diseases at River Nile State
    - Nursing Care of coronary heart Diseases at River Nile State
    - Prevalence of Malaria at River Nile State
    - Biochemical aspects of under six years malnourished Sudanese children at River Nile State
    - Reservoir of Leishmaniasis at Gedarif State
    - Clinical trial at visceral Leishmaniasis patients at Gedarif State
    - Breast Cancer at Gedarif state
    - Burden of Brucella at Gedarif State
    - Economic and social constrains that prevent the utilization of Mosquito nets at Gedarif State
    - Incidence of recurrent transient laryngeal injury at Gedarif state
    - Carcinoma of The esophagus at Gedarif state
    - Impact of pesticides in maternal milk at Gezira State
    - Prevalence of hepatitis(B) among students of health sector at Gezira State
    - Genetic factors and Susceptibility to cancer at Gazera state
    - Genetics and sexually transmitted diseases at Gazera State
- Types of other researches:
    - Impact of pesticides in vegetables and tomato at Gezira State
    - Chemical control of medical insects at Gezira State
    - Biological control of medical insects at Gezira State
    - Physical control of medical insects at Gezira State

6. Ever thought of ethical principles (to be mentioned) during the proposal development

- Nearly all of the participants mentioned that the research at the level of the proposal is not containing any ethical considerations, and they are believing that the ethical considerations is an afterward step that starts with the conduct of the research.
- Note :(some of them conducted research early before the development of the National Ethical Committee).
- The minority of the participants declared that there are certain research panels or committees that are putting the ethical considerations as a requirement of proposal submission particularity for the clinical trials and the laboratory research.

7. The review process of the proposal and by whom, and their opinion in the IRBs.

- All of the participants granted that the research proposals are subjected to ethical review, and the review is carried out by;
    - The research supervisor
    - The university board
    - Ministry of Health
- They also declared that there is no research review committees at the states and for the available committees are newly developed without plans, regulations or guidelines. There is also no certain time for these committees to review the proposals but it is dependent on the supervisor of the university board meeting. In addition to the fact that the currently the ethical clearance is obtained from National Research Ethical Committee.

8. To what extent is the application of the principles of ethics in health research in the conduction of your research

- The greater part of the participants affirmed that there is just ethical consideration because they are not acquainted with the principles of health research ethics, these ethical considerations are represented in the following;
    - Consent of the study participant
    - The approval of the accountable persons and the community leaders at the study areas.
    - Considering the confidentiality when collecting data.

- Minority of them attributed not applying the ethical principles on their researches to it is part as an obstacle to conduct researches. They also stated that there is an appalling number of researches that are lacking the credibility and not taking into consideration the simplest human rights due to the broaden spread of illiteracy in Sudan, and the best example for that is that there is a certain species of flies unobtainable unless through human beings, so there is a great need to humans volunteers Should be subjected for this species to facilitate the process Putting their lives at risk.

9. Knowledge about and use of informed consent and its importance

- Greater part of the participants mentioned that the informed consent implies the respondent approval to conduct research and the signing of that. Then they added that there is no obligation to admit using the informed consent and there is no adoption of a unified informed consent and it differs from person to the other.
- Few of the participants believed that there is no necessitate for the informed consent because most of the studies in Sudan are non invasive or based on recalling or secondary data.

The in-depth interviews results:

1. Knowledge of participants about the Researches conducted at the states and involving human subjects:

- The majority of the participants stated the following about their knowledge of the researches conducted at their states and involving human subjects;
    - They don't have any knowledge about the conducted researches in the health sector or health related sector.
    - There is no coordination or linkage between research bodies and statutory boards.
    - In the composition of the Council; There are no paragraph or law in the special issues of Scientific Research
- While the minority of them alleges that they are recognizing some of the researches for the reason that the body conducting the research needs some information about the research for instance the researches done at Gedarif State about Visceral Leishmaniasis and the nutrition survey.

2. The role of the Legislative Council in research and studies conducted in the states:

- The bulk of the participants declared that;
    - There is no specific role for the legislative council
    - There is no clear plan that defines the role of the Legislative Council
    - There is no law or legislation to pursue research that are conducted at the states
    - Regarding the researches or studies done on the state level, they are not receiving any feed back or copy of the results of those studies.
    - All agreements on health research, whether that was on the level of the organizations or others are made by the State Ministries of Health
    - Sometimes, not often, the role of the Legislative Council and humanitarian aid is a coordination role only to agree on the task of entering the community
- The minority stated that the Regulatory role of the Legislative Council take into account the security aspects Especially in the case of foreign research organizations.

3. The Knowledge of any universal or national or local laws governing research conducted in

the states.

- For the most part there is no knowledge of any laws governing the health research
- Marginal part declared that there are security laws which require that research is outside the scope of politics and ethnicity and military issues

4. The Knowledge of the basic principles of ethics when conducting research on human

- Consensus on that there is knowledge of the basic principles of ethics.

5. Knowledge, whether there is ethical committees or coordination bodies to review the research proposals

- They agreed on that there is lack of knowledge of any of the committees to review proposals or any representation in the committees of the legislative council members.

6. Role of the participants in the consolidation of the work of the research committees to review the ethical aspects of research on human subjects

- They granted that there is no role because there is no knowledge or relationship with the competent committees of research

5. Discussion

As shown in table (1): About 40% of the sampled institutes are medical and health colleges while about 24% of them are research centers and institutes. For these two categories of the sampled institutes' conduct of research involving human subjects is mandatory. This is indicated in table (2) as 70% of the sampled institutes confirmed the availability of institutional policy directed towards health research. About 50% of those institutions have their own institutional policies directed towards health research as can be seen in table (3) while for 82% of them; research ethics were included within their policies as shown in table (4). However about 67% of the sampled institutions have institutional plans supportive for the health research while for 84% of them, research ethics were included within the institutional plans as shown in tables (5) and (6). This is indicative of the institutional tendency to include research ethics pending that they develop policies/plans directed towards health research. The implemented institutional activities relevant to research ethics in 60% of the institutions that included research ethics within their policies/ plans are confined to training and establishment of the research ethics committees (table 7). Other research ethics activities such advocacy and development of guidelines are poorly addressed at the institutional level. This can be explained by the fact that the research ethics

culture is recently introduced in most of the sampled institutes and still extra efforts are needed.

Referring to table (8): 75% of the sampled institutions stated that they have research units/committees. This is expected as most of the sampled institutions are of academic nature and part of their mission is conduct of research. However in Sudan the Federal Ministry of health had well established a research unit since 1996 which is considered as one of the leading institutes in capacity building of research methodology and research ethics across the country.

As shown in table (9): 44.7 of the sampled institutes had trained cadres on research ethics which is indicative for the marked shortage of trained human resources on research ethics at the institutional level. About 89% of those institutes with trained cadres on research ethics had less than 10 trained staff (table 10). For 39% of the institutes with trained cadres, the type of training on research ethics showed to be short course of 1-2 weeks while about 32% of them had cadres subjected to orientation course less than a week. 17% of the institutes had their cadres subjected to training for more than two weeks and about 6% of them had trained cadres subjected to advanced training (table 11). As shown in table (12): the reasons for non-availability of trained cadres on research ethics are attributed to scarce human and financial resources at the institutional level for about 38%, about 15% of them did not mention any reason while about 45% of the sampled institutes mentioned other causes such as poor concern and lack of knowledge about the importance of training on research ethics.

The results of the focus group discussions showed that the knowledge of the participants are confined to basic knowledge about research ethics i.e. definition while the majority of them attitudinize the importance of research ethics. However the majority of the participants do not know much about the national and international codes of research ethics involving human subjects. Nearly all of the participants in the focus group discussions mentioned that the research at the level of the proposal is not containing any ethical considerations, and they are believing that the ethical considerations is an afterward step that starts with the conduct of the research. In addition the vast majority of the participants mentioned that the informed consent implies the respondent approval to conduct research and the signing of that. Then

they added that there is no obligation to admit using the informed consent and there is no adoption of a unified informed consent and it differs from person to the other. These findings indicate the marked gaps in the knowledge and skills of research ethics at the institutional level. This can be attributed to the short duration of the training courses and the limited exposure during such courses to the bulk of knowledge and information relevant to research ethics. EC members have a need for initial and continued education regarding the ethics and science of biomedical research. The conditions of appointment should state the provisions available for EC members to receive introductory training in the work of an EC as well as ongoing opportunities for enhancing their capacity for ethical review. These conditions should also include the requirements or expectations regarding the initial and continuing education of EC members. This education may be linked to co-operative arrangements with other ECs in the area, the country, and the region, as well as other opportunities for the initial and continued training of EC members (2).

The interviews with the members of the legislative council, representatives National Union of Youth, representatives Local committees, representatives of Humanitarian Aid showed that mostly they don't have any knowledge about the conducted researches in the health sector or health related sector. As well there is no coordination or linkage between research bodies and statutory boards. In addition all the interviewed individuals stated that they are not aware of the research ethics, the international codes on research ethics and the role of the IRBs at the state level. These findings indicate that the established IRBs especially at the state level are inadequately functioning to advocate for the research ethics outside the institutes.

Most of the participants in the focus group discussions stated that there are no available sources of knowledge about health research ethics, and they don't know where these sources in Sudan are to be accessed. Minority of the participants mentioned the periodicals and the internet as the main sources of knowledge about research ethics. Such sources are used as individual channels to access the information about research ethics with limited or scarce institutional sources of knowledge. Some of the participants mentioned the post graduate and higher studies programs as a source of knowledge about health research ethics, (research methodology). This reflects that the research ethics especially in the academic institutes are not well streamlined as training programs but rather the research ethics

are included within the elements of the other training programs such as research methodology. The Federal Ministry of Health, Directorate of Research was identified by all the participants in the focus group discussions as the main provider for training on research ethics. In conclusion, the institutional capacity on research ethics is limited and the need to be strengthened with emphasis on expansion of the duration and improving the quality of the training courses to ensure adequate institutional performance.

Referring to table (13); the institutional review boards are established in 65% of the sampled institutes while about 35% of them have not yet established such boards. This is lesser than the number of the institutes with established research committee/unit (table 8). This can be explained by the fact that most of the sampled institutes are academic with established research committees and still do not yet establish their IRBs to address the research ethics issues. However it is questionable in such situations, if research ethics will ever be adequately addressed within the research committees activities or not.

The type of the review usually practiced by 80% of the sampled institutes with established IRB is technical and ethical review, technical review for about 16% and ethical review for about 3% (table 14). Despite the vast majority of the IRBs in the sampled institutes used to practice technical and ethical review but the extent and quality of the practiced ethical review are questionable with marked limited institutional capacity on research ethics. The vast majority of the participants in the focus group discussions affirmed that there are ethical considerations to be addressed and included in the research proposals. In reality these considerations do not tally fairly with the universally accepted principles of health research ethics. The participants identified the ethical considerations as follows:

- Consent of the study participant
- The approval of the accountable persons and the community leaders at the study areas.
- Considering the confidentiality when collecting data.

About 48% of the institutes with established IRBs have their own institutional guidelines available while about 33% of them have the national guidelines available

to be used by the IRBs (table 15). The usage of both national and institutional guidelines for review purposes is practiced by the vast majority of the institutes which owned such guidelines as shown in table (16).

Table (17) showed that about 79% of the IRBs used to hold regular meetings for review of the submitted proposals while about 14% of them do not meet regularly. However on questioning about the periodicity of the meetings, about 21% of them meet monthly, 34% of them meet quarterly while about 38% of them meet ad hoc or occasionally. It seems that this is related to the workload and the number of the submitted proposals for ethical review. The meetings are quorum for about 71% of the IRBs.

Referring to table (18): The number of the submitted research proposals for review per year was less than 10 for 30% of the IRBs, 10-30 for about 25% while the number for 21% of them is more than 50 proposals. The results of the focus group discussion emphasized the result as most of the participants stated that the researches' conducted in the last three years are researches with involvement of human subjects, and they varied in number from one to two research at the personal level and from 6-21 research at the institutional level. This indicates the limited number of the submitted proposals for review by the sampled IRBs. Moodley and Mayer in their study in South Africa found the median estimated number of protocols reviewed during 2002 was 135, with a range from 30 to 360 (the total number of protocols reviewed during 2002 by the 12 committees was estimated at over 1600 (6).
Nevertheless some variations in the workload between the sampled IRBs cannot be denied. However other causes such as the tendency of some investigators to bypass the IRBs may be contributing to the result. For 19% of the IRBs it is not possible to identify the number of the submitted proposals for review per year. The participants in the focus group discussion identified numerous research conducted at the institutional or personal levels such as epidemiological studies on communicable diseases, epidemiology of non-communicable diseases, biochemical and genetics studies and others. Most of the conducted research are categorized as research involving human subjects and need to be reviewed ethically.

The number of the rejected proposals per year for about 51% of the IRBs was none and 5 for about 3%. While for about 19% of the IRB it is not possible to identify the

number of the rejected proposals per year. Almost similar results were obtained by Moodley and Mayer in their study in South Africa that Six RECs had data for the number of protocols rejected during 2002. The rejection percentage for these six committees ranged from 0% to 10% with a mean of 4, 52% (6).
In table (19): the reasons of submission of proposals are summarized as follows: the response of about 35% of the sampled institutes identified publications of the research findings and about 30% identified the facilitation of data collection process from the health facilities.

About 57% of the IRBs are issuing regular reports and they have archive system for the reports while about 43% of them are not issuing regular reports and they do not have archive system. About 42% of the IRBs that have archive systems use both hard recoding and electronic soft system (tables 20, 21). The results reflect the lack of standard reporting and archiving systems by most of the IRBs. As shown in table (22): about 71% of the IRBs used to submit reports to the concerned bodies while about 29% of them used not to submit such reports. Various concerned bodies are identified for receiving the IRBs depending on the nature of the institute. The national health research ethics committee and the Federal Ministry of Health are identified by 37% of the IRBs as the concerned body for receiving the IRBs reports. This is mostly the case within the health services sector to which the institutes such as hospitals and state ministries of health are affiliated to the Federal Ministry of Health. The IRBs within the academic institutes/universities identified other concerned bodies to which they are affiliated such as the institutional research committees and similar boards.

About 74% of the sampled institutes stated that they have incorporated research methodology within their curricula while about 26% of them have not yet incorporated such contents within their curricula (table 23). For those institutes which incorporated research methodology within their curricula about 74% have had research methodology curriculum documents while about 27% of them do not have such documents (table 24). Such documents are of importance to inform the staff and the students about the curricular contents including the research ethics. The allotted time (working hours) for the institutional research methodology curriculum as shown in table (25) is 1-19 hours for about 58% of the institutes, more than 40 hours for about 17% and 30-39 hours for 13% of them. This is indicative that more than 50% of the sampled institutes have allotted limited working hours for the research

methodology contents. Table (27) showed that the allotted time for the research ethics within the institutional research methodology is 1-19 hours for about 67% of the sampled institutes which is higher than the proportion of the sampled institutes that allotted 1-19 hours for the research methodology curriculum. This is due to the fact that some institutes even they allotted extra time for the research methodology but still the allotted time is limited for the incorporated research ethics within the institutional curricula.

Referring to table (26): about 75% of the institutes have included research ethics within the research methodology curriculum while 25% them do include such contents. For about 70% of the institutes have research ethics curricular documents while about 30% do not have such documents as shown in table (28). This is attributed to the fact that some institutes have incorporated research ethics within the research methodology curricula but without documentation.
The components of the research ethics curricula as shown in table (29): introduction to research ethics is identified by 69% of the sampled institutes. Other curricular components such as review process of the research proposal are identified by some institutes. It is clear that the curricula in the sampled academic institutes are confined to basic knowledge of the research ethics.
The availability of references for research ethics at the institutional level has been identified by 44% of the sampled academic institutions (table 30). The availability of references on research ethics for both investigators and the IRB members cannot be overlooked.
The types of references identified at the institutional level are textbooks (69%) and the internet websites (56%). Other types of references are identified by lesser number of the sampled institutes (table 31).
The research ethics are included within the under-graduate students research assessment by about 53% institutes while about 39% of the institutes include research ethics within post-graduate students assessment (table 32). The result may be related to the fact that not all the sampled institutes have established post-graduate studies. In addition some of the sampled institutes are service provision centers or research centers which conduct operational research without awarding academic degrees.

As shown in table (33): 87% of the sampled institutes stated that the students should conduct research as graduation requirement. This is expected as most of the medical and health sciences schools nowadays address the research competency as one of the major competencies to be grasped by the students before graduation. The approval method of the under-graduate students' research for about 62% of the sampled institutes is carried out through an accredited committee and for about 36% of them is the supervisor (table 34). It is questionable if the approval method could ever be left for the supervisors' discretion.

As shown in table (35); 64% of the sampled institutes stated that the students should conduct research a graduation requirement which is lower than the proportion of the institutes that require the under-graduate students to conduct the research as a requirement for graduation (80%) . This may be due to the fact that some institutes organize post-graduate degrees of short duration such as diplomas which usually do not require that the students should conduct research to be awarded the degrees. The approval method of the post-graduate students' research for about 81% of the sampled institutes is carried out through an accredited committee and for about 19% of them is the supervisor (table 36). This is indicative that the approval method for the post-graduate research in most of the sampled institutes is more structured in comparison to the approval method for the under-graduate research.

6. Conclusions

- The implemented institutional activities relevant to research ethics in 60% of the institutions that included research ethics within their policies/ plans are confined to training and establishment of the research ethics committees.
- 44.7 of the sampled institutes had trained cadres on research ethics which is indicative for the marked shortage of trained human resources on research ethics at the institutional level.
- For 39% of the institutes with trained cadres, the type of training on research ethics showed to be short course of 1-2 weeks while about 32% of them had cadres subjected to orientation course less than a week.
- The results of the focus group discussions showed that the knowledge of the participants are confined to basic knowledge about research ethics i.e. definition while the majority of them attitudinize the importance of research ethics. However the majority of the participants do not know much about the national and international codes of research ethics involving human subjects.
- The interviews with the members of the legislative council, representatives National Union of Youth, representatives Local committees, representatives of Humanitarian Aid showed that mostly they don't have any knowledge about the conducted researches in the health sector or health related sector.
- Most of the participants stated that there are no available sources of knowledge about health research ethics, and they don't know where these sources in Sudan are to be accessed.
- The research ethics especially in the sampled academic institutes are not well streamlined as training programs but rather the research ethics are included within the elements of the other training programs such as research methodology.

- The institutional review boards are established in 65% of the sampled institutes while about 35% of them have not yet established such boards.
- About 48% of the institutes with established IRBs have their own institutional guidelines available while about 33% of them have the national guidelines available to be used by the IRBs
- The vast majority of the participants in the focus group discussions affirmed that there are ethical considerations to be addressed and included in the research proposals. In reality these considerations do not tally fairly with the universally accepted principles of health research ethics.
- Despite the vast majority of the IRBs in the sampled institutes used to practice technical and ethical review but the extent and quality of the practiced ethical review are questionable with marked institutional capacity on research ethics.
- Most of the IRBs are lacking appropriately functioning standard reporting and archive systems.
- Most of the conducted research are categorized as research involving human subjects and need to be reviewed ethically
- The reasons of submission of proposals are summarized as follows: the response of about 35% of the sampled institutes identified publications of the research findings and about 30% identified the facilitation of data collection process from the health facilities
- About 74% of the sampled institutes stated that they have incorporated research methodology within their curricula while about 26% of them have not yet incorporated such contents within their curricula
- 50% of the sampled institutes have allotted limited working hours for the research methodology contents
- Some institutes even they allotted extra time for the research methodology but still the allotted time is limited for the incorporated research ethics within the institutional curricula.
- 75% of the institutes have included research ethics within the research methodology curriculum while 25% of them don’t include such contents
- 70% of the institutes have research ethics curricular documents while about 30% don’t have such documents

- The availability of references for research ethics at the institutional level has been identified by 44% of the sampled academic institutions
- 87% of the sampled institutes stated that the students should conduct research as graduation requirement

7. Recommendations

1. Finalization and dissemination of the national policy document on health research ethics is strongly recommended to strengthen political commitment.

2. Capacity building of the human resources at the institutional level is needed through formulation of comprehensive strategic plan in order to combat the marked shortage and to improve the institutional performance on research ethics.

3. Scaling up of the quality of training on research ethics through establishment of effective partnerships and collaboration with national, regional and international institutes with expertise on training on research ethics.

4. Formulation and operationalization of the national standard packages of training by the Federal Ministry of Health and other academic institutes in order to improve the quality of the provided training

5. Activation of the IRBs functioning to provide advocacy for research ethics among the community members and the laymen with inclusion of community members and laymen within the membership of the IRBs

6. Streamlining of IRB structure within the academic institutes in order to ensure its dependency from other academic bodies such as the research boards.

7. Establishment of IRBs in institutes currently without such boards especially at the state level.

8. Upgrading of the review process by the IRBs through establishment and dissemination of the national guidelines and the standard operational procedures with continuous training of the IRBs members.

9. Strengthening of the recording, reporting and archive systems of the IRBs to ensure appropriate documentation and exchange of information.

10. Organization of quality training on research ethics targeting the researchers and the investigators to improve their knowledge and skills in ethical conduct of research.

11. Strengthening of the curricula of research ethics with allotting extra working hours to improve the competency of both the under-graduate and post-graduate students on research ethics.

12. Increase availability of learning resources, training materials and references and journals on research ethics at the institutional level.

13. Establishment of the Sudanese Network on Research Ethics including all the partners and the academic institutes to strengthen the ethical standards and practices across the country.

8. References

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List of Annex

5 Total number and the estimated sample size of the *medical*, public health, medical laboratories and nursing schools and others

Annex (1) *A standardized administered questionnaire for the state ministries of health, hospitals and national centers*

جمهورية السودان

وزارة الصحة القومية

دراسة لتقييم أخلاقيات البحوث الصحية بالسودان

2009

الإدارة العامة للتخطيط والسياسات والبحوث

إدارة اقتصاديات الصحة والبحوث والمعلومات

قسم البحوث الصحية

استبيان وزارة الصحة و المستشفيات والمراكز القومية

إستمارة موافقة الشخص المشارك في بدراسة لتقييم اخلاقيات البحوث الصحية بالسودان

نحن باحثين من وزارة الصحة القومية بالتعاون مع منظمة الصحة العالمية، نقوم بدراسة لتقييم اخلاقيات البحوث الصحية بالسودان، تهدف هذه الدراسة الى معرفة وتحديد وضع اخلاقيات البحوث الصحية على المستوى القومي و الولائي في وزارات الصحة، الجامعات والكليات الصحية والمعاهد البحثية و المجتمع لتقييم مناهج أخلاقيات البحوث ووعي المجتمعات نحو اخلاقيات البحوث الصحية. نتائج هذه الدراسة ستساعد وزارة الصحة لوضع نظام محدد يضمن سلامةالمشاركين في البحوث وتعزيز ونشر ثقافة اخلاقيات البحوث الصحية .

لقد تم إختيارك لتشارك في هذا البحث ومعك عدد آخر من المشاركين ضمن عينة عشوائية يبلغ حجمها 118 متمثلة في المستشفيات والمراكز القومية الكليات و المعاهد الصحية من الولايات المختلفة في السودان بالاضافة الى وزارات الصحة و البرلمانيين و الاكاديميين و الباحثين في هذه الولايات.

نتوقع بمشاركتك أنت والمشاركين الآخرين أن نتحصل على نتائج تفيد وزارة الصحة لوضع نظام محدد يضمن سلامة المشاركين في البحوث وتعزيز ونشر ثقافة اخلاقيات البحوث الصحية .

خلال هذه الدراسة سأقوم بأخذ معلومات منك في شكل أسئلة (استمارة) او من خلال مجموعة نقاش بؤرية مع مشاركين اخرين ، ونحن إذ نأمل فى مشاركتك معنا فى هذا البحث ، نؤكد لك على سرية المعلومات و الوثائق الخاصة بك والتي ستحفظ بطريقة مشفرة وسرية ،ولن يظهر إسمك فى أى إستمارة ، و أنه لن يطلع عليها إلا الفريق المختص بالمسح ، و سوف تستخدم لأغراض الدراسة فقط ، ستكون مدة المقابلة حوالي(40) دقيقة و لديك الحق بعدم الاجابة على اي سؤال لا تود الاجابة عليه ولك الحق في الانسحاب من المقابلة في اي وقت تشاء؛علما بان قرارك بعدم المشاركة او الانسحاب لن يؤثر عليك سلبا.

إذا كان لديك أى سؤال أو إستفسار يخص البحث أو حقوقك كمشارك أثناء تنفيذ البحث يمكنك الإتصال على(0157845773) لجنة اخلاقيات البحوث الصحية وزارة الصحة القومية.

إقرار موافقة المشارك في البحث

إقرار المشارك :

لقد إطلعت على المعلومات الحالية والتي تم شرحها لي وأتيح لى طرح الأسئلة عنها كيفما شئت ، و قد تلقيت الإجابات الوافية عن كل الأسئلة ، و أنا أقر بالموافقة على المشاركة طواعية فى هذه الدراسة .

إسم المشارك : ..... توقيع المشارك :

.....

اسم الباحث : ..... توقيع الباحث :

.....

الرقم المتسلسل للاستمارة.....(يملأ عند الادخال)

استمارة (أ): استبيان تقييم أخلاقيات البحوث الصحية في السودان

هذا الاستبيان يملأ في وزارة الصحة و المستشفيات والمراكز القومية مع المدير العام بوزارة الصحة الصحية و مدراء المستشفيات والمراكز القومية:

1. **التاريخ: ..... 2. الولاية:**

.....

3. **الجهة/ المؤسسة : ..... 4. القسم:**

.....

5. **وظيفة مصدر البيانات:..... 6. اسم الباحث:.....**

1. **الالتزام وبيئة البحوث:**

1. **هل يوجد لديكم سياسات واضحة توجه البحوث الصحية؟ (اطلع على نسخة) إذا كانت الاجابة لا انتقل الى السؤال (4)** ☐

   1/ نعم 2/ لا

2. **اذا كانت الاجابة نعم، هل هي ؟**

   1. **السياسات القومية** ☐
   2. **سياسات خاصة بالمؤسسة**

3. **اذكر هذه السياسات؟ (اذكر الخيارات و تحتمل الاجابة اكثر من خيار)**

   1. **سياسة للبحوث لا تتضمن اخلاقيات البحوث** ☐
   2. **سياسة البحوث التي تشتمل على الاخلاقيات** ☐
   3. **سياسة او دلائل موجهه فقط لاخلاقيات البحوث** ☐
   4. **التشريعات والقوانين العامة الداعمة لأخلاقيات البحوث** ☐
   5. **اخرى (حدد).....** ☐

4. **هل توجد خطة تدعم البحوث الصحية؟اذا كانت الاجابة لا، انتقل الى السؤال (7)** ☐

   1/ نعم 2/ لا

5. **اذا كانت الاجابة نعم، هل تتضمن هذه الخطة جزء خاص باخلاقيات البحوث الصحية؟ اذا كانت الاجابة لا، انتقل الى السؤال (7)** ☐

   1/ نعم 2/ لا

6. **اذا كانت الاجابة نعم، ماهي نشاطات اخلاقيات البحوث الصحية الاساسية في الخطة؟ (لا تذكر الخيارات وتحتمل الاجابة اكثر من خيار)**

   1. **تدريب** ☐
   2. **استقطاب الدعم والتاييد** ☐
   3. **عمل دلائل وارشادات للاخلاقيات** ☐

4. تكويبن لجان اخلاقيات بحوث صحية

5. اخرى حدد.....

7. هل يوجد لديكم قسم بحوث او لجنة بحوث في وزارة الصحة المستشفى او المركز القومي؟ إذا كانت الاجابة لا انتقل الى السؤال (10)

1/ نعم 2/ لا

8. اذا كانت الاجابة نعم، حدد موقع قسم البحوث أو اللجنة بالنسبة للهيكل العام للوزارة المستشفى او المركز القومي؟

.....

.....

.....

9. اذكر عدد ومؤهل الكادر العامل بالقسم

مؤهل الكادر	عدد الكادر	
	ذكر	انثى

10. هل يوجد كادر مدرب على اخلاقيات البحوث الصحية؟ إذا كانت الاجابة لا انتقل الى السؤال (13)

1/ نعم 2/ لا

11. اذا كانت الاجابة نعم، اذكر عددهم

12. اذا كان يوجد كادر مدرب على اخلاقيات البحوث بالقسم او اللجنة ، حدد مستوى التدريب؟

1. كورس تنويري اقل من اسبوع
2. تدريب 1-2 اسبوع
3. تدريب اكثر من اسبوعين(غير دبلوم /ماجستير)
4. تدريب متقدم (دبلوم / ماجستير)

5. اخرى (حدد)

13. اذا كان لايوجد كادر مدرب على اخلاقيات البحوث بالقسم او اللجنة حدد السبب؟

1. لا يوجد مصادر مالية للتدريب
2. لا توجد كفاءت مناسبة لتدريب الكادر
3. اخرى (حدد).....

2. **الدلائل والمعايير المتبعة لمراجعة مقترحات البحوث الصحية:**

14. هل يوجد مجلس او لجنة مسئولة عن مراجعة مقترحات البحوث الصحية؟اذا كانت الاجابة نعم انتقل الى السؤال رقم 16

1/ نعم 2/ لا

15. اذا كانت الاجابة لا ، وضح لماذا؟

1/..... 2/ .....

3/..... 4/ .....

16. اذا كانت الاجابة نعم، كيف انشأت هذه اللجنة او المجلس؟

1. بناء على مرسوم وزاري او من سلطة عليا
2. بناء على منشور او قرار اداري
3. سياسة ومتطلبات الكلية أو القسم
4. اخرى (حدد).....

17. عضوية اللجنة او المجلس:

ID	اسم العضو	الجنس: 1. ذكر 2.انثى	المؤهل	التخصص	مهام العضو في اللجنة: 1.رئيس 2.نائب 3.عضو 4. مقرر	نوع العضوية: 1. دائمة 2. غير دائمة

					5. سكرتير 6. اخرى	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

18. حدد نوع المراجعة التى تتم لمقترحات البحوث الصحية؟

1. **مراجعة فنية فقط**
2. **مراجعة أخلاقية فقط**
3. **مراجعة فنية وأخلاقية معا** ☐

19. اذكر الوسائل المتوفرة والمستعملة لمراجعة مقترحات البحوث و التجارب السريرية ؟

الرقم	الوسيلة	التواجد		التوفر		الاستعمال	
		1.نعم	2.لا	1.نعم =≤5	2.لا=5<	1.نعم	2.لا
1	قائمة مراجعة المقترحات المرجعية						
3	استمارات خاصة بتقديم المقترحات للجنة						
5	تقارير متابعة التجارب السريرية						
6	الدلائل والارشادات القومية						
7	دلائل ارشادية خاصة بكم						

20. هل تعقد اللجنة الاخلاقية للمؤسسة او المجلس اجتماعات دورية؟

1/ نعم 2/ لا

21. اذا كانت الاجابة نعم، حدد دورية اجتماع اللجنة او المجلس؟

1. **شهريا**
2. **ربع سنويا**
3. **نصف سنويا**
4. **عند اللزوم/ اذا طرات الحاجة**

22. هل يوجد نصاب محدد للجنة او المجلس؟

1/ نعم 2/ لا

23. كم عدد المقترحات التي تقدم سنويا للمراجعة في اللجنة اوالمجلس بالتقريب ؟

24. كم عدد المقترحات التى تم رفضها من قبل اللجنة او المجلس؟

25. ماهي العوامل التى تدفع الباحثين الى تقديم مقترحات البحوث التى تختص بالانسان للمراجعة الاخلاقية؟ لا تذكر الخيارات (تقصي) يحتمل اكثر من اجابة

1. **التقديم الى الجهات الداعمة(منظمة الصحة العالمية وTDR)**
2. **لنشر نتائج البحث العلمي في المجلات الصحية العالمية**
3. **لتسهيل الية جمع البيانات في المؤسسات الصحية**
4. **اخرى حدد.....**
5. **كل الخيارات**

28. هل تصدر اللجنة الاخلاقية او المجلس تقارير دورية خاصة بعمل اللجنة او المجلس؟

1/نعم 2/ لا

29. اذا كانت الاجابة نعم، هل يوجد نظام لحفظ هذه التقارير؟اذا نعم، (اطلع)

1/نعم 2/ لا

30. اذا كانت الاجابة نعم، ماهو نظام حفظ هذه التقارير؟

1. نظام السجلات الورقية
2. النظام الاكتروني
3. النظامين معا

31. هل ترفع هذه التقاريرالى الجهات المختصة؟

1/نعم 2/ لا

32. اذا كانت الاجابة نعم، اذكر هذه الجهات ؟

1. لجنة اخلاقيات البحوث القومية
2. وزارة الصحة القومية
3. وزارة الصحة الولائية
4. اخرى .....

33. هل هناك ميزانية مخصصة لعمل اللجنة؟

1/نعم 2/ لا

34. اذا كانت الاجابة نعم، اذكر مصدر هذه الميزانية؟

1. وزارة الصحة القومية
2. وزارة الصحة الولائية
3. دعم خارجي
4. اخرى .....

3. توجهات مستقبلية:

35. اذكر الشركاء الحاليين والمتوقعين في مجال اخلاقيات البحوث الصحية، وحدد دورهم؟

الشركاء الحاليين	دور الشراكة	الشركاء المتوقعين	دور الشراكة

36. كيف تُقييم مدى رضاكم عن الية التنسيق مع الشركاء فيما يختص باخلاقيات البحوث الصحية؟

1.مرضي جدا 2. مرضي 3. غير مرض 4. لاينطبق ☐

37. كيف يمكن ان تشارك مؤسستكم بتعزيز اخلاقيات البحوث في مؤسستكم ؟

.....

.....

.....

.....

38. كيف يمكن ان تشارك مؤسستكم بتعزيز اخلاقيات البحوث السودان؟

.....

.....

.....

.....

وزارة الصحة القومية، قسم البحوث تشكركم على حسن تعاونكم

Annex (2): *A standardized administered questionnaires for health research institutes, medical, public health, medical laboratories and nursing schools within the targeted universities*.

جمهورية السودان

وزارة الصحة القومية

دراسة لتقييم أخلاقيات البحوث الصحية بالسودان

2009

الادارة العامة للتخطيط والسياسات والبحوث

ادارة اقتصاديات الصحة والبحوث والمعلومات

قسم البحوث الصحية

استبيان الكليات الصحية و المعاهد و المراكز البحثية

إستمارة موافقة الشخص المشارك في بدراسة لتقييم اخلاقيات البحوث الصحية بالسودان

نحن باحثين من وزارة الصحة القومية بالتعاون مع منظمة الصحة العالمية، نقوم بدراسة لتقييم اخلاقيات البحوث الصحية بالسودان ، تهدف هذه الدراسة الى معرفة وتحديد وضع اخلاقيات البحوث الصحية على المستوى القومي و الولائي في وزارات الصحة، الجامعات والكليات الصحية والمعاهد البحثية و المجتمع

لتقييم مناهج أخلاقيات البحوث ووعي المجتمعات نحو اخلاقيات البحوث الصحية. نتائج هذه الدراسة ستساعد وزارة الصحة لوضع نظام محدد يضمن سلامةالمشاركين في البحوث وتعزيز ونشر ثقافة اخلاقيات البحوث الصحية .

لقد تم إختيارك لتشارك في هذا البحث ومعك عدد آخر من المشاركين ضمن عينة عشوائية يبلغ حجمها 118 متمثلة في الكليات و المعاهد الصحية من الولايات المختلفة في السودان بالاضافة الى وزارات الصحة و المستشفيات والمراكز القومية البرلمانيين و الاكاديميين و الباحثين في هذه الولايات.

نتوقع بمشاركتك أنت والمشاركين الآخرين أن نتحصل على نتائج تفيد وزارة الصحة لوضع نظام محدد يضمن سلامة المشاركين في البحوث وتعزيز ونشر ثقافة اخلاقيات البحوث الصحية .

خلال هذه الدراسة سأقوم بأخذ معلومات منك في شكل أسئلة (استمارة) او من خلال مجموعة نقاش بؤرية مع مشاركين اخرين ، ونحن إذ نأمل فى مشاركتك معنا فى هذا البحث ، نؤكد لك على سرية المعلومات و الوثائق الخاصة بك والتي ستحفظ بطريقة مشفرة وسرية ،ولن يظهر إسمك فى أى إستمارة ، و أنه لن يطلع عليها إلا الفريق المختص بالمسح ، و سوف تستخدم لأغراض الدراسة فقط ، ستكون مدة المقابلة حوالي(40) دقيقة و لديك الحق بعدم الاجابة على اي سؤال لا تود الاجابة عليه ولك الحق في الانسحاب من المقابلة في اي وقت تشاء؛علما بان قرارك بعدم المشاركة او الانسحاب لن يؤثر عليك سلبا.

إذا كان لديك أى سؤال أو إستفسار يخص البحث أو حقوقك كمشارك أثناء تنفيذ البحث يمكنك الإتصال على(0157845773) لجنة اخلاقيات البحوث الصحية وزارة الصحة القومية.

في البحث إقرار موافقة المشارك

إقرار المشارك :

لقد إطلعت على المعلومات الحالية والتي تم شرحها لي وأتيح لى طرح الأسئلة عنها كيفما شئت ، و قد تلقيت الإجابات الوافية عن كل الأسئلة ، و أنا أقر بالموافقة على المشاركة طواعية فى هذه الدراسة .

إسم المشارك : ..... توقيع المشارك :.....

اسم الباحث : ..... توقيع الباحث : .....

الرقم المتسلسل للاستمارة.....(يملأ عند الادخال)

أستمارة (أ): استبيان تقييم أخلاقيات البحوث الصحية في السودان

هذا الاستبيان يملأ في الكليات الصحية و المعاهد و المراكز البحثية مع عمداء الكليات الصحية و رؤساء المراكز والمعهد البحثية

2. التاريخ: ..... 2. الولاية: .....

4. الجهة/ المؤسسة : ..... 4. القسم: .....

5. وظيفة مصدر البيانات:..... 6. اسم الباحث:.....

2. الالتزام وبيئة البحوث:

26. هل يوجد لديكم سياسات واضحة توجه البحوث الصحية؟ (اطلع على نسخة) إذا كانت الاجابة لا انتقل الى السؤال (4)

☐

1/ نعم 2/ لا

27. اذا كانت الاجابة نعم، هل هي ؟

3. السياسات القومية

☐

4. سياسات خاصة بالمؤسسة

28. اذكر هذه السياسات؟ (اذكر الخيارات و تحتمل الاجابة اكثر من خيار)

6. سياسة للبحوث لا تتضمن اخلاقيات البحوث ☐

7. سياسة البحوث التي تشتمل على الاخلاقيات ☐

8. سياسة او دلائل موجهه فقط لاخلاقيات البحوث ☐

9. التشريعات والقوانين العامة الداعمة لأخلاقيات البحوث ☐

10. اخرى (حدد).....

29. هل توجد خطة تدعم البحوث الصحية؟اذا كانت الاجابة لا، انتقل الى السؤال (7)

☐

1/ نعم 2/ لا

30. اذا كانت الاجابة نعم، هل تتضمن هذه الخطة جزء خاص باخلاقيات البحوث الصحية؟ اذا كانت الاجابة لا، انتقل الى السؤال (7) ☐

1/ نعم 2/ لا

31. اذا كانت الاجابة نعم، ماهي نشاطات اخلاقيات البحوث الصحية الاساسية في الخطة؟ (لا تذكر الخيارات وتحتمل الاجابة اكثر من خيار) ☐

6. تدريب ☐

7. استقطاب الدعم والتاييد ☐

8. عمل دلائل وارشادات للاخلاقيات ☐

9. تكويبن لجان اخلاقيات بحوث صحية ☐

10. اخرى حدد.....

32. هل يوجد لديكم قسم بحوث او لجنة بحوث في المعهد او المركز/ الكلية؟ إذا كانت الاجابة لا انتقل الى السؤال (10) ☐

1/ نعم 2/ لا

33. اذا كانت الاجابة نعم، حدد موقع قسم البحوث أو اللجنة بالنسبة للهيكل العام للكلية / المعهد او المركز البحثي ؟

.....

.....

.....

34. اذكر عدد ومؤهل الكادر العامل بالقسم

مؤهل الكادر	عدد الكادر	
	ذكر	انثى

35. هل يوجد كادر مدرب على اخلاقيات البحوث الصحية؟ إذا كانت الاجابة لا انتقل الى السؤال (13)

1/ نعم 2/ لا

36. اذا كانت الاجابة نعم، اذكر عددهم

37. اذا كان يوجد كادر مدرب على اخلاقيات البحوث بالقسم او اللجنة في المعهد او المركز او الكلية ، حدد مستوى التدريب؟

6. كورس تنويري اقل من اسبوع

7. تدريب 1-2 اسبوع

8. تدريب اكثر من اسبوعين(غير دبلوم /ماجستير)

9. تدريب متقدم (دبلوم / ماجستير)

10. اخرى (حدد)

38. اذا كان لايوجد كادر مدرب على اخلاقيات البحوث بالقسم او اللجنة في المعهد او المركز او الكلية حدد السبب؟

3. لا يوجد مصادر مالية للتدريب

4. لا توجد كفاءت مناسبة لتدريب الكادر

5. اخرى (حدد).....

3. <u>الدلائل والمعايير المتبعة لمراجعة مقترحات البحوث الصحية:</u>

39. هل يوجد مجلس او لجنة مسئولة عن مراجعة مقترحات البحوث الصحية؟اذا كانت الاجابة نعم انتقل الى السؤال رقم 16

1/ نعم 2/ لا

40. اذا كانت الاجابة لا ، وضح لماذا؟

1/..... 2/ .....

3/..... 4/ .....

41. اذا كانت الاجابة نعم، كيف انشأت هذه اللجنة او المجلس؟

5. بناء على مرسوم وزاري او من سلطة عليا

6. بناء على منشور او قرار اداري

7. سياسة ومتطلبات الكلية أو القسم

8. اخرى (حدد).....

42. عضوية اللجنة او المجلس:

اسم العضو	الجنس: 1. ذكر 2.انثى	المؤهل	التخصص	مهام العضو في اللجنة: 1.رئيس 2.نائب 3.عضو 4. مقرر 5. سكرتير 6. اخرى	نوع العضوية: 1. دائمة 2. غير دائمة

43. حدد نوع المراجعة التى تتم لمقترحات البحوث الصحية؟

4. مراجعة فنية فقط

5. مراجعة أخلاقية فقط

6. مراجعة فنية وأخلاقية معا ☐

44. اذكر الوسائل المتوفرة والمستعملة لمراجعة مقترحات البحوث و التجارب السريرية ؟

الرقم	الوسيلة	التواجد		التوفر		الاستعمال	
		1.نعم	2.لا	1.نعم 5≤=	2.لا=5<	1.نعم	2.لا
1	قائمة مراجعة المقترحات المرجعية						
3	استمارات خاصة بتقديم المقترحات للجنة						
5	تقارير متابعة التجارب السريرية						
6	الدلائل والارشادات القومية						
7	دلائل ارشادية خاصة بكم						

45. هل تعقد اللجنة الاخلاقية للمؤسسة او المجلس اجتماعات دورية؟ ☐

1/ نعم 2/ لا

46. اذا كانت الاجابة نعم، حدد دورية اجتماع اللجنة او المجلس؟

5. شهريا ☐

6. ربع سنويا ☐

7. نصف سنويا ☐

8. عند اللزوم/ اذا طرات الحاجة ☐

47. هل يوجد نصاب محدد للجنة او المجلس؟ ☐

1/ نعم 2/ لا

48. كم عدد المقترحات التي تقدم سنويا للمراجعة في اللجنة اوالمجلس بالتقريب ؟ ☐☐

49. كم عدد المقترحات التى تم رفضها من قبل اللجنة او المجلس؟ ☐☐

50. ماهي العوامل التى تدفع الباحثين الى تقديم مقترحات البحوث التى تختص بالانسان للمراجعة الاخلاقية؟ لا تذكر الخيارات (تقصي) يحتمل اكثر من اجابة

6. التقديم الى الجهات الداعمة(منظمة الصحة العالمية وTDR)
7. لنشر نتائج البحث العلمي في المجلات الصحية العالمية
8. لتسهيل الية جمع البيانات في المؤسسات الصحية
9. اخرى حدد.....
10. كل الخيارات

35. هل تصدر اللجنة الاخلاقية او المجلس تقارير دورية خاصة بعمل اللجنة او المجلس؟

1/نعم 2/ لا

36. اذا كانت الاجابة نعم، هل يوجد نظام لحفظ هذه التقارير؟اذا نعم، (اطلع)

1/نعم 2/ لا

37. اذا كانت الاجابة نعم، ماهو نظام حفظ هذه التقارير؟

4. نظام السجلات الورقية
5. النظام الاكتروني
6. النظامين معا

38. هل ترفع هذه التقاريرالى الجهات المختصة؟

1/نعم 2/ لا

39. اذا كانت الاجابة نعم، اذكر هذه الجهات ؟

5. لجنة اخلاقيات البحوث القومية
6. وزارة الصحة القومية
7. وزارة الصحة الولائية
8. اخرى .....

40. هل هناك ميزانية مخصصة لعمل هذذ اللجنة او المجلس ؟

1/نعم 2/ لا

41. اذا كانت الاجابة نعم، اذكر مصدر هذه الميزانية؟

5. وزارة الصحة القومية

6. وزارة الصحة الولائية

7. دعم خارجي ☐

8. اخرى ..... ☐

3. **توجهات مستقبلية:**

35. اذكر الشركاء الحاليين والمتوقعين في مجال اخلاقيات البحوث الصحية، وحدد دورهم؟

الشركاء الحاليين	دور الشراكة	الشركاء المتوقعين	دور الشراكة

36. كيف تُقييم مدى رضاكم عن الية التنسيق مع الشركاء فيما يختص باخلاقيات البحوث الصحية؟

1.مرضي جدا 2. مرضي 3. غير مرض 4. لاينطبق ☐

37. كيف يمكن ان تشارك مؤسستكم بتعزيز اخلاقيات البحوث في مؤسستكم ؟

.....

.....

.....

.....

38. كيف يمكن ان تشارك مؤسستكم بتعزيز اخلاقيات البحوث السودان؟

.....

.....

.....

.....

أستمارة (ب): منهج تدريس البحث العلمي و اخلاقيات البحوث الصحية

ينطبق هذه الجزء من الاستمارة على الجامعات والمعاهد والمراكز البحثية و تملأ الاستمارة مع عمداء الكليات الصحية ورؤساء المعاهد و المراكز البحثية:

1. **هل منهجية البحث العلمي جزء من المنهج الكلي؟**

1/ نعم 2/لا ☐

2. **هل منهج تدريس منهجية البحث العلمي موثق؟ (اذا كانت الاجابة نعم، الرجاء طلب عينة من المنهج الموثق)**

1/ نعم 2/لا ☐

3. **عدد ساعات دراسة منهجية البحث العلمي ..... ساعة** ☐☐

4. **هل دراسة منهجية البحث العلمي تشتمل على تدريس اخلاقيات البحوث الصحية؟ اذا كانت الاجابة لا انتقل الى السؤال 12**

1 / نعم 2/لا ☐

5. **اذا كانت الاجابة نعم، اذكر عدد ساعات دراسة كورس اخلاقيات البحوث (يحسب الباحث النسبة)** ☐☐

6. **هل منهج تدريس اخلاقيات البحث الصحي موثق؟**

1 / نعم 2/لا ☐

7. **اذا كانت الاجابة نعم، الرجاء طلب عينة من المنهج الموثق)**

8. **هل المنهج يحتوي على(اكثر من اجابة ممكنة)**

   1. **مبادئ اخلاقيات البحوث** ☐
   2. **اسس مراجعة المقترحات لنيل البراءة الاخلاقية** ☐
   3. **حقوق الانسان والفئات المستضعفة** ☐
   4. **اخرى حدد.....** ☐

9. **هل لديكم مراجع في تدريس اخلاقيات البحوث متوفرة للطلبة؟**

   1/ نعم 2/ لا 3/ لا ينطبق ☐

10. **اذا كانت الاجابة نعم، ماهي المراجع المتوفرة في اخلاقيات البحوث للطلبة؟(توفير لسته)**

    1. **كتب دراسية** ☐
    2. **كتب مرجعية** ☐
    3. **دوريات** ☐
    4. **افلام فيديو** ☐
    5. **اسطوانات مدمجة** ☐
    6. **انترنت** ☐

11. **هل تشتمل الامتحانات او تقييم بحث الطالب على جزء لتقييم اخلاقيات البحوث ؟**

    1. **طلبة الكلية 1/ نعم 2/ لا 3/ لا ينطبق** ☐
    2. **طبة الدراسا العليا 1 / نعم 2/ لا 3/ لا ينطبق** ☐

12. **اذا كانت الاجابة نعم، حدد نسبة تقييم أخلاقيات البحوث من الامتحان أو بحث الطالب ؟ (عينة من اخر امتحان) .....**

13. **في حالة عدم وجود برنامج تدريسي على اخلاقيات البحوث ضمن المنهج الكلي، هل توجد اي خطة لتعزيز تدريس اخلاقيات البحوث اكاديميا؟**

    1/ نعم 2/ لا ☐

14. اذا كانت الاجابة نعم، اذكر مكونات (المناشط الاساسية) هذه الخطة؟

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.....

.....

15. هل يقوم طلاب الجامعات بتنفيذ بحوث كمتطلبات تخرج؟ إذا كانت الاجابة لا انتقل الى السؤال (18)

1/ نعم 2/ لا

16. اذا كانت الاجابة نعم، هل يحتاج الى تقديم مقترح بحث؟

1/ نعم 2/ لا 3/ لا ينطبق

17. حدد الطريقة التى تتم بها الموافقة على المقترحات المقدمة من قبل طلاب الجامعة؟

1. اللجنة المعتمدة
2. الاستاذ المباشر

18. هل يقوم طلبة الدراسات العليا بتنفيذ بحوث كمتطلبات تخرج؟إذا كانت الاجابة لا انتقل الى السؤال رقم (21)

1/ نعم 2/ لا

19. اذا كانت الاجابة نعم، هل يحتاج الى تقديم مقترح بحث؟

1/ نعم 2/ لا

20. حدد الطريقة التى يتم بها الموافقة على المقترحات؟

1. اللجنة المعتمدة
2. الاستاذ المباشر

21. هل يوجد برنامج تدريبي لهيئة التدريس والباحثين على منهجية البحث العلمي؟

1/ نعم 2/ لا

22. هل يوجد برنامج تدريبي لهيئة التدريس والباحثين على اخلاقيات البحث العلمي؟

1/ نعم 2/ لا

وزارة الصحة القومية، قسم البحوث تشكركم على حسن تعاونكم

Annex (3): Research institutes in Sudan

قائمة بأسماء المراكز التي تعمل في مجال البحث الصحي و العلوم ذات الصلة بالسودان- 2003

الرقم	المركز	الجهة التي يتبع اليها	العنوان و الموقع
1	معهد النيل الأزرق للتدريب و البحوث	وزارة الصحة الاتحادية	ود مدني- ص. ب. 101 ت 46183

			فاكس 42040 بريد الكتروني osman_saeed@hotmail.com
2	المعمل القومي الصحي	وزارة الصحة الاتحادية	شرق كلية الطب جوار مستشفي الذرة جوار صينية السكة حديد ت 772521- 778370
3	معهد الأمراض المتوطنة	جامعة الخرطوم	الخرطوم- مجمع العلوم الطبية- جامعة الخرطوم ص.ب. 102 ت 779712 فاكس 779712 mmukhtar@iend.org
4	معهد أبحاث طب المناطق الحارة	المركز القومي للبحوث	الخرطوم- يقع بالمعمل القومي الصحي ص.ب. 1304 ت 781845 فاكس 781845
5	مركز أبحاث المايستوما	جامعة الخرطوم	مستشفي سوبا الجامعي ص. ب. 102 alfahal@hotmail.com
6	مركز الطب النووي	وزارة الصحة	مستشفي العلاج بالذرة- الخرطوم ص.ب. 648 تلفون 799296
7	معمل أبحاث الأحياء الدقيقة	جامعة الأحفاد	امدرمان شارع العرضة- ص.ب. 167 ت 554870
8	مركز أبحاث السكري و الغدد الصماء	قطاع خاص(مركز الملازمين الطبي)	امدرمان شمال محطة التلفزيون بحي الملازمين ص.ب. 1118 ت 552000 فاكس 50582 mohamedeltom@yahoo.com
9	مركز جامعة الخرطوم لغسيل و زراعة الكلي	جامعة الخرطوم	الخرطوم شرق- شمال القيادة العامة ص.ب. 102 ص. ب. 10716 ت. 777925-798140 فاكس 779458

			sudankidney@hotmail.com
10	مركز التغذية للتدريب و البحوث	جامعة الأحفاد كلية العلوم الأسرية	امدرمان ص.ب. 167 ت 012384189 NRTC@sudanham
11	مركز بحوث الأغذية	وزارة العلوم و التقانة	الخرطوم بحري- شمبات ص.ب. 213 ت 311294 فاكس 311049 frc@sudanmail.net
12	مركز الخرطوم للخصوبة	قطاع خاص	الخرطوم- شارع أفريقيا- خلف السفارة الهندية ص.ب. 11543 ت 482216 فاكس 482218 rfcsudan@hotmail.com
13	مركز جراحة الفم و الوجه و الفكين و أبحاث السرطان	مستشفي الأسنان التعليمي	الخرطوم ص.ب. 102 ت 77254
14	معهد الطب النووي و الأحياء الجزيئية و علاج الاورام	جامعة الجزيرة	ود مدني- أمام برج الجزيرة جوار مستشفي ود مدني التعليمي ص.ب. 20 ت 51143232 فاكس 51146640
15	المركز القومي للعلاج بالأشعة و الطب النووي		المركز القومي للعلاج بالأشعة- الخرطوم ص.ب. 846 ت 776905 فاكس 774780 profhussein@hotmail.com
16	هيئة الطاقة الذرية السودانية	وزارة العلوم و التقانة	شرق مدرسة الخرطوم القديمة ص. ب. 3001 ت 771993 فاكس 774179 saec@sudanmail.net
17	مركز أبحاث التمباك	جمعية علماء الأمراض- الجمعية الطبية العلمية	مستشفي الذرة ص.ب. 102 ت 785381 فاكس 785381 TSRC@sudanmail.net

18	معهد أبحاث النباتات الطبية و العطرية	وزارة العلوم و التقانة- المركز القومي للبحوث	المركز القومي للبحوث ص.ب. 2404 ت 784882 فاكس 773771
19	مركز المعامل و البحوث البيطرية	هيئة بحوث الثروة الحيوانية	العمارات – ص.ب. 80067 ت 830012
20	هيئة التقانة الحيوية	وزارة العلوم و التقانة	شارع محمد نجيب- غرب شارع 57 ص.ب. 2404 ت 466373 فاكس 770701 elgaali@hotmail.com
21	مجلس الدراسات الطبية العليا	كلية الطب- جامعة الخرطوم	شارع المك نمر- ص.ب. 321 ت 778169
22	المجلس القومي السوداني للتخصصات الطبية	مجلس الوزراء	مستشفي الخرطوم التعليمي ت 785207- 785194- 785194 فاكس 785194
23	مركز الدراسات السكانية	جامعة الجزيرة	مدينة الرازي- جامعة الجزيرة- ود مدني ص.ب. 20 ت 051145024 فاكس 051161161 Alnoury_pop@hotmail.com
24	مركز اقتصاديات الصحة	منظمة الصحة العالمية	كلية الدراسات الاجتماعية و الاقتصادية- جامعة الخرطوم ت 790337
25	معهد الأبحاث الاقتصادية و الاجتماعية	وزارة العلوم و التقانة- المركز القومي للبحوث	شارع البرلمان غرب مكتب القبول ص.ب. 1166 ت 778805 فاكس 779611
26	هيئة البحوث الزراعية	وزارة العلوم و التقانة	هيئة البحوث الزراعية- ود مدني ص.ب. 126 ت 43890 فاكس 43213 Elahmedi41@yahoo.com
27	مركز بحوث الانتاج الحيواني	هيئة بحوث الثروة الحيوانية	الخرطوم بحري ص.ب. 1355 ت 381148 فاكس 385269 Elkhidir2002@yahoo.co.uk
28	مركز أبحاث الايمان		الخرطوم العمارات شارع 25 ص.ب. 44791 ت 472088 فاكس 472088 info@imanonlinesd.net

29	اكاديمية السودان للعلوم	
30	اكاديمية العلوم الصحية	وزارة الصحة القومية (التدريب)
31	المركز القومي للبحوث	هيئة بحوث الثروة الحيوانية

Annex (4): National hospitals and centers

مستشفيات وزارة الصحة الاتحادية للعام 2008

الرقم	اسم المستشفي	نوع المستشفي
1	ابن سينا	تخصصي باطنية –المسالك البولية -- ENT
2	الخرطوم	تعليمي
3	امدرمان	تعليمي
4	الخرطوم بحري	التعليمي
5	الشعب	التعليمي
6	الولادة	تخصصي ولادة
7	طب المناطق الحارة	التعليمي
8	التجاني الماحي والطب النفسي	تخصص نفسي
9	حواداث الاطفال امدرما ن	تخصصي اطفال
10	د. جعفر بن عوف	تخصصي اطفال
11	ابوعنجة التعليمي لامراض الصدر والباطنية	تخصصي صدر باطنية
12	الاسنان الخرطوم	تخصصي اسنان
13	الامراض الجلدية والتناسلية الخرطوم	تخصصي جلدية
14	الخرطوم ENT الانف والاذن والحنجرة	تخصصي ENT
15	الصداقة امدرمان	تعليمي
16	الامراض العصبية والنفسية بحري	تخصص نفسي

مستشفيات وزارة الصحة الاتحادية –الجزيرة

1	ودمدني لامراض النساء والتوليد	تخصصي نساء ولادة
2	حوادث الاطفال ودمدني	تخصص اطفال
3	الشيخ الصائم االعيون وجراجة العيون	تخصص عيون ودمدني

مراكز وزارة الصحة الاتحادية للعام 2008م

الرقم	اسم المركز	نوع التخصص
1	مستشفى الشهيد عبد الفضيل الماظ القومي لطب وجراحة العيون	عيون
2	مستشفى القومي للعلاج بالاشعة والطب النووي الخرطوم مستشفى	علاج اشعة
3	مركز جراحة القلب وزراعة الكلي مستشفي احمد قاسم مستشفى	قلب
4	المركز القومي لامراض وعلوم الجهاز العصبي مستشفى	جهاز عصبي
5	مركز الشهيدة د.سلمي لغسيل وجراحة الكلي	كلي
6	المركز القومي لامراض الجهاز الهضمي والكبد مستشفى	جهاز هضمي وكبد
7	المركز القومي لامراض وجراحة القلب والصدر مستشفى	قلب وصدر
8	مركز الجزيرة لغسيل وجراحة الكلي	غسيل كلي
9	مركز الجزيرة لمناظير الجهاز الهضمي وجراجة المناظير	جهاز هضمي ومناظير
10	مركز محمد صالح للنزيف المعوي مستشفى	للنزيف المعوي
11	مركز الدويم لغسيل الكلي	غسيل كلي
12	مركز ودمدني لامراض وجراحة القلب مستشفى	جراحة القلب
13	مركز بحري لغسيل الكلي	غسيل كلي
14	المركز القومي لامراض وجراحة الكلي والمراكز الاخري مستشفى	كلي
15	*مركز معالجة وجراحة امراض الكلي شندي*	كلي
16	*مركز نورة لغسيل الكلي للاطفال (سوبا)*	كلي

Annex (5): Total number and the estimated sample size of the medical, public health, medical laboratories and nursing schools and others:

الرقم	الكلية	العدد الكلى	حجم العينة
1	كليات الطب	25	13
2	كليات الاسنان	10	6
3	كليات الصيدلة	12	6
4	كليات علوم المختبرات	19	8
5	كليات التمريض	9	4
6	كليات العلاج الطبيعى والاشعة	8	4
7	كليات العلوم	6	3
8	كليات علم النفس	2	1
9	كليات التخدير	2	1
10	كليات الصحة العامة	4	2
المجموع		97	48