

Perspectives of Egyptian Chairs of Research Ethics Committees Regarding Barriers That Affect Proper Functioning

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Background

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- Clinical trials have increased in the developing world lately.
- RECs also have increased in developing countries.
- We want to get a better idea on perspectives of IRB chairs/designates' experiences, concerns and barriers to functioning.

Methodology

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- Qualitative method
- A semi structured questionnaire
 - ▣ REC operations and their barriers,
 - ▣ Members' training and qualifications,
 - ▣ Major ethical concerns encountered by the RECs

Methodology

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□ Interviews

- 13 in depth interviews of chairs (or their designees) of RECs in several areas in Egypt

- Online or face to face



- Cairo, Upper Egypt, Delta
- Medical Schools. Research institutes
- New and old

Methodology

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□ Analysis

- Recorded and transcribed the interviews
- Identifying themes and sub themes

Qualitative Methodology

Advantages

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graph TD; A[Advantages] --- B[Build up hypothesis not test them]; A --- C[Increase the depth of understanding phenomenon under investigation]; A --- D[Methods are flexible];
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Build up hypothesis
not test them

Increase the depth
of understanding
phenomenon under
investigation

Methods are
flexible

Qualitative Methodology

Disadvantages

Sample size are sometimes too small.

Data reliability is affected - researchers may lose objectivity

Can not use statistical methods to analyze data

Results (10 interviews)

REC operations and their barriers

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□ Administrative help

‘Even the secretary she is a multi disciplinary person who is working in 5 departments beside her load of work in the REC

‘I do all the administrative work of the committee’

‘I have this problem because our secretary; she is ok but not for the English. She cannot for example write an approval letter in English.’

‘We have a secretary and we have a younger member who takes the minutes and I take the minutes as well.’

Results

REC operations and their barriers,

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□ Capital Resources

‘We are having an office where we are keeping the files, the secretary, a computer , internet, telephone’

‘From the start we do not have a place. We do not have a secretary. We do not have equipment or computers. We do not use our own. We do not have a room. Nothing is available actually, the meeting room of school faculty, I have to book in advance and ask them to please give me the room. And there is no internet available. So I have to keep everything in my locker or in one of the member’s locker. And how we pay most of the things donations from our pockets’

Results

Members' training and qualifications,

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‘The training received is not enough and I am suffering with them for not understanding a lot of expressions a lot of things regarding ethics, regarding contents of consent forms, regarding research methodologies’

‘(Members received)no training at all.’

‘I believe that if you talk about patients and you focus on patients’ rights and you do not need much to know because you may call it intuition or common sense’

Results

Members' training and qualifications

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‘In each meeting I usually start the meeting by giving a topic as an on the job training for the members’

‘This is the weakest point of our IRB the lack of continuous training.’

Results

Major ethical concerns encountered by the RECs

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□ Informed Consent

‘Researchers wrote the consent form in way that the patient cannot understand what he means. So we ask them to rewrite the consent form in a way that the lay people can understand it.’

‘Patients get scared when they see the IC and they do not want to sign it. And I say take verbal consent rather than signing. The patients would say I would sign on my death certificate and birth of my son not to sign anything else’

Results

Major ethical concerns encountered by the RECs

13

□ Informed Consent

‘The committee was *not* fully convinced that the investigator will explain this 15 paper consent to the patients in details and would like very much to have this ICF reduced to not more than 3 pages.’

‘We actually have the feeling that it needs more supervision more than just writing the consent and taking the signature of the patient. We have the feeling that we need more supervision of the process itself’

Results

Major ethical concerns encountered by the RECs

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□ Biological Sample Research

‘Something we do in the informed consent he will not stigmatize the Egyptian population.’

‘The protocols should be restricted, we understand from the protocol there maybe stigma to the community or the Egyptian population’

‘The fear of the unknown, the high tech study, the study that they will know and many fears actually.’

Results

Major ethical concerns encountered by the RECs

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□ Biological Sample Research

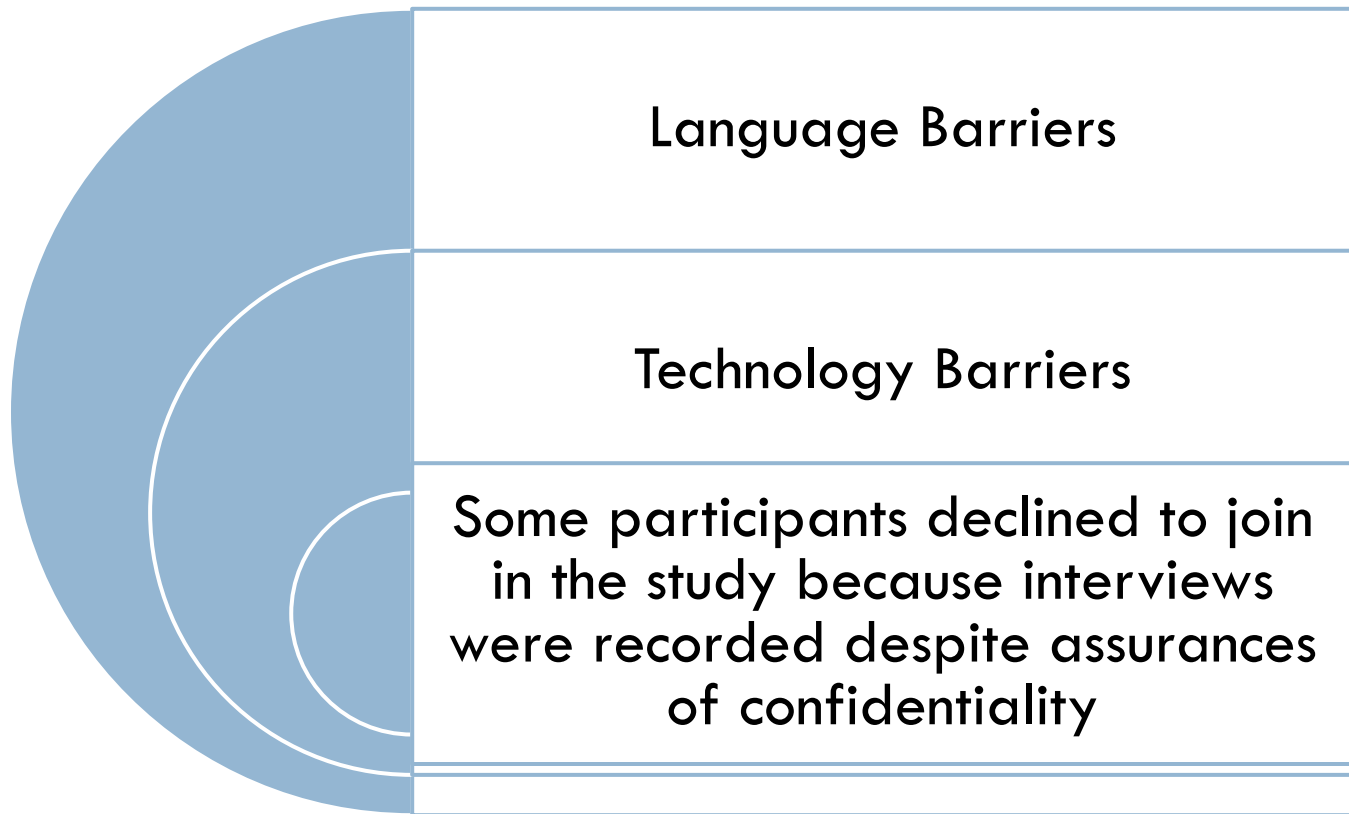
‘It is prohibited to make biological sample transfer; it is governmental regulations and should be reviewed by the security or authority.’

‘It needs to be justified why there is a need for biological sample transfer and the National Security approval was needed and this may take 3-6 months.’

‘To transfer samples to international pharmaceutical companies I think this is national security. We can not transfer samples outside without their approval’

Limitations to the study

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Conclusions

- Our interview study reveals several issues that impede adequate functioning of RECs in Egypt
- Addressing these issues can enhance the functioning of these RECs.

Future Steps

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Involve other regions



Thank You