The Ethical Review System in Sudan and Role of Research Ethics Committees

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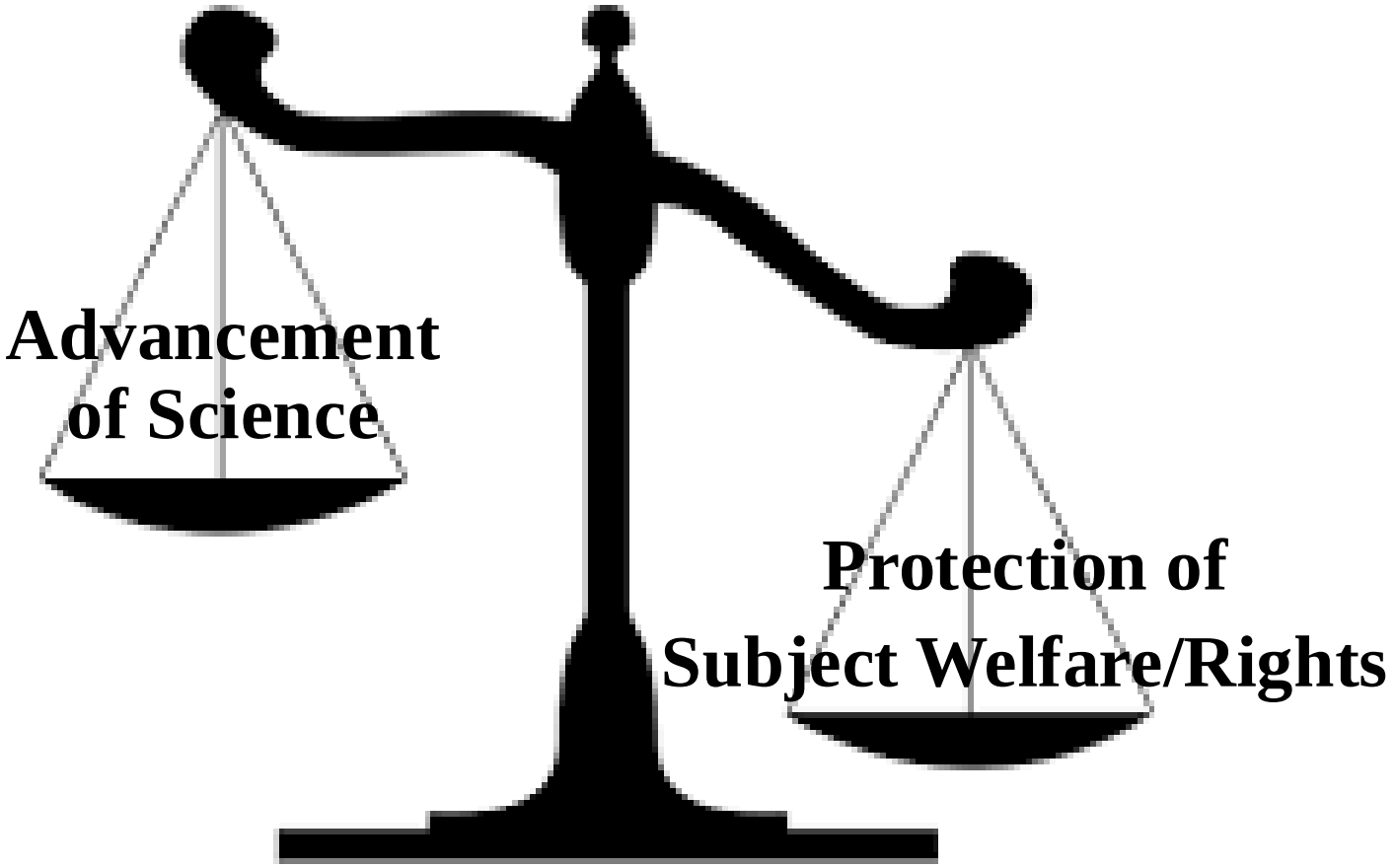
Learning Outcomes

By the end of this module the learner should be able to

- ✓Understand the ethics review system in Sudan
- ✓Appreciate the role of the regulatory bodies that govern human subjects research in Sudan
- ✓Recognize the role of research ethics committees in protecting the rights and welfare of human subjects
- ✓Understand the constitutions and functions of Research Ethics Committees

Balancing Two Goals



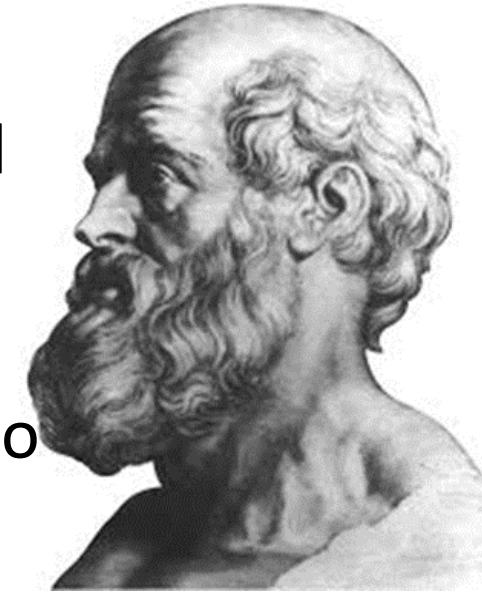
History of Research Ethics

- Ethics have been there since the beginning of humanity

- “Amen-Hu-Tep” - Papyri that describes that medical conduct should be following the “Ma’at” which was the patron of truth.

History of Research Ethics

- More than 2000 years later, Hippocrates (~460 to ~375 B.C.) put his Oath- still stated in most medical schools .

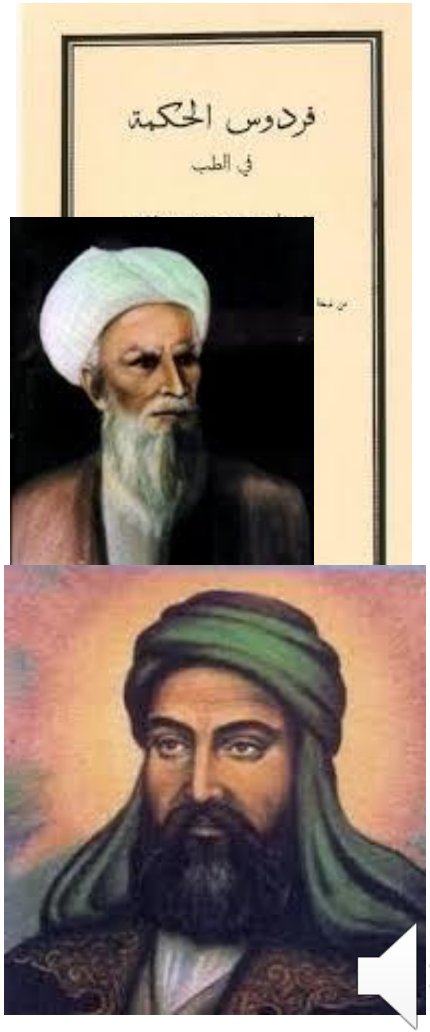


- It starts with the famous doctrine 'First do no harm" and included many ethical principles that govern the medical practice.

"I Swear by Apollo the physician and Aesculapius....., I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous… I will give no deadly medicine to any one …. I will not give to a woman a peccary to produce abortion … Whatever, .. I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, .."

History of Research Ethics

- Al-Tabari -“Firdaus Al-Hikma”
- Razi-mentioned ethical conduct deeply rooted from the Islamic teachings of human rights, morality and justice.
- Al-Rahawessy, -“Adaab Al-Tabib” - first to explicitly mention the patients rights. It advocates that any physician should have high morals standards.



Research Ethics

- The origin of research ethics, as it is known and practiced today, can be traced back to three different but interrelated events:
    - a set of scandals in biomedical research
    - advancement in medical technology
    - and the civil rights movement

The Situation in Sudan

History of Research in Sudan

1903 Welcome Tropical Research Labs were established as part of Gordon Memorial College- Pioneer research in environmental health, control of endemic diseases such as leishmaniosis, schistosomiasis and malaria,.

1924 Kitchener School of Medicine served with the WTRL

History of Research in Sudan

1935	Research became the responsibility of the Research Section of the Sudan Medical Services (SMS). This included Stack Medical Laboratory (National Health lab)/ Welcome lab ,Medical Entomology Department/Wad Madani.
1968	Sudan Medical Council (estb1964) established the Medical Ethical Committee, which latter issued “The Principle of Medical Ethics and Medico-moral Problems 1968” -Medical practice rather than Research.

National Council of Research

- In 1970, the National Council for Research was established to encourage, organize and promote the scientific research.

- 1970s and due to increased research activities in biomedical field the director of The National Health Laboratory was entitled to give ethical clearance

- Restructured and named the National Centre for Research (NCR)of Ministry of Higher Education and Scientific Research.

History of Research Ethics in Sudan

- 1979, first ethical review committee was established by a group of scientists from the National Health Research Laboratory - Committee of Ethics in Research Involving Human (CERIHS)
    - respond to ethical dilemmas in health research;
    - protect human subjects
    - protect Sudanese citizens from exploitation by expatriate researchers.

- This committee had neither political nor institutional recognition and was dissolved shortly after its inception.

- In 1980 the Faculty of Medicine, University of Khartoum, established its own Ethical Committee- It was the first institutional research Ethics committee in Sudan

Elsayed, 2004

Research Ethics Situation in Sudan

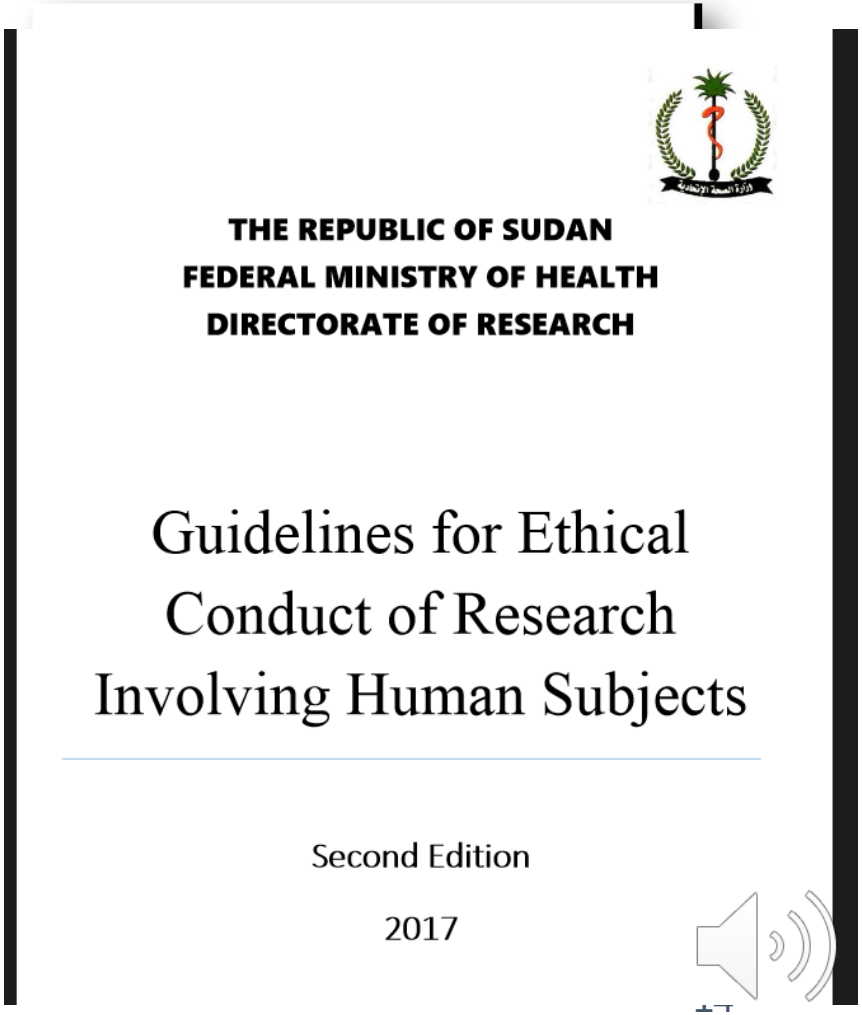
- In **1998**, the Undersecretary of the FMOH, issued **Decree No. 60/1998** for forming a committee to review health research ethics.

- In 2002, the Federal Minister of Health issued a Ministerial Decree no 11 / 2002 for the constitution National Ethical Committees (NEC) now the NHREC.

National Guidelines

- It was not until 2008 that the NHREC issued a document “National Guidelines for Human Subject Protection” as a guideline to be followed for research involving human subjects

- This was further reviewed and amended in 2017 through a grant from the EDCTP



What are the Tasks of NHREC?

1. Formulating guidelines.

2. The approval of Research involving human subjects
   - Health research at a national level
   - Research with external participants
   - The experimental research on human.

Tasks of NHREC

3. Reviewing and approving:

- Research on human participants directing or indirectly.
- Justice, in planning, conduct and reporting of the research.
- Aspects of informed consent process, risk-benefit ratio, before start, throughout and after completion of the study.
- Annual reports, final reports and site visits etc.
- Compliance with all regulatory requirements and guidelines

Ethical Review Decentralization

- In 2007, a ministerial decree enhanced the decentralization of the RECs at states, hospitals and research institutes through forming their own RECs
- Institutional and State RECs

REPUBLIC OF THE SUDAN
FEDERAL MINISTRY OF HEALTH
MINISTER

جمهوريـــة السودان
وزارة الصحة الإتحادية
الوزيـــــر

قرار وزاري رقم (١٣) لسنة ٢٠٠٧م

وزير الصحة الاتحادي

عملاً بأحكام المادة (٨١) من قانون الصحة العام لسنة ١٩٧٥م وإنفاذاً لدستور جمهورية السودان للعام ٢٠٠٥م وبعد الاطلاع علي القرار الوزاري رقم (١١) لسنة ٢٠٠٢م الصادر بتاريخ ٢٠٠٢/١١/١١م والخاص بتشكيل مجلس البحوث الصحية والذي تضمن الفقرة (٢) اعتماد وتفويض الصلاحيات للجان اخلاقيات البحوث واللجان الفنية الاستشارية الولائية عليه تقوم المؤسسات والمراكز البحثية بتشكيل لجان فنية وأخلاقية .

قرر

أولاً : اسم القرار وبدء العمل به .

يسمى هذا القرار (قرار بتشكيل لجان الإجازة الفنية والأخلاقية للبحوث الصحية بالمؤسسات والمراكز البحثية) ويعمل به من تاريخ التوقيع عليه .

ثانياً : اختيار لجنة الإجازة الفنية والأخلاقية للبحوث الصحية بالمؤسسات والمراكز البحثية :

١/ رئيس من ذوى الخبرة فى مجال البحوث الصحية وعدد من المختصين بالموسسات و المراكز البحثية .
٢/ يكون مقر اللجان بالمؤسسات و المراكز البحثية
٣/ يرفع تشكيل اللجان للامانة التنفيذية بمجلس البحوث الصحية للاعتماد

ثالثاً : مهام واختصاصات اللجنة :

١/ متابعة وتطبيق موجهات الإجازة الفنية والأخلاقية المجازة من الامانة التنفيذية بمجلس البحوث الصحية
٢/ الاضطلاع بالإجازة الفنية و الاخلاقية للبحوث التى تتم على مستوى المؤسسات والمراكز البحثية واصدار البراءة الاخلاقية لها ويستثنى من ذلك البحوث التى تقع ضمن اختصاص اللجان القومية والمتمثلة فى :-
٤. البحوث التجريبية على الانسان
٥. البحوث المرتبطة بجهات اجنبية
٦. البحوث التى تجرى فى اكثر من ولاية
٣/ رفع تقرير نصف سنوى للامانة التنفيذية بمجلس البحوث الصحية يحوى نتائج اجتماعات اللجان والبحوث المجازة فنيا و اخلاقيا على مستوى المؤسسات والمراكز البحثية .

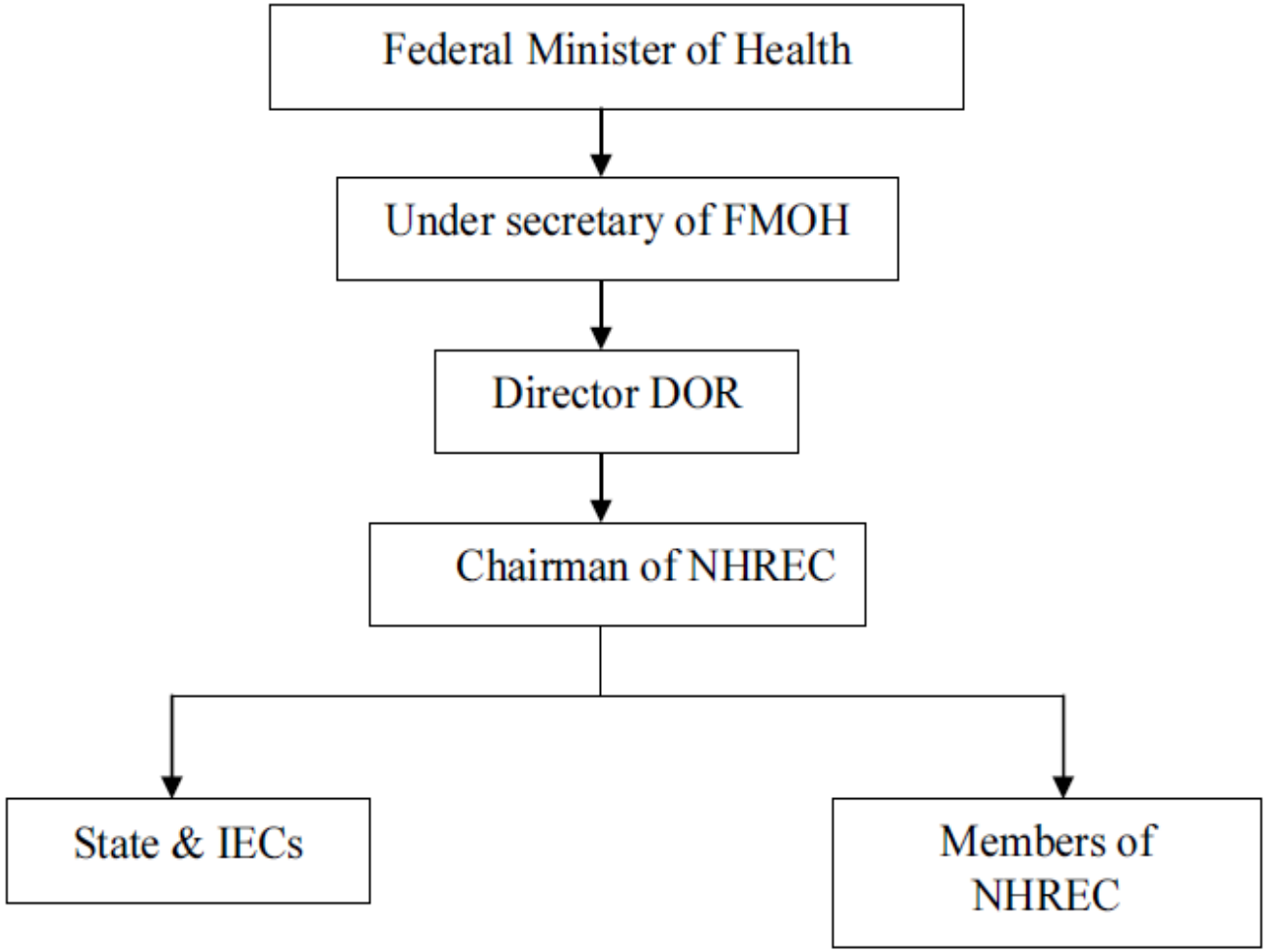
خامساً : يبلغ هذا القرار لمن يلزم لإنفاذه .

صدر تحت توقيعي في هذا اليوم الأحد الثاني والعشرون من شهر رجب لعام ١٤٢٨هـ الموافق الخامس من شهر أغسطس سنة ٢٠٠٧م .

د . تابيتة بطرس شوكاي
وزير الصحة الاتحادي

ص.ب ٣٠٣ الخرطوم تلفون: ٨٣٧٧٣٠٠١ - ٨٣٧٧٤٣٨١ - ٨٣٧٧٤٧١٠ (٢٤٩+) فاكس: ٨٣٧٧٨٧٠٤ - ٨٣٧٦٩٩٢٩ (٢٤٩+) تلكس: ٢٢٨٩٦ تلغراف: دوا،
P.O. Box: 303 Khartoum Tel: (+249) 83773001 - 83774381 - 83774710 Fax: (+249) 83769929 - 83778704
Telex: 22896 Telegraphic Address (DAWA) E-mail: headmothar@yahoo.com

Organogram of the ethics committee



States and Institutional Ethics Committees

Endorsement and delegation of NHREC powers to the state and institutional RECs.

- The state and institution ethics committees should follow the same guidelines of NHREC.
- The State Ministries of Health and Head of the research institutions should constitute RECs.
- State and research institutions ethics committee should be approved by the NHREC

States and Institutional Ethics Committees

- State and institutions RECs have the authority to issue ethical approval for all health research except:

i. Experimental research on human subjects
ii. Researches linked to external bodies.
iii. Interstate Research

States and Institutional Ethics Committees

- State review and institutional board should provide NHREC
  - Biannual reports .
  - A copy of approved research proposals
  - Copies of the ethical certificates issued

The NHREC discusses the research proposals and the reports of the State and institutions ethics committees in their regular meetings.

National, Medicine and Poisons Board

- The NMPB was established in 2005 as the main body that govern clinical trials in humans and animals.

- The NMPB has its own issued guidelines and according to these guidelines only universities, academic and research institutes are allowed to conduct clinical trials.

- In 2009 and under the government of Sudan constitution a law was issued that dictated that all medicinal clinical trials should be reviewed by NMPB.

National Governing Bodies

NHREC

بسم الله الرحمن الرحيم

وزارة الصحه الإتحاديه

المجلس القومى للبحوث الصحيه

اللجنه القوميه لأخلاقيات البحوث الصحيه

لائحـة تنظيم أعمال لجنة أخلاقيات البحوث

الـصـحـيـة الـقـومية لعام ٢٠٠٦

عملا بالسلطات الممنوحة لها بالقرار الوزارى برقم (١١) بتاريخ السادس من رمضان ١٤٢٣هـ الموافق اليوم الحادي عشر من شهر نوفمبر ٢٠٠٢م والخاص بتشكيل مجلس البحوث الصحية، اصدرت لجنة اخلاقيات البحوث الصحية اللائحة الآتية لتنظيم أعمالها.

اولا: اسم اللائحـة وبـدء العمل بها :

١- تسمى هذه اللائحة (**لائحة تنظيم أعمال لجنة اخلاقيات البحوث الصحية القوميه**) ويعمل بها من تاريخ التوقيع عليها.

ثانيا: تفسير

١- تكون للعبارات التالية المعانى الموضحة امام كل منها :-

ادارة البحوث : يقصد بها ادارة البحوث بوزارة الصحة الاتحادية

الوزير : يقصد به وزير الصحة الاتحادى

الوزارة: يقصد بها وزارة الصحة الاتحادية

الوزارة الولائية: يقصد بها وزارة الصحة فى اى من ولايات السودان

المؤسسة البحثية: يقصد بها أية جهة إعتبارية يصدق لها بإجراء البحوث.

المجلس: يقصد به مجلس البحوث الصحية والذي تم تشكيله بواسطة وزير الصحة الاتحادي بالقرار الوزاري رقم(١١) لسنة ٢٠٠٢.

لجنة ولائية: يقصد بها لجنة أخلاقيات البحوث في الوزارة الولائية:

لجنة مؤسسية: يقصد بها لجنة أخلاقيات البحوث في المؤسسة البحثية.

NMPB

بسم الله الرحمن الرحيم

جمهورية السودان

المجلس القومي للأدوية والسُّموم

لائحة إجراء التجارب الطبية على الإنسان والحيوان لسنة2010

عمـلاً بالسـلطة المخولـة لـه بموجـب المـادة 40 مـن قـانون الأدويـة والسُّـموم لسـنة 2009 أصـدر المجلـس القومي للأدوية والسُّموم اللائحة الآتي نصها:

الفصل الأول

أحكام تمهيدية

اسم اللائحة وبدء العمل بها

1– تسـمي هـذه اللائحـة "لائحـة إجـراء التجـارب الطبيـة علـى الإنسـان والحيـوان لسـنة 2010"و يعمـل بهـا مـن تاريخ التوقيع عليها.

تفسـير

2– في هذة اللائحة:

(أ) تكون للكلمات والعبارات الواردة فيها المعاني المعبر عنها في قانون الأدوية والسُّموم لسنة 2009.

(ب)ما لم يقتض السياق معنى آخر تكون للكلمات والعبارات الواردة أدناه المعاني المبينة أمام كلٍ:

القانون يقصد به قانون الأدوية والسُّموم لسنة 2009.

المجلس يقصد به المجلس القومي للأدوية والسُّموم المنشأ بموجب أحكام المادة 4(1) من القانون.

اللجنة يقصد بها لجنة إجراء التجارب الطبية على الإنسان والحيوان المنشأة بموجب أحكام المادة13 (1) من قانون الأدوية والسُّموم لسنة 2009.

حيوانات التجارب الحيوانات التي تُجرى عليها التجارب في المختبرات الطبية والمعروفة باسم (Experimental Animals).

يقصد بها الابقار والاغنام و الماعز والابل والفصيله الخيلية والدواجن والحيوانات البرية.

تجارب قبل السريرية يقصد بها التجارب الطبية التي تُجرى على حيوانات التجارب.

National Governing Bodies

NHREC

- According to the regulation of the NHREC, it is the task of the committee to license the ethical aspects of health research proposals carried out at
  - the national level or in more than one state,
  - the licensing of ethics of research involving external parties,
  - Experimental research on humans except medicinal, herbal or new devices

NMPB

- According to the regulating documents, the NMPB is responsible for reviewing and ethical clearance for
  - pharmaceutical, therapeutic and non-therapeutic medical experiments on human and animals.

RESEAECH ETHICS COMMITTEES
RECs

Research Ethical Committees

- “Contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participant”

WHO Guidelines 2011

Research Ethical Committees

- Committees have the authority to approve, reject or stop studies

- Require modifications to research protocols.

They may also perform other functions, such as setting policies or offering opinions on ongoing ethical issues in research.

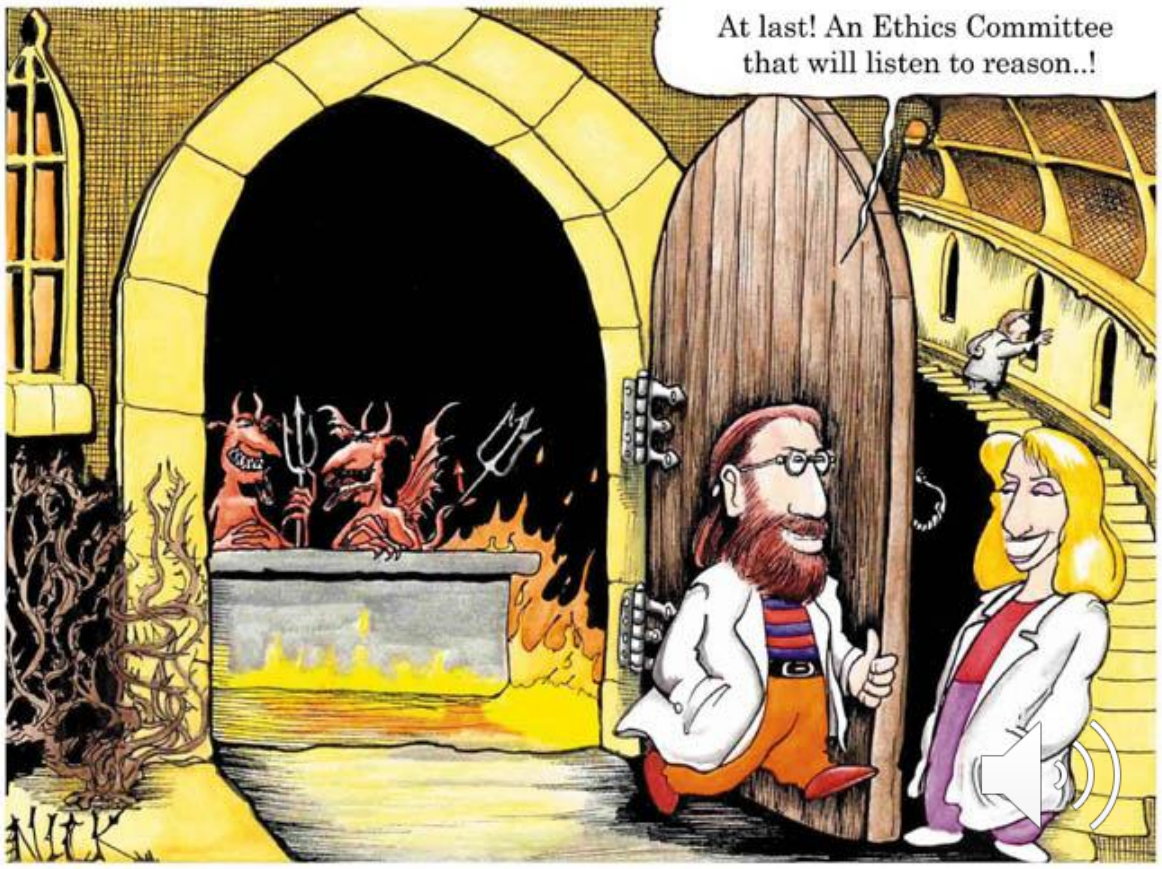
Research Ethical Committees

- Review by a research ethics committee is required by international and local standards governing research.

- Review is also essential for publication

Types of RECs

- National/Central
- State/Regional
- Institutional



Functions of RECs

- Identifying and weighing up the risks and potential benefits of research
- Evaluating the informed consent process and materials (printed documents and other tools) assessing the recruitment
- Asses the recruitment process and any incentives that will be given to participants
- Ensure participants' privacy and data confidentiality .

To function properly RECs has to be

- Properly constituted
- Competent members
- Adequate Resources
- Regulatory Framework

Composition of RECs

The REC must have at least five members. (6-8)

- Chair
- Scientist / experts
- Non Scientist – social/legal considerations
- Community representative
- Non affiliated member
- Gender Representation

- Members must have enough experience, expertise, and diversity

Members must avoid conflict of interest

Composition of REC

- Only members participating in review should vote
- Investigator may provide information on study, but should not be involved in review or vote
- Nonmembers with expertise in special areas may be invited to assist with review (but cannot vote)

Decisions rendered with quorum in attendance

Support and Oversight

The REC should be supported by its establishing body providing it with adequate staff, facilities, and financial resources to allow the REC to carry out its responsibilities independently.

- Members should receive training in the international and local ethical and legal standards governing research, as well as in the process the committee uses to review and approve protocols. *CONTIONOUS TRAINING*

- Non scientific members should be given sufficient training to enable them to participate intelligently in the committee's discussions

Support and Oversight

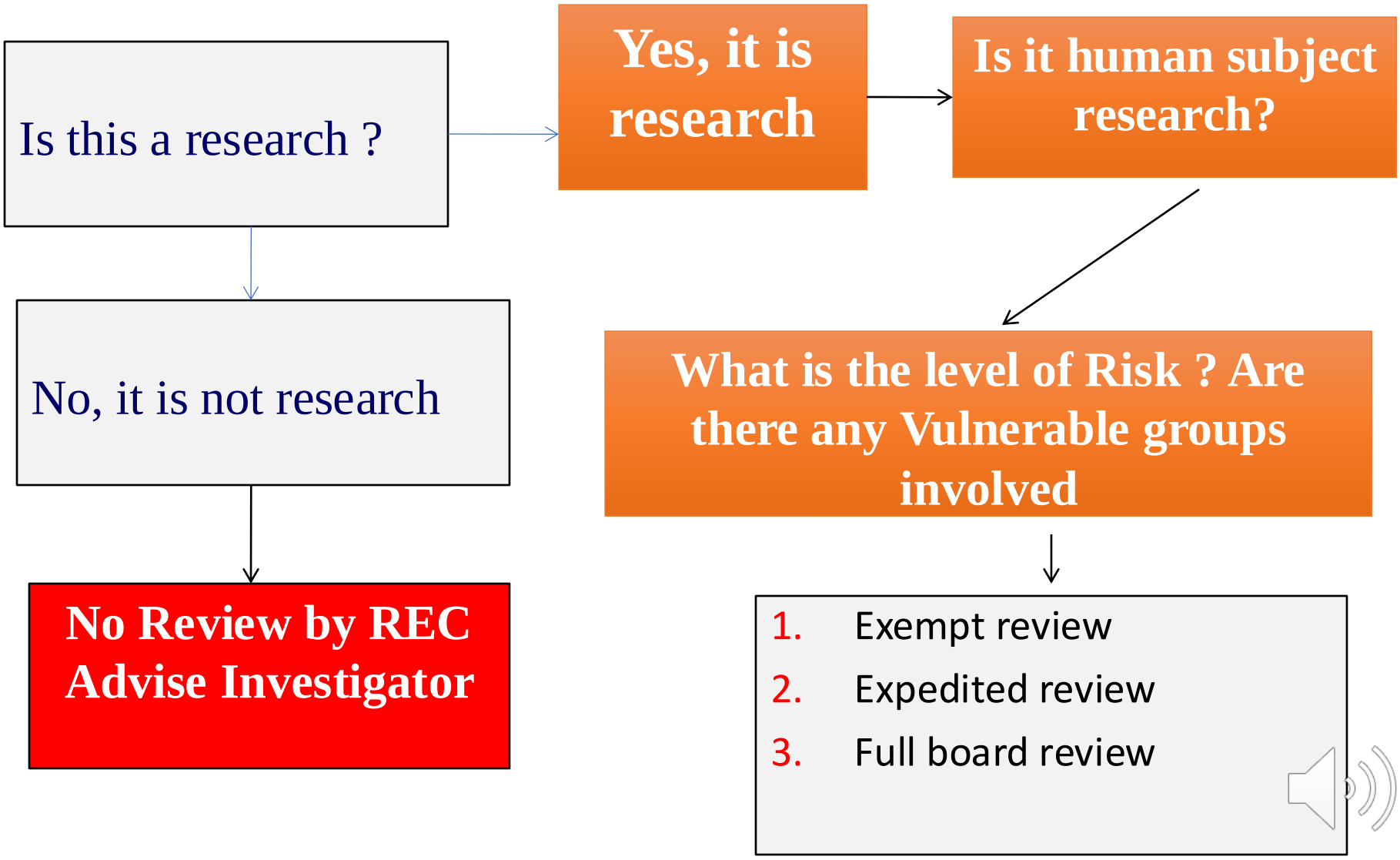
- **There should be a measure of performance through**
  - Auditing
  - Accreditation
  - Self-Assessment

Functioning of RECs

Described in terms of

- Review procedures
- Decision making processes
- Documentation requirements

Review process starts with asking essential question



Definition of Research

- **Research** means a **systematic** investigation, including research development, testing, and evaluation, designed to develop or contribute to **generalizable** knowledge

Definition of Human Subject Research

- A **human subject** is a living individual about whom an investigator conducting research obtains
  - Data through intervention or interaction with the individual, or
  - Identifiable private information

Obtains Data Living Individual

Identifiable private information:

1. Private information: information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (medical records).

2. Information must be individually identifiable: the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Intervention: physical procedures by which data is gathered

Interaction: communication or interpersonal contact between investigator and subject.

Analysis of Risks and Benefits

What is ethics review?

- It is a process involves reviewing all research involving human subjects for ethical aspects
- It is done by independent Research Ethics Committee (REC)
- Not all protocols require full committee review

Categories of Review

1- Exempt review

Done by the Chair of REC

- Less than minimal risk
- Unidentifiable information
- No vulnerable population
- No progress or annual report(s) is/are required

2- Expedited review

- Done by the chairperson or one or more experienced members of REC designated by the chairperson for the purpose

- Designated members may exercise all authorities of the REC *BUT* can not disapprove the research.

2- Expedited review

Applicable for research activities that involve no more than minimal risk to the human participants

- No vulnerable population
- No progress or annual report(s)

3- Full Board Review

- It is the default procedure for all research projects involving human participants.

- The following are examples of research projects that may require a Full Board REC review:
  - Projects involving moderate to serious physical, emotional, psychological, legal, social, or economic risk to participants.
  - Projects involving sensitive questions or invasive procedures.
  - Projects involving vulnerable populations
  - Projects where there is a possibility of coercion
  - Projects involving partial disclosure or deception

- Progress report(s),Annual report(s) and Final report are required

Review Process

Is it Research ?

Does it involve Human Subjects ?

Application → REC chairman → Exempted

REC chairman → Expedited

REC chairman → Full Board Review

Full Board Review → **2 Members assigned as primary and secondary reviewers**

2 Members assigned as primary and secondary reviewers → **Protocol and consent form and other documents discussed at meeting**

Protocol and consent form and other documents discussed at meeting → VOTE

VOTE →
- **Approve**
- **Approval with minor changes**
- **Deferral**
- **Disapprove**

The Situation

Questionable (Elsayed and Kass 2007)

- Approximately 50% of researchers do not know a NHREC exists.
- Only 34% of researchers provide a definition for what an REC is and there are wide variations in describing its functions

There are no websites that researchers can refer to explaining IRB functions, requirements or processes

Conclusions and Suggestions

- Sudan has regulations that guide conduction of Human Subjects Research
- National Committees include the National Health Research Ethics Committee and the National Medicine and Poison Committee
- Institutional and State Committees have limited capacity of research review
- All research involving human subjects have to be reviewed by a well established, independent , well trained RECs
- Review by RECs ensures the protection of rights and welfare of human subjects in research as well as the investigators and the institution.

"إنما الأمم الأخلاق ما بقيت.. فإن هم ذهبت أخلاقهم ذهبوا"