Understanding EC!

Pristyn

1. What constitutes an EC?
2. What is its authority?
3. Who all are members?
4. What are their roles?
5. What does EC review?

Institutional Review Board (IRB)

An independent body constituted of medical, scientific, and non scientific members, whose responsibility it is to ensure the protection of the rights, safety, and wellbeing of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

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Institutional Review Board

Some EC/IRB around world

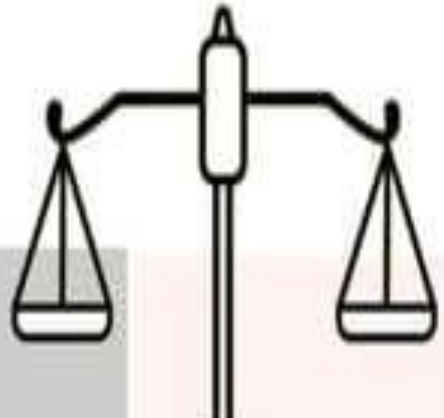
- ✓ Research Ethics Committee (REC) in the United Kingdom
- ✓ Medical Research Ethics Committee (MREC) in the Netherlands
- ✓ Comités de Protection des Personnes (CPP) in France
- ✓ Institutional Review Board in United States
- ✓ Research Ethics Board (REB) in Canada
- ✓ Human Research ethics committee (HREC) in Australia

What is an EC/IRB!

- An **independent** body
- Made of **medical** professionals and **non-medical** members
- **Protect the participant** & provide public assurance

What authority does EC/IRB have!

- It is required by law
- It is mandated (give someone authority) by national & International guidelines
- Established by the Institutions highest body
  - Mandated to act independently



Who all should be members!

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- **Reasonable** number of members
- Collectively have **qualifications** and **experience** to review and evaluate the proposed research
  - ✓Science
  - ✓Medical aspects
  - ✓Ethics

Composition as per Schedule Y

EC- Basic Medical Scientist

Who can be a Basic Medical Scientist?

- ✓ Scientific
- ✓ Specialized or professional knowledge of subject matter (Pharmacology)*
- ✓ Qualification of an expert (MD- Pharmacology)*

EC- Lay Person

Who can be a lay person?

- Non Scientific
- No Specialized or professional knowledge of subject matter (in this case bio medical research, health/medicine)*
- No qualification of an expert
- Should be from the community/society served by the hospital

Why a lay person!

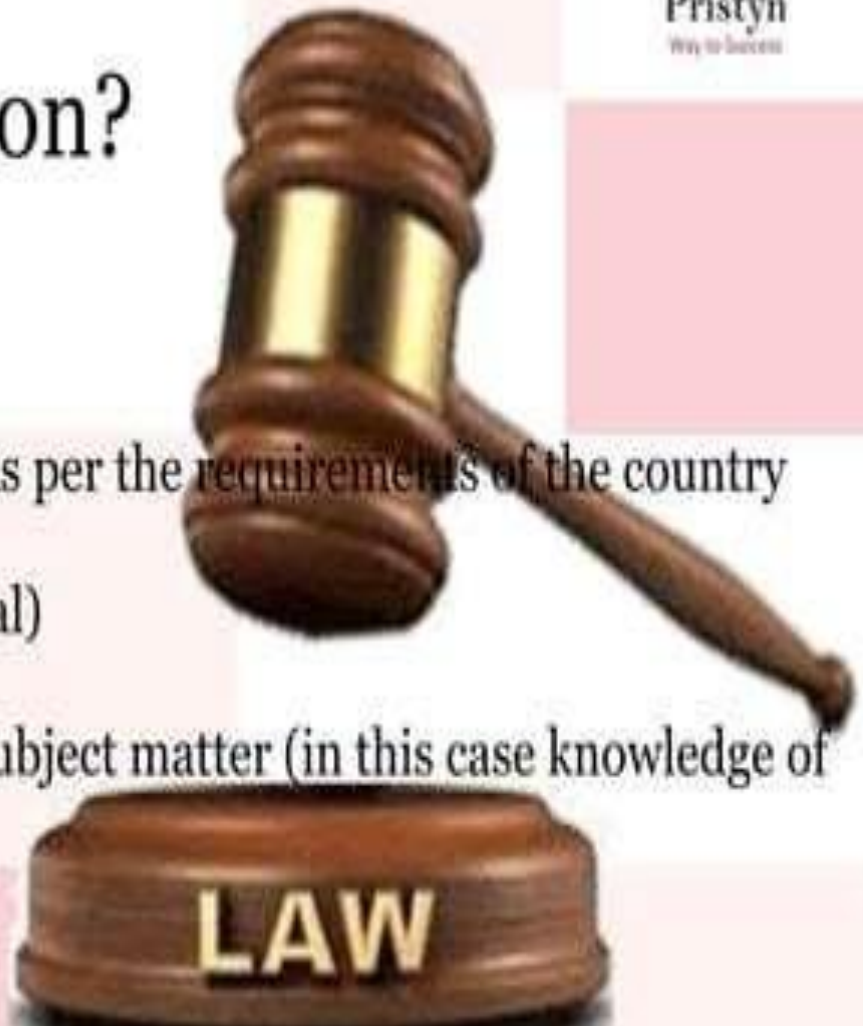
What is a Lay person's perspective?

- ✓**Safeguard the public interest**
- ✓To contribute a **user perspective or 'patient voice'** to professional discussions
- ✓Review the **ICF for language & understanding**

EC- Legal Person

Who can be a legal person?

- ✓Non Scientific
- ✓Professional Qualification to practice law as per the requirements of the country
- ✓An expert in given field of knowledge (Legal)
- ✓Specialized or professional knowledge of subject matter (in this case knowledge of medico-legal cases)



Why have a legal person!

- What is a Legal person's perspective?
- Ensure EC decisions do not contravene the law
- Ensure the legal rights of patient are protected
- Review ICF
- Review Insurance
- Review CTA (Clinical trail approval)

EC- Social Worker

Who can be a Social Worker?

- Non scientific
- Social worker engaged with a NGO
- An expert in given field of knowledge (Bioethics)
- Specialized or professional knowledge of subject matter (in this case knowledge of public health policy and societal risk/impact)

Why a Social worker!

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What does a SW person do?

- Is any project **likely to cause any social harm?** (eg-discrimination)

- **Review ICF** from to protect rights of participants
  - Language understandable and will help in decision making
  - No harm due to Socio- economic vulnerability
  - Culturally acceptable
  - No risk due to Social hierarchy
  - No language to undue influence participation

- In cases of **vulnerable participants, help EC determine measures to enhance protection**

What is the purpose of EC/IRB review!

The primary purpose of such review is –

" Assure the protection"

- ✓Rights
- ✓Safety
- ✓Welfare

} of the human subjects

What does an EC/IRB do?

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Reviewing and providing opinion on-

- Trial protocol
- Suitability of the investigator(s)
- Suitability of facilities
- Methods and material used in obtaining and documenting informed consent of trial subjects

"Make sure everything's done ethically.
Within reason, of course."

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THANKYOU