المؤتمر السنوي الدولي للجمعية الرمدية المصرية
INTERNATIONAL CONGRESS OF THE
EGYPTIAN OPHTHALMOLOGICAL SOCIETY
EOS 2023

Course 12: Research Methodology and Ethics Course

REC in Accordance with New Egyptian Clinical Research Law

Prof. Azza Saleh

Professor of Clinical and Chemical Pathology, TBRI

Diploma of TQM in Healthcare, AUC

Certified International Trainer in Research Ethics, USA

CIPT, Missouri State U, USA/Cairo U, Egypt

Honorary President of ENREC

Coordinator of the 3 committees established for the creation of the Egyptian CT law and its executive regulations {Ministerial Decrees nos 491(2016) and 135 (2021)} and Prime Ministerial Decree no 2716 (2018)

EOS 2023

EOS 2023

EOS 2023

Intended Learning Objectives (ILOs)

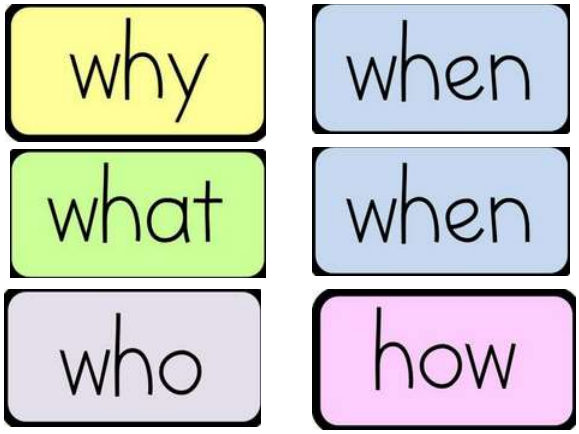
By the end of this lecture you will be able to:

1. Recognize the structure and role of REC
2. Identify the method of dealing with it

8 Ethical Requirements

- Community partnership
- Social value
- Scientific validity
- Fair subject selection
- Favorable risk/benefit ratio
- Independent review
- Informed consent
- Respect for enrolled subjects

Emanuel et al,JAMA. 2000;283:2701-2711



EOS 2023

What is the difference between

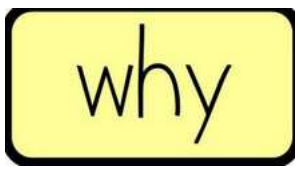
REC & IRB

Institutional Review Board (IRB)

are similar terms

EOS 2023

~~PLEASE DON'T SAY THAT~~



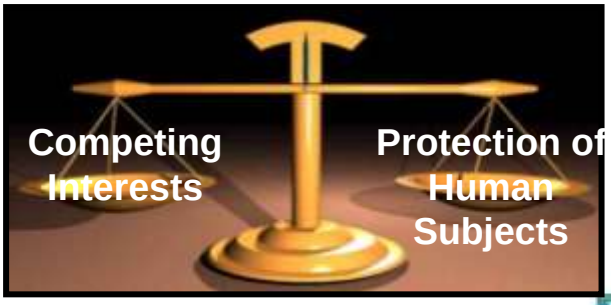
Conflicting obligations might lead even well-intentioned investigators to fail to notice the proper protections of human subjects

Independent review balances the possibility that

competing interests

may override the

protection of human subjects



الباب الرابع

إجراء التجارب والبحوث الطبية على الآدميين

رقم 238 لسنة 2003 بتاريخ 5 سبتمبر 2003

مادة (57) :

يلتزم الباحث بإعداد تقرير مفصل وواضح عن أهداف البحث ومبررات إجراؤه على الآدميين ويقدم هذا التقرير إلى الجهة المختصة للحصول على موافقتها على إجراء البحث.

قانون رقم ٢١٤ لسنة ٢٠٢٠

بإصدار قانون تنظيم البحوث الطبية الإكلينيكية

قـرار رئيـس مجلـس الـــوزراء
رقـــم ٩٢٧ لسنة ٢٠٢٢
بإصدار اللائحة التنفيذية لقانون تنظيم البحوث الطبية الإكلينيكية
الصادر بالقانون رقم ٢١٤ لسنة ٢٠٢٠

قـــرر

(المادة الأولى)

يعمل بأحكام اللائحة التنفيذية المرافقة لهذا القرار في شأن قانون تنظيم البحوث الطبية الإكلينيكية الصادر بالقانون رقم ٢١٤ لسنة ٢٠٢٠.

(المادة الثانية)

يلتزم المخاطبون بأحكام اللائحة المرافقة بتوفيق أوضاعهم بما يتوافق مع أحكامها خلال سنة من تاريخ العمل بها.

(المادة الثالثة)

ينشر هذا القرار في الجريدة الرسمية، ويعمل به من اليوم التالي لتاريخ نشره.

رئيس مجلس الوزراء

(الدكتور/ مصطفى كمال مدبولي)

صدر برئاسة مجلس الوزراء في ٩ شعبان سنة ١٤٤٣هـ

الموافق ١٢ مـــارس سنة ٢٠٢٢م

باسم الشعب

رئيس الجمهورية

قرر مجلس النواب القانون الآتي نصه ، وقد أصدرناه :

(المادة الأولى)

يعمل بأحكام القانون المرافق في شأن البحوث الطبية الإكلينيكية التي تجرى على الإنسان وبياناته الطبية بالجهات المختلفة داخل جمهورية مصر العربية .

(المادة الثانية)

يصدر رئيس مجلس الوزراء اللائحة التنفيذية للقانون المرافق خلال ثلاثة أشهر من تاريخ العمل به .

(المادة الثالثة)

ينشر هذا القانون في الجريدة الرسمية ، ويعمل به من اليوم التالي لتاريخ نشره .

يبصم هذا القانون بخاتم الدولة ، وينفذ كقانون من قوانينها .

صدر برئاسة الجمهورية في ٨ جمادى الأولى سنة ١٤٤٢ هـ

(الموافق ٢٣ ديسمبر سنة ٢٠٢٠ م) .

عبد الفتاح السيسي

الفصل الرابع

اللجان المؤسسية لمراجعة أخلاقيات البحوث الطبية الإكلينيكية وهيئة الدواء المصرية
المواد ٨ و ٩

مادة (٨) تشكل داخل كل جهة بحثية بقرار من السلطة المختصة بهذه الجهة، لجنة واحدة تسمى "اللجنة المؤسسية لمراجعة أخلاقيات البحوث الطبية"، من رئيس وأربعة أعضاء على الأقل، وتكون مدة عضويتها ثلاث سنوات قابلة للتجديد مرة واحدة، على أن يتم تغيير عضوين على الأقل كل ثلاث سنوات، ويكون لكل لجنة مقرراً يُحدد في قرار تشكيلها.

الفصل الرابع

اللجان المؤسسية لمراجعة أخلاقيات البحوث الطبية الإكلينيكية وهيئة الدواء المصرية
المواد ٨ و ٩

ويراعى في تشكيل تلك اللجان ما يلي:

- أن يكون أحد الأعضاء على الأقل من ذوى التخصصات غيرالطبية
- أن يكون أحد الأعضاء على الأقل من خارج الجهة التي يجرى بها البحث.

وتعقد اللجنة المؤسسية إجتماعاتها بصفة دورية وفقا لما يحدده قرار تشكيلها.ويجب أن تتقدم الجهة البحثية بطلب إلى المجلس الأعلى لتسجيل هذه اللجنة خلال شهرعلى الأكثر من تاريخ تشكيلها

الفصل الثانى عشر

المسئولية والعقوبات
المواد ٢٥ ـ ٣٢

- العقوبات تشمل الحبس والغرامات المالية فى حال عدم الإلتزام عامة بمواد هذا القانون من قبل كل المعنيين به
- يوجد سجن مشدد فى الحالات التى بها عدم إلتزام نتج عنه حدوث آثار جانبية خطيرة على المبحوث

DoH

World Medical Association Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Subjects *October (2013)*

"The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins"

- Enhance protection of subjects
- Enhance researcher and Institute reputation minimize the potential for claims of negligence made against them
- Increasing demand of REC approval from different scientific bodies in Egypt
- It is an essential requirement for national & international sponsors or grants

صندوق العلوم والتنمية التكنولوجية
Science & Technology Development Fund

وزارة البحث العلمي
Ministry of Scientific Research

The form for bioethical considerations

Please respond to the following questions:

a) Does your project have any bioethical considerations? (Yes/No)

b) If yes; has an ethical clearance been obtained for the conduct of study and what is the date of obtaining such clearance? (Please attach a copy of the ethical clearance)

d) In this research proposal, please indicate if an Informed consent is needed, (if applicable, please attach a blank consent form as an annex)

e) In this research proposal, please indicate if the subject confidentiality will be guarded?

EOS 2023

f) Please provide the following information about the Ethical Review Committee that reviewed and cleared this research proposal:

- Type of the Ethical Review Committee (Institutional/national)
- Number of members of the Ethical Review committee
- Structure of the Ethical Review committee (membership comprising institutional specialists only or other non-institutional society representatives)
- How many years has the Ethical Review Committee been functional?
- How many proposals has the Ethical Review Committee examined in the last two years and how many of them were rejected/accepted?
- If applicable, number of members of the Ethical Review subcommittee that reviewed the proposal

EOS 2023

NIH GRANTS POLICY STATEMENT

U.S. Department of Health and Human Services
National Institutes of Health

4.1.15.2 Certification of IRB Approval

Recipients must provide a certification to NIH that the research application has been approved by an appropriate IRB, consistent with 45 CFR 46 and OHRP guidance. IRB approval must have been granted within 12 months before the budget period start date to be valid. Note that NIH requires the date of final IRB approval; conditional IRB approval is not sufficient. According to OHRP, in the case of IRB approval with conditions, IRB approval only becomes effective when the IRB has approved all information submitted in response to their conditions.

EOS 2023

European Commission

RESEARCH & INNOVATION

Participant Portal H2020 Online Manual

International cooperation	Social Sciences & Humanities	Open access & Data management	Climate action & Sustainable development
Ethics	Gender	SMEs	ERA-NETs
Links to regional policy	Intellectual property	Innovation procurement	

ETHICS REVIEW PROCEDURE

All proposals above threshold and considered for funding will undergo an Ethics Review carried out by independent ethics experts and/or qualified staff working in a panel. The Review starts with an **Ethics Screening** and if appropriate a further analysis called the **Ethics Assessment** is conducted. **The Ethics Review can lead to ethics requirements that become contractual obligations.**

EOS 2023

- Enhance protection of subjects
- Enhance researcher and Institute reputation minimize the potential for claims of negligence made against them
- Increasing demand of REC approval from different scientific bodies in Egypt
- It is an essential requirement for national & international sponsors or grants
- To give chance for international publication

A global nonprofit voluntary association of editors of peer-reviewed medical journals

Recommendations on Publication Ethics Policies for Medical Journals

Study Design and Ethics

Documented review and approval from a formally constituted review board (Institutional Review Board or Ethics committee) should be required for all studies involving people, medical records, and human tissues. For those investigators who do not have access to formal ethics review committees, the principles outlined in the Declaration of Helsinki should be followed. If the study is judged exempt from review, a statement from the committee should be required. Informed consent by participants should always be sought. If not possible, an institutional review board must decide if this is ethically acceptable. Journals should have explicit policies as to whether these review board approvals must be documented by the authors, or simply attested to in their cover letter, and how they should be described in the manuscript itself.

What is REC ?

Composition of REC

-Authorized committee consists of a reasonable number of members at least (5), having a time schedule

-Committee must have chairperson

Composition of REC

- At least one member is non-medical
- At least one member is non-affiliated

Role of REC

Review biomedical research and ensure that the research does not violate the rights and welfare of the human subjects participating in it

Role of REC

Protect the

Researchers & their Institutions

EOS 2023

Role of REC

EOS 2023

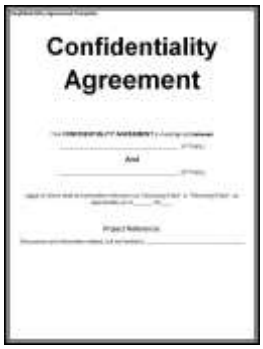
Role of REC

- Continuing reviews
- Review of Changes
- Review Adverse events
- Suspend or terminate approval
- Conduct educational exercises

Members must reveal and manage any

potential conflict of interest

Members must sign confidentiality agreement


Confidentiality Agreement

And

Project Reference

+

EOS 2023

What is 

?

EOS 2023

It is a systematic investigation designed, including research development, testing, and evaluation, to develop or contribute to generalizable knowledge

common Rule, USA

What is 

?

What is 

?

A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information

What is 

?

Intervention includes physical procedures, manipulations of the subject or manipulations of the subject's environment for research purposes

What is 

?

Interaction includes communication between the investigator and the subject. This includes face-to-face, mail and phone interaction

EOS 2023

What is 

?

Identifiable Private Information

-Information that has been provided for specific purposes and not to be public

EOS 2023

What is 

?

Identifiable Private Information

-Coded private information or biological specimens identifiable through accessible coding systems

- All research must be reviewed & approved before any research activities may begin (recruitment or data collection)
- An estimated timeline is provided in most of RECs SOPs in Egypt

- Submitting the application at least two weeks before the next scheduled monthly meeting
- Allow at least one month for approval

No post-conduction approval

how

Standard Operating Procedures (SOPs)

Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

World Health Organization

8 Ethical Requirements

- Community partnership
- Social value
- Scientific validity
- Fair subject selection
- Favorable risk/benefit ratio
- Independent review
- Informed consent
- Respect for enrolled subjects

Emmanuel et al,JAMA. 2000;283:2701-2711

EOS 2023

The Responsibilities of the Principal Investigator (PI)

- Protect the rights and welfare of human participants
- Understand the ethical standards and regulatory requirements
- Obtain REC approval and other regulatory requirements

EOS 2023

The Responsibilities of the Principal Investigator (PI)

- Implement the research activity as it was approved by the REC
- Obtain REC approval for any proposed change
- Timely reporting of adverse / serious adverse events

EOS 2023

The Responsibilities of the Principal Investigator (PI)

Serious Adverse Event (SAE)

Fred

Doesn't

Have

Any

Money

Left

Fatal

ficant

ıg

Office of Research Education and Regulatory Management

EOS 2023

The Responsibilities of the Principal Investigator (PI)

- Maintain written records of REC reviews and decisions
- Obtain and document the informed consent as approved by the REC

EOS 2023

The Responsibilities of the Principal Investigator (PI)

- Ensure the confidentiality and safety
- Verify that REC approval has been obtained from all participating institutions in collaborative activities
- Obtain continuing approval

EOS 2023

-Approval is for up to one year

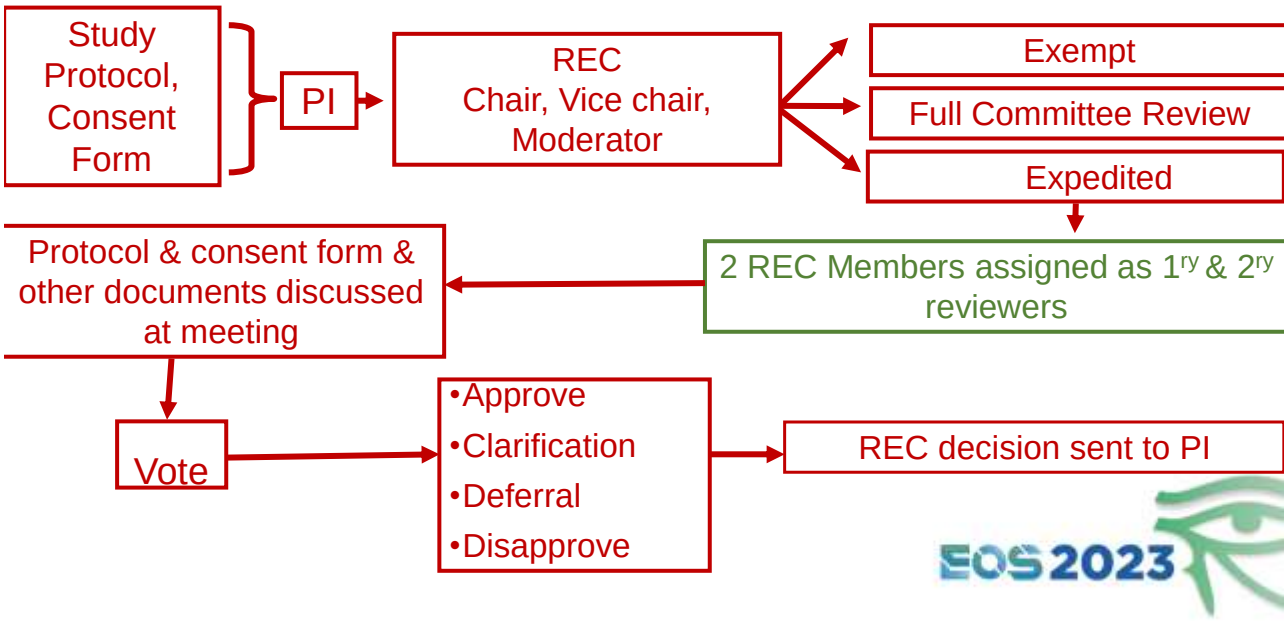
-May be less depending on level of risk

-Required documentation for Continuing Review

- Number of subjects enrolled
- Description of any adverse events or unanticipated problems
- Summary of any recent literature
- Copy of the current informed consent

Final Report to REC will be required **before** publication of paper, discussion of thesis or the final report of the project

REC Procedures



What is Minimal Risk?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily lives of the general population or during the performance of routine physical or psychological examinations or tests

What is Minimal Risk?

Whose daily life?

EOS 2023

What is Minimal Risk?

Which routine physical or psychological examinations or tests?

EOS 2023

What is a Federal Wide Assurance (FWA)?

It is the only type of new assurance of compliance accepted and approved by Office for Human Research Protections(OHRP),USA, for institutions engaged in human subjects research conducted or supported by Health and Human Services (HHS),USA

86 RECs / IRBs registered

أكدت الدكتورة عزة صالح رئيس الإدارة المركزية للبحوث والتنمية الصحية في وزارة الصحة والسكان، الانتهاء من عمل الدليل الإرشادي الخاص بتسجيل لجان أخلاقيات البحث العلمي في الجمهورية، ونشرها على جميع الهئيات والمؤسسات والجامعات لبدء تسجيل لجان الأخلاقيات التابعة لهم لدى وزارة الصحة.

EOS 2023

RHD

الدليل الإرشادي لتسجيل لجان أخلاقيات البحوث
وزارة الصحة المصرية
Guideline for Research Ethics Committees Registration – MoHP

EOS 2023

35 RECs/IRBs registered

Ibcommuler.com

Violation?

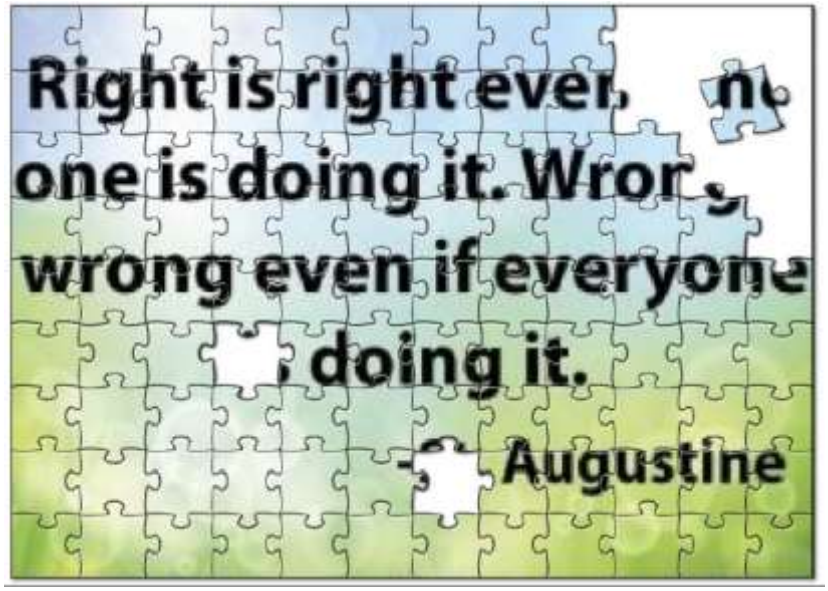
REC will notify the institute chair, sponsor of the grant or if this discovered after publication REC chair can contact the journal editorial board

EOS 2023

•Following ethical g arch, on the opposite, it will enh

•REC is important a

EOS 2023


Right is right even
one is doing it. Wror
wrong even if everyone
doing it.
Augustine

EOS 2023


Thank You
For Your Atten